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11 YEARS OF TRANSPARENCY IN SPAIN AND ITS IMPACT ON MEDICINES. WHAT HAS BEEN DONE WELL AND WHAT NEEDS TO CHANGE

FUNDACIÓN CEFi
Centro de Estudios para el Fomento de la Investigación

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INTRODUCTION

Fundación CEFI, within the framework of its Transparency Observatory and driven by its concern about the impact on economic and commercial interests and in terms of competition, has been studying the implications of the new Transparency Law in the field of medicine for years. In particular, as regards the requirement for information related to the net price and commercial offers of medicinal products within the public procurement of innovative medicinal products.

Throughout these years, we have reviewed doctrine and jurisprudence in the journal *Cuadernos de Derecho Farmacéutico,* seeking to address the novel aspects of this issue from different perspectives: private interest, public interest, aspects of competition and economic implications.

We began this analysis with the necessary step of hearing from third parties whose rights and legitimate interests may be affected if the administration agrees to provide information and / or documentation that is their property without allowing them to intervene before making this decision. This issue was resolved judicially, establishing the right of hearing of the interested party.

Once this first question had been tackled, we went on to study the subject in detail, the balance of interests at stake, each line of reasoning, the analysis of comparative law; all this has led us to advocate the confidentiality of commercial offers of medicines.

Naturally, we support necessary transparency within the actions of the Administration and its procedures. Confidentiality responds to a series of characteristics, rights and interests at stake that prevail over transparency and which are very clear in the pharmaceutical industry. The authors will explain it very well over the next few pages.

This is a special issue of *Cuadernos de Derecho Farmacéutico* in which we have compiled all the articles published over the years in the journal and brought them all together in this themed issue. It also includes five previously unpublished articles: The first one provides a general analysis from an economic perspective of the necessary confidentiality; the second focuses on the new approaches that can be taken and regulatory alternatives; the third examines the scope of the exception for commercial interests in the context of a request for access to advance purchase agreements for COVID-19 vaccines following the recent judgment of the General Court of July 17, 2024; the fourth explores exceptions to the principle of transparency regarding drug prices and the issue of proving future harm as analyzed in the ruling of the Federal Administrative Court of Switzerland; and the final new article that completes the collection refers to transparency and confidentiality in the procurement of COVID-19 vaccines, analyzing Judgment 3935/2024 of the National Court.

The reference to comparative law, as well as examples of how confidentiality has been handled in the procurement of COVID vaccines has been particularly interesting in this study of transparency vs. confidentiality of the commercial offers and unit prices of medicines.

We would like to thank all the authors and the members of the CEFI Transparency Observatory for their great contributions to this study.

We hope it will be of interest to you.

Fundación CEFI

EVIDENCE-BASED PHARMACEUTICAL PRICE TRANSPARENCY

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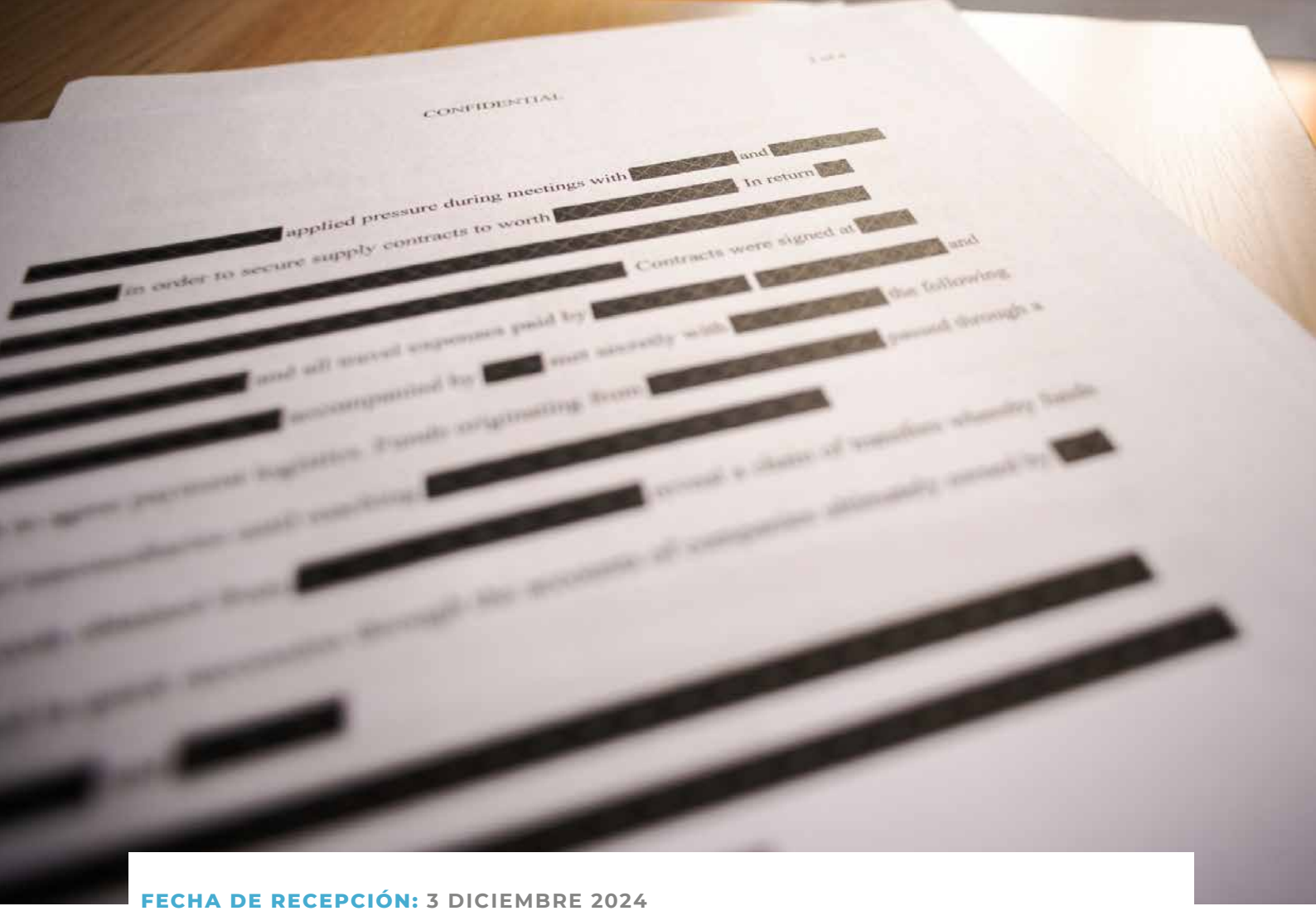

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RESUMEN: La transparencia de los precios netos de los medicamentos innovadores ha estado en el centro de un animado debate en los últimos años. Este artículo revisa el estado de la literatura, enfocándose en la disponibilidad de evidencia empírica para respaldar la formulación de políticas. La literatura teórica no proporciona una orientación clara sobre el posible impacto de la transparencia de los precios netos en los niveles de precios y la dispersión de precios. A nivel empírico, la evidencia es escasa y no generalizable, ya que actualmente no existen análisis de alta calidad disponibles. Se citan ejemplos recientes de evidencia de alta calidad sobre el impacto de la transparencia de precios en los servicios médicos como el estándar de referencia para futuras investigaciones sobre este tema. También se destacan posibles falacias en el debate actual para fomentar políticas rigurosas, coordinadas internacionalmente y basadas en evidencia.

PALABRAS CLAVE: Fijación de precios farmacéuticos; transparencia de precios; precio de referencia internacional; innovación farmacéutica; Unión Europea.

ABSTRACT: The net price transparency of innovative medicines has been at the center of a lively debate in recent years. This paper reviews the state of the literature, focusing on the availability of empirical evidence to support policy-making. The theoretical literature does not provide clear guidance on the potential impact of net price transparency on price levels and price dispersion. At the empirical level, the evidence is sparse and not generalizable, as no high-quality analyses are currently available. Recent examples of high quality evidence on the impact of price transparency in medical services are cited as the gold standard for future research on this topic. Potential fallacies in the current debate are also highlighted to promote rigorous, internationally coordinated and evidence-based policy.

KEYWORDS: Pharmaceutical pricing; price transparency; international reference pricing; pharmaceutical innovation; European Union.

A stronghold of perfectly competitive markets is price transparency. Perfect competition in textbooks requires buyers and sellers who are too small to influence the price (price takers). There are no barriers to entering or exiting the market, and companies produce a homogeneous good, i.e. customers do not care whether they buy a version of the product from one particular company or another. Finally, all buyers and sellers are *perfectly informed*, i.e. they know exactly the price that other sellers are charging. In this case, prices are equal to marginal costs and thus maximize social welfare. This ideal situation assumes that all conditions are *fulfilled simultaneously*. In the case of generic drugs, for example, companies produce a homogeneous good and customers should not care which version of the product they buy. Since the patents have expired, there are almost no barriers to market entry or exit. Therefore, *perfect competition* is considered the prototype for generic markets, and there is a general consensus among economists that price transparency in generic markets helps to increase competition and reduce prices close to the marginal cost of production.

However, this approach cannot be naturally extended to all pharmaceutical products. In most cases, pharmaceutical products are by no means homogeneous, especially when a product can guarantee better clinical results and patients do care whether they are cured with better or worse treatments. In these circumstances, innovative pharmaceutical products are, in most cases, patented and the manufacturer has a considerable degree of market power. Consequently, demand is generally in the hands of a few public or private payers, resulting in a *bilateral monopoly* (a single buyer and seller) in some national markets. In this scenario, is price transparency still desirable to stimulate competition? In other words, is price transparency good in the case of monopolistic competition and in the more extreme case of bilateral monopoly? This question is at the center of a lively debate on price transparency in pharmaceutical markets.

Of course, other considerations apply in the case of public payers, as general considerations of transparency in public procurement and, more generally, in public administration are relevant. However, this review focuses on prices and the economic tenants of the debate, as transparency in price negotiations is a more general issue that concerns not only prices but also the transparency of the process, contracts, possible conflicts of interest, etc. Moreover, the rules of public administration vary from country to country and from jurisdiction to jurisdiction.

With this in mind, we will examine the latest evidence on the pros and cons of price transparency to ensure wider access to innovative medicines at lower prices.

With this in mind, we will examine the latest evidence on the pros and cons of price transparency to ensure wider access to innovative medicines at lower prices. Before we turn to the economic debate, a final reflection on prices as part of contractual agreements is in order. As customers know very well, the price we find when booking a hotel or a flight in the aggregators can be misleading, as some additional services may be excluded (e.g. breakfast). Similarly, the price is only one of many elements of the negotiated contractual agreement. Take conditional payments, for example. The negotiated price might look lower if conditional payments are included. On the other hand, it is almost impossible to include contingent payments in the price because these payments depend on uncertain future circumstances. As a result, pressure on price transparency, as in online markets, could translate into additional complexity in contractual solutions, such as more frequent use of managed entry agreements.

Because more information is not always better, it is important to analyze the real-world evidence supporting the pursuit of transparency in drug pricing to avoid unintended consequences of price transparency.

Another interesting comparative case is provided by pay transparency (Cullen, 2024). Even if we all agree in principle that wage transparency is a good thing that many elected officials support, Cullen's recent article shows that *"[a]mong the lessons learned in the study of pay transparency is that more information is not always better."* (pag. 155). Because more information is not always better, it is important to analyze the real-world evidence supporting the pursuit of transparency in drug pricing to avoid unintended consequences of price transparency.

1. LITERATURE REVIEW

Transparency in the pharmaceutical markets has been examined from various perspectives. These include transparency of costs, profits, prices, HTA and regulatory procedures, decision-making and public procurement. Therefore, we need to start with an appropriate definition of price transparency. We can adopt the definition of Joosse et al. (2023), which defines full transparency in this context as *"[t]he sharing, disclosure and dissemination of information related to medicine prices to the public and relevant parties to ensure accountability."* (Fig. 1 in Joosse et al., 2023). Since ex-factory and list prices are available in most cases, the debate focuses on the transparency of net transaction prices, i.e., the price paid by payers/buyers net of confidential discounts and the impact of managed entry agreements. Sometimes, the call for transparency also includes price determinants based on cost-plus or value-based logic and pricing strategies. In our analysis, however, we will only address the most critical point of the debate, namely net price transparency.

Additional complications arise, among other things, from the different pricing depending

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on volume, packaging, dosage or indication. Especially when managed entry agreements are present, even complete transparency does not ensure that payers and purchasers can compare net prices between suppliers/markets. However, for simplicity, we consider the average net price transparency for a standard unit of a medicine sold in a given market in a reference year. This can be the expected average net price at the time of negotiation or the actual price based on real-world data. Another dimension that we need to preliminarily clarify concerns the question of who the "*relevant parties to ensure accountability*" are. This certainly includes patients, prescribers and payers, but other stakeholders should also be considered (e.g. disclosure among payers).

Because net price transparency is rare, there is little evidence that it helps to reduce costs and improve access. There is a paucity of rigorous empirical evidence on the impact of increased drug price transparency on relevant outcomes such as lower prices and higher volumes. Joosse et al (2023) conducted a systematic review of more than 32,000 studies published in the period 2004-2019. They found that only two publications were eligible. Langley et al. (2018) examined the impact of cost feedback to prescribers in the UK for antibiotics and inhaled corticosteroids. Only the effects on price were considered (weekly therapy costs). The authors found a significant reduction in costs for antibiotics and no effect for inhaled corticosteroids. The GRADE rating of the study is moderate. The second study reported (Moodley & Suleman, 2019) analyzed the impact of the Single Exit Plan (SEP) on 50 originators and associated generics in the South African private sector. The SEP required the disclosure of net prices on the South African price registry website. The study showed that prices fell immediately after the introduction of the SEP, with the average price reduction being more pronounced for generics. The GRADE rating of the study is low. This literature review, supplemented by a third study (Moodley & Suleman, 2019), was the primary reference for the World Health Organization's (2020) guideline on country pharmaceutical pricing policies. The WHO concluded that "*[t]he evidence presented in the systematic review suggests that mandatory disclosure of the weighted average of all sales prices after*

considering all discounts and off-invoice rebates [...] might deliver lower prices for the health-care system" but *"[t]he generalizability of the findings is unclear"* (page 22).

A more recent and comprehensive review (Barrenho & Lopert, 2022), covering publications between 2015 and 2022, found 22 empirical studies. While earlier reviews focused on effects within a country, Barrenho & Lopert (2022) also considered international spillover effects. However, almost all studies analyzed do not consider net prices, and some of the remaining studies make estimates of most likely discounts (e.g. Riccaboni et al., 2022) or survey data (e.g. Den Ambtman et al., 2020), as studies with actual net prices are rare (Mardetko et al., 2019). Overall, the results in the literature are mixed, with most studies finding no significant or inconsistent effects on prices (e.g. Den Ambtman et al., 2020). In a policy brief, Webb et al. (2022) also report that there is essentially no reliable evidence in the European setting, while the available evidence for less developed countries is mixed. All in all, the current debate on the pros and cons of full price transparency for medicines, as unanimously recognized by the scientific community, the WHO, the European Union and the OECD, is based on sparse and low-quality research with limited generalizability. This is no longer acceptable in the age of big data and real-world evidence-based policy. Priority must therefore be given to developing reliable evidence of the impact of increased price transparency compared to an appropriate counterfactual scenario.

2. WITHIN-COUNTRY EFFECTS OF NET PRICE TRANSPARENCY

Conventionally, the potential consequences of transaction price transparency can be divided into effects on the demand side and on the supply side. The simplest demand-side effect is based on the usual economic arguments: when payers/buyers are better informed about prices, they can better compare prices, which discourages pharmaceutical companies from charging different (higher) prices. When search costs decrease, price elasticity increases, reducing profits and increasing consumer welfare. As a result, both price dispersion and price levels should fall. Price comparisons can take place within or between markets. This type of reasoning usually applies to comparisons within a market when there are multiple suppliers and

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In the off-patent pharmaceutical segment, better information on prices, especially in combination with direct incentives such as off-the-pocket payments of the price difference to the cheapest available version, can effectively reduce prices and improve access. However, even in this case, as medical services and medicines are "*credence*" goods (Dulleck & Kerschbamer, 2006), patients may view price as a proxy for quality, limiting the potential benefits of price transparency. A similar result can be achieved if public procurement is done through auctions with multiple sellers and bidders (Allende et al., 2024). Another option is to combine price transparency with internal reference pricing schemes to limit reimbursement or cap prices.

However, as already noted, for the vast majority of patent-protected medicines there is only one supplier or a limited number of differentiated (inhomogeneous) alternatives. In these cases, an appropriate comparison must include several relevant dimensions, such as in the context of cost-effectiveness and cost-benefit analyses when net prices are already routinely used. As the impact on the demand side within the pharmaceutical market is marginal, especially when there is only one or a few national payers, the current debate focuses on the impact between markets, with a particular focus on international reference price systems. For innovative medicines, the predominant market structure is a bilateral monopoly, where a single seller (a monopolist) faces a number of local/national buyers (a monopsony).

When considering supply-side effects, we need to take into account the potential impact on the prices that firms will offer when they have better access to information about competitors' prices. This could contribute to tacit collusion between suppliers in the form of conscious parallelism, as in the well-known case of the concrete market in Denmark (Shaw & Mestre-Ferrandiz, 2020; Webb et al., 2022; Van Baal & Strang, 2024). Although these effects have not yet been proven, they may limit the benefits of price transparency. More profound supply-side effects relate to other dimensions of pharmaceutical companies' strategic behavior, such as R&D and national market entry deci-

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sions, product differentiation, and contracting solutions. Before looking at the indirect effects of transparency resulting from the countermeasures that pharmaceutical companies will take in the event of full price transparency, in the next section, we consider the spillover effects of net price transparency in international markets.

3. INTERNATIONAL SPILLOVER EFFECTS OF NET PRICE TRANSPARENCY

The most critical direct implication of net price transparency in international markets arises from the widespread use of external reference pricing (ERP) systems. Confidential discounts account for a significant proportion of net price differences between countries. Not knowing the actual price paid for

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the same medicine in different countries makes price discrimination in the form of Ramsey prices more acceptable. With full global net price transparency, all payers around the world will ask to be charged the same price and international price discrimi-

nation is no longer a viable strategy. Transparency combined with ERPs will lead to global convergence to a single price. Unless the international community agrees to take dedicated policy measures to limit convergence, this will have a detrimental effect on less developed countries (Kyle & Ridley, 2007). However, this cannot be taken for granted as countries have divergent interests (Barrenho & Lopert, 2022).

Some of the proponents of full transparency do not internalize this spillover effect on foreign markets. Sometimes, especially in high-income countries, they even consider potential spillover effects to be beneficial, in the hope that low-income countries will adopt similar measures. This argument is overly simplistic because it does not take into account the likely best reaction of the other players in this strategic game. Expert surveys among payers underline this crucial aspect. As an example, consider a negotiation scenario in which the manufacturer of a drug offers a visible price of 80 or a visible price of 100 with a confidential discount of 50%, resulting in a net confidential price of 50. The rationale for the proposal is that the best discount the manufacturer can offer is 20% with full transparency and 50% with confidential information. This is because the same discount (20%) applies in all countries for full disclosure, whereas prices may differ for confidential information. This offer illustrates the trade-off between transparency and price differences between countries. Such a trade-off is evident in middle- and low-income countries where the price of transparency could become prohibitive.

4. STRATEGIC IMPLICATIONS OF FULL PRICE TRANSPARENCY

As highlighted by Barrenho & Lopert (2022), most of the current debate does not take into account some of the most critical implications of full price transparency:

As an example, consider a negotiation scenario in which the manufacturer of a drug offers a visible price of 80 or a visible price of 100 with a confidential discount of 50%, resulting in a net confidential price of 50. The rationale for the proposal is that the best discount the manufacturer can offer is 20% with full transparency and 50% with confidential information. This is because the same discount (20%) applies in all countries for full disclosure, whereas prices may differ for confidential information. This offer illustrates the trade-off between transparency and price differences between countries.

- The strategic impact of full price transparency on relevant stakeholders. In particular, the best response of pharmaceutical companies needs to be considered in a game-theoretic framework.

- The heterogeneity of payers in terms of willingness to pay, bargaining power, cost of living and other relevant factors that could influence the likelihood of adopting a full price transparency strategy.

- Dynamic vs. static framework if we do not consider the set of pharmaceutical products as fixed and given and introduce innovation into the picture.

4.1. The lack of response fallacy

When considering the introduction of net price transparency in an open economy, we must consider the strategic implications of this move on the likely best response of pharmaceutical product manufacturers in a bilateral monopolistic competition and the impact of such a decision on other countries. A sudden disclosure of net prices that does not violate existing contractual agreements will have some direct consequences for pharmaceutical companies that will cause them to reconsider their approach to future negotiations. This crucial aspect has been highlighted in Barrenho & Lopert (2022) and is the focus of the recent paper by Dubois et al. (2022). Their paper analyzes the impact of the introduction of a reference pricing strategy in the US on Canada. They describe the equilibrium that occurs when firms internalize the cross-country spillovers induced by the reference pricing mechanism. The main conclusion is that the policy will lead to a small price decrease in the US and a large price increase in Canada. This framework was generalized by Riccaboni et al. (2022) to account for the potential impact of net price transparency in combination with international reference prices. Following the same logic as Dubois et al. (2022), price transparency leads to a price increase in countries that serve as a reference point, i.e. countries with below-average prices. Therefore, the main negative spillover of price transparency stems from pharmaceutical companies, which will internalize the consequences of the new price regulation and change their pricing policy to increase reference prices in future negotiations. This scenario is likely because, with unchanged bargaining power, the best response of pharmaceutical companies is to adapt their negotiation strategy to the new policy of full transparency. Furthermore, as the decision to enter national markets lies with the pharmaceutical companies, they will likely change the order in which medicines are launched and postpone launches in countries with low and transparent prices. Countermeasures to force companies to enter certain markets, such as compulsory licenses, could prove ineffective in this case (Barrenho & Lopert, 2022).

4.2. The lack of cooperation between payers in transparency agreements

The main interest of payers is to obtain the lowest price in order to secure access to treatments in their reference market. As payers are very heterogeneous in terms of their bargaining power, purchasing power and willingness to pay, they have different incentives to adhere to international transparency agreements. In general, it is a classic prisoner's dilemma, where it is in the best interest of payers to benefit from full information on other payers' prices while continuing to rely on confidential discounts to ensure low prices in their reference market. Unilateral deviations from full transparency or lack of commitment are very likely among payers in low-income countries, where transparency costs much more than in high-income countries. This lack of commitment will significantly reduce the impact of the full transparency policy.

In general, it is a classic prisoner's dilemma, where it is in the best interest of payers to benefit from full information on other payers' prices while continuing to rely on confidential discounts to ensure low prices in their reference market.

4.3. Short-sightedness or lack of attention to the long-term consequences of transparency

Another potential fallacy of the current transparency debate is the focus on the market game between a payer and a manufacturer. Typically, this transaction is viewed with a request to make the price transparent in a single-stage game. As we have seen, this will have implications for similar negotiations with other payers, as manufacturers internalize the consequences of net price transparency and other payers will deviate from transparency agreements. Moreover, in repeated games with international spill-over effects, the manufacturer is incentivized to postpone negotiations with payers implementing the net price transparency and increase the complexity of contractual agreements to hide the actual price.

Indeed, the market strategic interaction is only the last stage of a sequence of strategic moves. In the beginning, firms must decide which technology to invest in. Then, when a new drug is available, manufacturers establish an international pricing strategy in negotiations with payers, including the sequence of drug launches and the target price of each negotiation. Since some payers are unlikely

Since some payers are unlikely to commit to full transparency, the negotiation strategy will be modified accordingly. In addition, requests for price transparency will have long-term implications in allocating R&D investments.

to commit to full transparency, the negotiation strategy will be modified accordingly. In addition, requests for price transparency will have long-term implications in allocating R&D investments. Consider two assets, one with high uncertainty and the other with low uncertainty at the time of launch. As a result, the asset with uncertainty is more likely to require the use of managed entry agreements to deal with its uncertain value. In complex contractual solutions, determining the price actually paid is much more difficult and the net price will only be available later when the uncertainty has been resolved. Investments are, therefore, reoriented towards more uncertain assets to restore the price differences in more complex contract solutions. In this case, payers face a clear trade-off between granting early access with solutions to manage uncertainty or deferring access in anticipation of reduced uncertainty and more transparent contractual solutions.

5. FREEDOM OF INFORMATION AND PROTECTION OF COMMERCIAL INTEREST

As we said at the beginning, more general considerations apply in the case of public payers, as citizens' access to information is guaranteed in many jurisdictions with freedom of information laws. Although freedom of information laws relate to the public sector, they may also have implications for private companies dealing with public authorities, such as in the case of contractual agreements to secure market access in the pharmaceutical sector. In this case, information that could harm the commercial interest is generally exempt from disclosure.

The unilateral disclosure of net prices, even if it does not violate express contractual confidentiality obligations, may impact the commercial interests of private companies. However, the impact on commercial interests cannot be simply hypothetical but must be demonstrated case by case. A relevant example is provided by the recent judgments of the Court of Justice of the European Union (Judgments of the General Court in Cases T-689/21 and T-761/21) on the purchase contracts for COVID-19 vaccines. In that case the Commission stated that "*the information redacted under the exception relating to the protection of commercial interests contained commercially sensitive elements regarding, inter alia, prices and individual prices per dose [...]*" (T-689/21, 100). In particular "*by providing the amount of the down payment, it would be possible to make an assessment, based on market practice, and*

A relevant example is provided by the recent judgments of the Court of Justice of the European Union (Judgments of the General Court in Cases T-689/21 and T-761/21) on the purchase contracts for COVID-19 vaccines.

to determine the full value of the agreement and ultimately the price per dose, which constitute commercially sensitive information for all undertakings" (T-689/21, 102). Since the Commission provided detailed information on the relevant commercial interest to protect the information on prices the Court rejected the request to access information on payments of COVID-19 vaccines. This case is by no means representative of all possible situations in which a commercial interest can be proven. However, access to information on net prices could fall into this category.

6. CONCLUSIONS

Since the theory of oligopolistic competition offers little evidence of the benefits of price transparency in pharmaceutical markets, it is crucial to gather real-world evidence of the impact of net price transparency on relevant outcomes of interest, such as the cost of therapies and improved access. Unfortunately, the available evidence is sparse and cannot be easily generalized. Even in the case of health care provision, where more evidence has been gathered recently, the results are mixed. For example, in a randomized trial on medical charge transparency in New York State, Barnes et al. (2024) found that transparency induced a slight increase in bill charges. In this case, the trade-off between consumer shopping and better access to competitors' prices thus turned out to be negative. Similar controlled studies should be conducted on drug price transparency in controlled settings to identify the key drivers of potential benefits. For sure, based on the available evidence and theoretical arguments, we cannot take for granted that transparency will decrease prices and improve access. On the one hand, net price transparency might increase the payers' bargaining power, thus reducing prices. On the other hand, the potential gains and losses from transparent pricing are not evenly distributed between payers, whereby payers in lower-income countries may choose to maintain confidential discounts. In addition, pharmaceutical companies will internalize international spillovers and change their negotiation strategy to limit the impact of transparency in other markets. Therefore, international coordination is needed to ensure that payers work together to set the standard for the transmission of price information and maintain Ramsey's differential pricing. A clearer picture emerges when there are substitutes for medicines, as in the case of generics. In these cases, greater transparency can stimulate competition in the off-patent market.

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Massimo Riccaboni

CONFIDENTIALITY OF COMMERCIAL OFFERS AND UNIT PRICE OF MEDICINES: AN ECONOMIC PERSPECTIVE

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RESUMEN: Transparentar precios unitarios de los medicamentos es un tema complejo, debido principalmente a las características del mercado de los medicamentos. Tanto desde la oferta como la demanda, el mercado está altamente regulado, sin olvidar las importantes interrelaciones entre decisiones tomadas por los diferentes países. Sin embargo, la falta de confianza entre los diferentes agentes hace que el debate en torno a este tema esté politizado, con poco consenso sobre los objetivos de una mayor transparencia de los precios, o sobre qué información debe ser de acceso público, y con poca evidencia sobre las probables consecuencias de una mayor transparencia de precios en todo el mundo. El objetivo de este artículo es ofrecer unas reflexiones sobre las implicaciones de una mayor transparencia en precios, en base la protección de los intereses públicos, comerciales privados y de defensa de la competencia.

PALABRAS CLAVE: Transparencia; precios de referencia internacionales; precios diferenciales; costes farmacológicos; intereses públicos.

ABSTRACT: Making net prices of medicines transparent is a complex issue, mainly due to the characteristics of the medicines' market. Both the supply and demand of the market are highly regulated, and we need to consider the important interrelationships between decisions made by different countries. However, the lack of trust between the different agents means that the debate around this issue is politicised, with little consensus on the objectives of greater price transparency or on what information should be publicly accessible, and with little evidence on the likely consequences of greater price transparency around the world. The objective of this article is to offer some reflections on the implications of greater transparency in prices, based on the protection of public, private commercial and competition interests.

KEYWORDS: Transparency; international reference prices; differential pricing; medicines costs; public interests.

1. INTRODUCTION, CONTEXT AND OBJECTIVES OF THE ARTICLE

The net price paid by health systems for medicines (and health technologies) should be public and transparent. This statement seems very laudable, since good governance is important for accountability of public spending (and medicines account for a significant fraction of this spending). However, given the characteristics of the sector in which we find ourselves, I believe it is necessary to reflect on and evaluate the consequences of a particular country making its prices transparent. To do this, two dimensions must be taken into account:

(i) Geographical scope: impact inside and outside the country;

(ii) Timing: Short-term vs. medium/long-term impact.

This article aims to offer some reflections on these implications, due to the importance of the topic. But to do this, I think it is important to put certain elements on the table before going into detail on the issue that concerns us.

As a starting point, and from my perspective, the current context of pharmaceutical policy (at a global level) can stand out for a lack of trust between the different agents involved. This has important implications for the debate around one of its most complex issues: the relationship between access to and prices of new (and not so new) medicines. And within this debate, the issue that concerns us, the transparency of net prices.

But let's take it one step at a time. Within the issue of access, a key element in the debate is the *difference* in access to new therapies between countries (both in number of medicines and for which patients), but also within the countries themselves. At the European level more specifically, the *EFPIA Patients W.A.I.T. Indicator*[1] highlights these differences, and, in fact, reducing these inequalities is one of the keys behind the recent European Pharmaceutical Strategy[2]. How can we explain these differences, even with the marketing authorisations granted for the whole of Europe? The reasons are many and complex, but a key one is that *"health"* is the competence of the Member States, including the decision of price and reimbursement, so it is up to them to decide which treatments to include in their portfolio of benefits. Among the arguments put forward by the different actors, we find at one extreme the *"exorbitant"* prices, while at the other, the lack of resources and the low willingness of some countries to pay for these treatments while waiting for other countries to pay higher prices[3]. And within this debate, the relationship between prices and R+D costs is introduced[4].

At the same time, there is no doubt that technological progress, understood in its broadest spectrum has made it possible to develop new therapies, already available or in the pipeline (in the area of oncology, rare diseases, and gene therapy, among others) that are different from the more traditional and older drugs. For example, greater scientific complexity, in number of patients (very few cases of gene therapy per year), there is more clinical and economic uncertainty when it is launched on the market, and in some cases they are potentially curative single-use therapies. In economic terms, the impact is that the cost per patient is significantly higher now than it was two or three decades ago. And in part this has generated (more) inequality in accessing these therapies.

We cannot forget, of course, the various initiatives to try to improve this situation (e.g. the *WHO's* Novel Medicines Platform[5]), and where greater action is called for by all the agents involved. While these initiatives try to go beyond the debate around prices, a recurring theme continues to be the demand

by several agents for greater transparency in the unit costs of these therapies for health systems. An example can be found in the 72nd *WHA Resolution* of 2019 *Improving the transparency of markets for medicines, vaccines, and other health products*[6] – although its implementation has been very limited.

With this context, it might seem at first glance that we have a relatively simple topic on our hands; in other words, knowing and making unit prices transparent brings positive net benefits. However, from my point of view, this is far from reality. Making these net prices transparent can have important implications, at various levels, as we will discuss later – at least, in the global regulatory and pricing policy context in which we currently find ourselves.

In Spain specifically, it has been an important issue in recent years, due to several (not final) judicial decisions, on the need to make transparent the financing conditions of some treatments, including the net price agreed between the National Health System and pharmaceutical companies.

To conclude this introduction, it is important to highlight two characteristics of the sector when we talk about drug prices. In particular, the interrelationships:

- Between countries, through international reference prices (and parallel trade within the EU).
- Between decisions made by the funder in a given country over time, as decisions made today will affect decisions in the future.

With these interrelationships, from an economic point of view, the question is, for a medicine: is it preferable to have price differentiation between countries, or to have a single global price? Here the economic theory is clear: if there is an increase in total demand, price differentiation is preferable.

At the same time, and beyond the biopharmaceutical sector, more transparency is sought around the decisions of the various public entities[7], with important legislative steps in Spain in this regard during the last 5-10 years, including Law 19/2013, of 9 December, on transparency, access to public information and good governance (LTAIBG)[8]. It is also important to note that this legislation includes,

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of course, exceptions to promote a certain confidentiality, but always under more or less restrictive conditions, depending on how you interpret them[9].

Therefore, the aim of this article is to offer, from an economic perspective, my reflections on the transparency/confidentiality of commercial offers and unit prices of medicines. As I will discuss later, my reflections revolve around three aspects:

- Public Interests.
- Private commercial interests.
- Impact on competition.

To do this, the structure is as follows. First of all, the characteristics of the biopharmaceutical sector are briefly summarized, due to their implications when we talk about price regulation. Section 3 breaks down the three effects just mentioned, one by one, ending with some final thoughts.

2. CHARACTERISTICS OF THE BIOPHARMACEUTICAL SECTOR

The biopharmaceutical sector is complex for many reasons, and it is highly regulated. From an economic point of view, we distinguish between supply and demand, to assess the implications for price regulation.

2.1. Offer

The **offer is R+D intensive**[10], which implies the need to offer intellectual property rights (patents) as well as data/market exclusivity. Although patents can last up to 25 years (including supplementary protection certificates), the *"effective"* protection period is shorter since, on average, almost the first half of this time is dedicated to R+D, and therefore, in this time no financial return is generated.

In addition, there is a high risk, as success rates during the research and development phases are relatively low, and a significant proportion of molecules never become *"medicines"*. However, this high risk can prove to be a potent incentive for dynamic efficiency, as the prize is a "temporary monopoly" if successful.

But static competition is also important. In other words, in the short term we must also try to find a competitive market for generic medicines once the patents/exclusivity have expired.

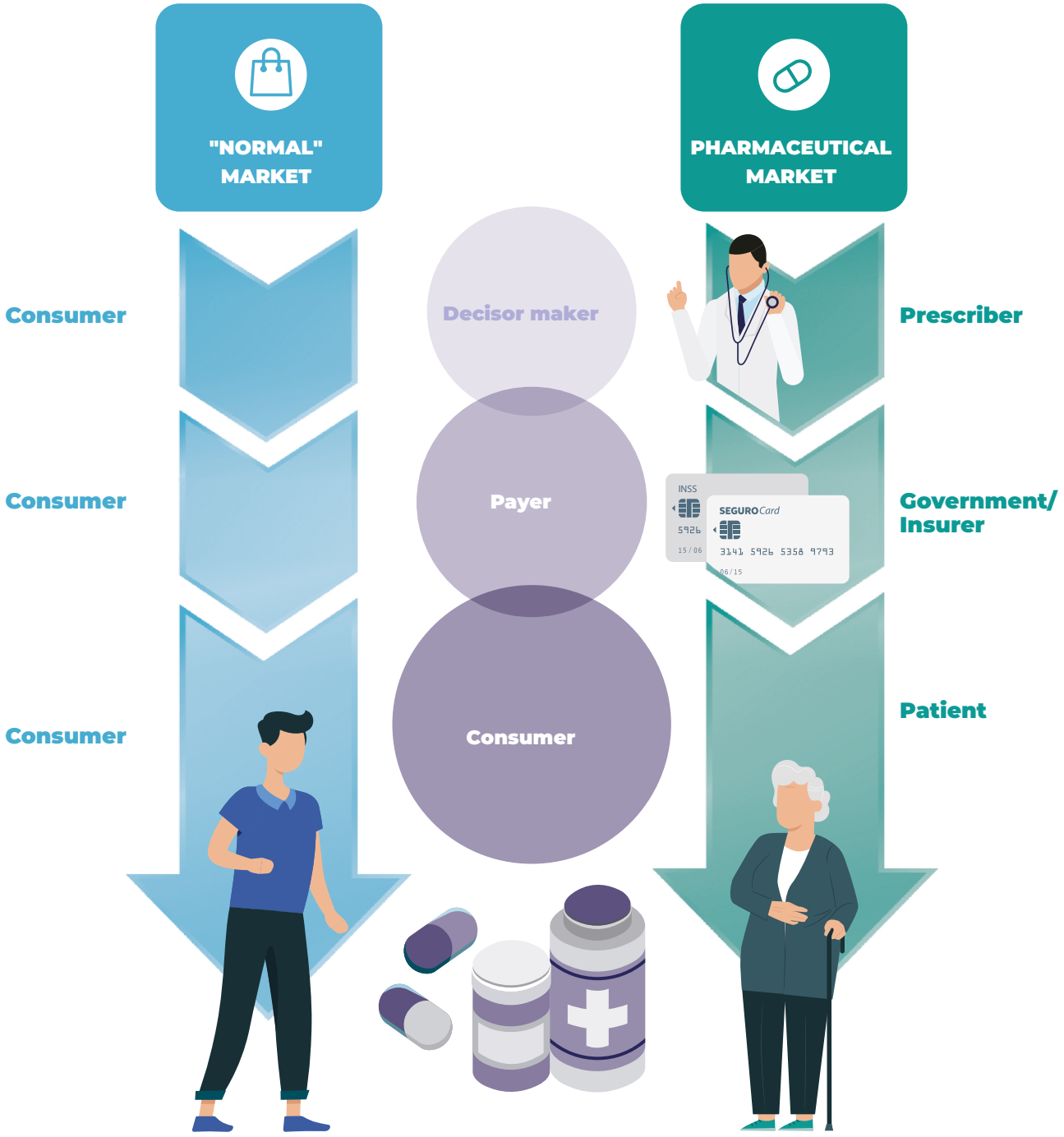
In terms of types of treatments, we have already discussed the evolution thanks to technological progress, among other things; therefore, while the profits of some pharmaceutical companies used to be generated by the sales of so-called *"blockbusters"* with significant numbers of patients, we now have therapies aimed at much smaller subpopulations of patients. This better direction in treatment has given rise to so-called *"precision medicine"*[11].

2.2. Demand

From the point of view of demand, a differentiating factor in the medicines sector is that

From the point of view of demand, a differentiating factor in the medicines sector is that we have several *"consumers"*, and specifically, we can think of three: decision-maker, payer and user/ consumer.

"DEMAND" ACTORS:
NORMAL MARKET VS MEDICINES



we have several *"consumers"*, and specifically, we can think of three: decision-maker, payer and user/consumer[12]. Table 1 shows the difference between these three agents for the drug market and a 'normal' market.

With this diversity of agents, each with their own incentives and objectives, and taking into account that governments and insurers are the main buyers of medicines, **demand is (highly) regulated.** There are incentives (economic and non-economic) and/or recommendations to prescribers and patients introduced by the payer to try, with greater or lesser success, to make both aware of the economic cost of their decisions, and to go beyond considering only efficacy/effectiveness and safety when deciding on the treatment to be used. In addition, and to increase the complexity, the distinction between these three agents is currently more *"grey"*, since there is, at least from my perspective, a greater importance of the 'payer' in the decision, which implies a more financial approach and budgetary impact.

2.3. Price regulation: alternatives

In addition to regulating demand and supply, countries/payers can use multiple mechanisms to regulate and price medicines at the time of marketing, linked to their financing by public health systems. The mechanisms with the most presence in the policies of different countries or in the recent debates that have arisen on the subject would be value-based prices, international reference prices (IRPs), controlled entry/risk-sharing agreements, profit controls, and cost-plus[13]. The first two mechanisms help to determine (directly or by comparison) the price level, either in terms of its value or the price of the same drug in other countries. We will then take a closer look at PRIs because of their relationship to price transparency. The third mechanism includes a dynamic element to establish the price, since it will depend either on the evolution of expenditure or on the health outcomes derived from the use of the drug. The last two mechanisms —profit control and cost-plus— are somewhat related, since both formulas seek to determine price in terms of costs. They differ, however, in the way they control the price level; indirect in the first case and direct in the second. There are also other mechanisms for controlling public spending through linear price reductions, price freezes, and discounts to which medicines are subjected, from time to time or continuously.

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With all this context, we are in a situation, relatively generalized at the international level, of differences (probably important) between the *"list"* prices of medicines and their real costs (net price) for the health system, and especially those of hospital dispensing. This difference between list and real price is maintained. On the one hand, thanks to *"controlled entry/risk-sharing agreements"*, which are usually based on health outcomes; and on the other hand, through financial agreements and mostly, but not exclusively, confidential discounts on the list price, which have proliferated much more than agree-

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ments based on health outcomes that are much more complex to implement. Figure 1 shows the evolution of financial agreements and results-based agreements at the global level and without specifying any country or region, respectively.

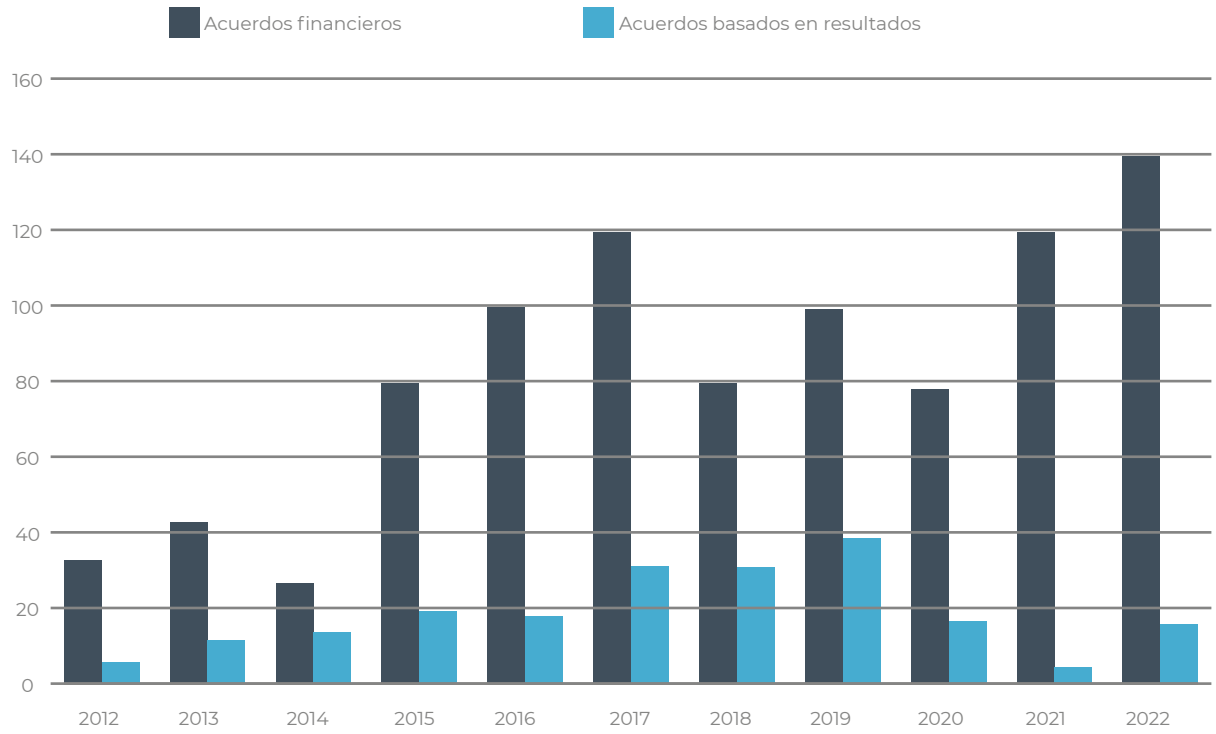
There are few analyses assessing this difference between list and net prices, in part because there is no evidence; one exception[14] is that (i) there is a significant difference between list and net prices, and this difference has been increasing over time (ii) it was not possible to magnify the total discounts, due to the existence of confidential agreements.

But when we talk about transparency, we have to go beyond the specific variables about the cost or value of the treatment: transparency in the process is also key if we want good governance. Finding the balance between transparency and confidentiality is not easy. This is reflected in the comments on NICE in England, a world leader in the world of (economic) evaluation in health, both for its technical rigour and its transparency. But in the decisions/recommendations of NICE (through the *Patient Access Schemes*), we find transparency in the process, with a multitude of reports and evaluations published, but with confidential discounts: *"Appropriate censorship (redaction) ensures that discounts remain confidential, but maintains the transparency of the decisions made by the Agency."*[15]

2.4. International Reference Prices, Transparency and International Comparisons

Given that international reference prices (IRPs) are one of the main mechanisms conveying the global impact of greater net price transparency, it is important to summarize what we know to date about the impact of this price regulation policy, particularly on international relative prices. As argued above, the question to be evaluated would

Figure 1. Number of Joint Venture Agreements Globally, by Year and by Type



EMBED SOURCE: GlobalDAta

Source: https://www.pharmaceutical-technology.com/pricing-and-market-access/risk-sharing-agreements/?cf-view&cf-closed

be whether it is preferable, from the point of view of social welfare, to have differential prices between countries, or a single price, for medicines. It is therefore necessary to assess whether PRIs lead to greater price convergence in Europe for innovative patent medicines. If this were the case, the implication would be that greater transparency in drug prices could reinforce, and increase, this convergence, making such differentiation unfeasible.

The WHO has published guidelines/recommendations on various pricing policies, including PRIs[16], which highlight the significant challenges surrounding PRIs, recommending their conditional use by countries. Partly, and something very relevant to the question at hand, is that there is rather limited evidence on whether or not there is price convergence[17]. In part, the lack of evidence is due to the difficulty of measuring real prices, but also because market dynamics are different between medicines (either by market size, available alternatives, unmet needs, among others), and between regions. In addition, as discussed above, access to medicines is unequal across countries. What we seem to know is that there are price declines in countries with PRIs in the short run, but at the expense of longer lags in countries with lower prices. In addition, there is even more limited evidence on the long-term impact of PRIs and effects on health outcomes.

International comparisons of drug prices also provide relevant evidence on relative prices between countries at a more general level[18]. This type of analysis aggregates the prices of the drugs included in the analysis to estimate an 'average' price, country by country, so that comparisons can be made. These analy-

ses have their challenges and complexities, but they offer an interesting perspective. The different studies reinforce that at this general level, there is some price differentiation at the global level, with some countries always appearing in the highest positions. As far as Spain is concerned, it is usually in the lowest positions, that is, the prices of medicines (under patent) are relatively low compared to many of our neighbouring countries. And this is very important, considering the potential impacts of greater transparency on net prices.

Within this limited evidence, it is important to highlight a study that simulates, with real data on drug prices in Europe, the effects of

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greater transparency – which we will discuss below.

3. EFFECTS OF GREATER TRANSPARENCY ON NET PRICES

The importance of the interconnection of prices between countries, with *"repeated games"* between the funder and the pharmaceutical companies over time, implies that the impact of making unit costs transparent in the short and medium/long term must be considered. But it is also necessary to assess the possible effect of such transparency on the functioning of the market within each country. Therefore, a distinction is made between three effects, which are detailed below: effects on public interests, effects on pharmaceutical companies, and effects on competition and market functioning.

3.1. Protection of public (financial) interests

Due to the nature of *"repeated play"*, one of the biggest challenges that the decision-maker/financier may face with greater price transparency at the national level is not to receive future discounts for new therapies, or for new indications of drugs with other indications already funded. This would be mainly due to PRIs and the pricing and reimbursement systems currently in place, and the potential effects on pharmaceutical companies pricing and launch decisions.

And this is where the study by Riccaboni et al. (2020) comes in, simulating the impact of such transparency at the European level.[19] Here I briefly summarize its main results, and particularly for Spain, as it reflects a possible medium-term scenario if there were greater transparency in unit prices of medicines. To do this, and as a starting point, they calculate the list prices of medicines, based on expenditure and consumption data from IQVIA, for

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EU countries. Then, based on these prices, they simulate the possible impact of a situation of *full* price transparency (relative to a situation with estimated list prices and adding confidential discounts).

Regarding relative prices at present and in reference to the starting point of the analysis, it is important to highlight that at the country level and for all medicines on average, Riccaboni et al. (2020) reinforce the results discussed above on international comparisons: they find price differentiation in Europe, and prices in Spain are among the lowest. This has important implications for the results of your analysis.

Figure 2 shows one of these main results. Countries above the horizontal line marked '1.0' would be the countries that would suffer the highest prices thanks to transparency (Spain included); those below would have lower prices.

In the case of Spain specifically and given the relatively low prices currently relative to other European countries, a considerable impact can be observed (and fifth largest among all countries): prices would increase, according to this study, by 150% with total transparency.

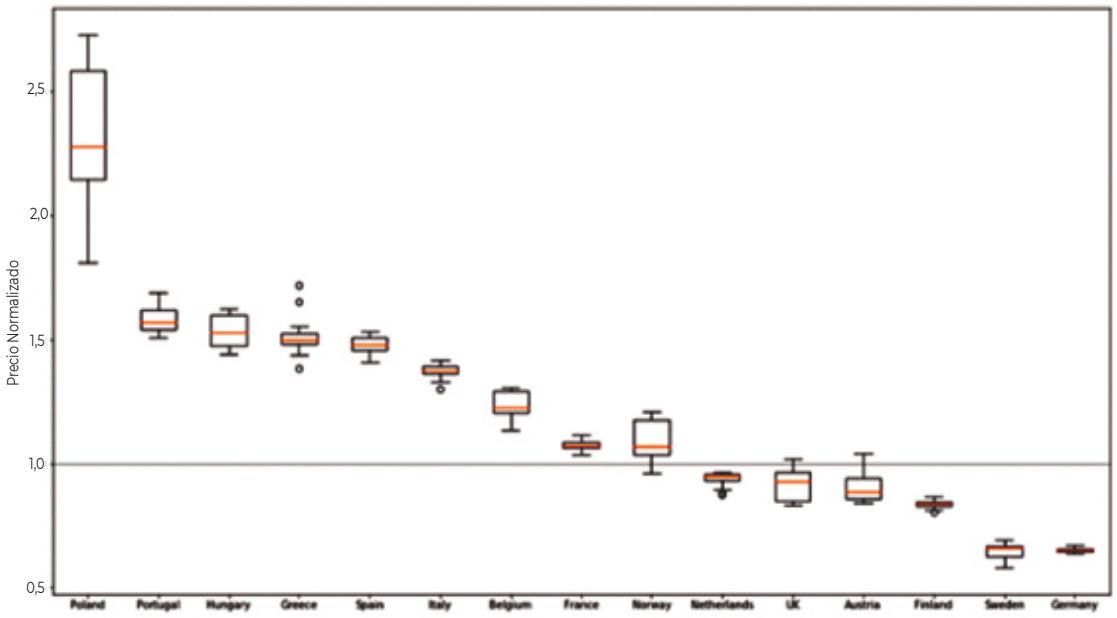
These authors also simulate the impact of *partial* price transparency, and based on their results, the authors classify countries into three groups, according to the type of impact:

(i) Group A, with Sweden and Germany, would be indifferent between full and partial transparency;

(ii) Group B, which includes the United Kingdom and Austria, among others, could eventually benefit from full transparency:

(iii) Group C, in which Spain is located, and where they would never benefit from total transparency.

Figure 2. Change in price under the assumption of full transparency in net price



Souarce: Riccaboni et al. (2022). Reprinted with permission.

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The potential implications for demonstrating greater transparency are reflected in the views expressed by several European Ministries of Health, including Spain, Ireland and Italy. Ireland's decision, for example, argues that *"if the conditions (of prices) were to be disclosed urbi et orbe, probably no company would offer them, so that the public purse would be deprived of the possibility of significant savings."*[20] In fact, the Irish *Information Commissioner*'s Resolution of 2018 makes estimates for the case in question, and where financing a single cystic fibrosis drug at a list price would mean a disbursement of more than 100 million euros per year, for 700 patients for this country – something that did not happen in practice due to confidential discounts. Another example is in Italy, where it is argued that making these discounts transparent can lead to the control of public spending. For Spain specifically, the Ministry of Health[21] has already argued that giving access to this information would lead to a negotiating disadvantage when it comes to achieving more competitive prices – we have

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already highlighted the relatively low prices in Spain today.

3.2. Protection of the economic and commercial interests of pharmaceutical companies

The Transparency and Good Governance Laws highlight the importance of keeping certain strategic information confidential as it can affect the ability of companies to compete (see for example art. 14.1 LTAIBG) - including the final price, but also product costs among others. It is also important to remember that the prices of medicines are regulated, and normally, and in the case of Spain in particular, *"the public financing of medicines is preceded by a negotiation procedure with pharmaceutical companies in which the costs of manufacturing the medicine, business profit margin and the therapeutic utility of the product are weighed – all of them derived from the analysis of data of reserved knowledge"*.[22]

Therefore, pharmaceutical companies would have a legitimate interest in keeping the financing price of medicines confidential, since it is obtained from confidential information. Its disclosure could cause serious damage to the company's ability to compete, and such a price should be considered a trade secret worthy of protection. In addition, in most, if not all, cases, it turns out to be an exclusive supplier, protected by a patent right – although it is true that there may be some therapeutic alternatives.

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3.3. Protection of competition and the proper functioning of the market

The third effect to be taken into account is in the functioning of the market itself, since, as just argued, unit prices could be considered a strategic variable. This is evident in the position of various competition authorities regarding the transparency of this type of information in other markets. Although in this case the exchange of strategic information (including real prices and discounts) between companies has been sanctioned, the result of this concerted practice could be similar to the effect of making unit prices of medicines transparent: transparency on key strategic variables is increased and the uncertainty associated with competition is weakened or eliminated.

Two examples of warnings identified regarding the impact of greater transparency in the market (including but not exclusively) can be found in Europe and the US. Firstly, the EC guidelines[23] on horizontal agreements between companies, facilitating collusive activities. Second, the FTC[24] in the U.S., and specifically for health technologies, refers to the impact of making agreements between different health plans and healthcare providers transparent. It is reasoned that it would be possible for providers, knowing their competitors' prior agreements, to use this information during their negotiations with health plans. On the other hand, health plans could also agree in advance on the agreements to offer, rather than competing with lower prices – therefore, it is argued that the disclosure of such agreements will offer minimal benefits to users in exchange for significantly increasing the risk of reducing competition[25].

The OECD, for example, has expressed itself in similar terms[26], warning of the potential anti-competitive risks arising from procure-

The third effect to be taken into account is in the functioning of the market itself, since, as just argued, unit prices could be considered a strategic variable.

ment tender manipulation, in which governments publish too much price information in procurement tenders: *"when publishing the results of a tender, carefully consider what information is published and avoid disclosing competitively sensitive information, as this may facilitate bid-rigging schemes in the future"*. In a subsequent review[27], the OEC recommends designing tenders based on what should be achieved, and not on how to do it, as well as limiting the exchange of information between bidders as much as possible, among others. The aim is to reduce predictability among possible alternatives to complicate collusion between bidders. The importance of having rules or guidelines on transparency in procurement processes, as well as on the conditions and timing of the publication of tender-related information, is highlighted.

4. FINAL REFLECTIONS

During 2023, in Spain there have been two court rulings of first instance, and therefore not[28] final, which are important to mention as an introduction to my final reflections, as it gives the feeling that there has been a change relative to previous judgments. In these last two judgments, and without going into detail, the Ministry of Health is urged to send the defendants the express resolutions issued by the General Directorate of the Basic Portfolio of Services of the National Health and Pharmacy System, establishing the financing and price conditions within the scope of the National Health System for two therapies specifically. Two aspects deserve special attention from my point of view. First, both argue that knowing the price of the drug does not imply knowing the factors that determine the price and that therefore the resolution does not include that private information provided by the pharmaceutical laboratory. Secondly, one of them does not accept that this transparency will (i) harm the economic interests of the National Health System, (ii) may pose a risk to negotiation in other cases and thus worsen the conditions of access, and (iii) be relevant for the purposes of negotiations with other competitors.

(...) : "when publishing the results of a tender, carefully consider what information is published and avoid disclosing competitively sensitive information, as this may facilitate bid-rigging schemes in the future".

On the first aspect, I believe that knowing the unit price can reveal important information about the commercial strategies of companies, artificially reducing the uncertainty associated with competition. Regarding the second aspect, although it is true that there is little real evidence regarding the impact of greater transparency in unit prices, the analysis discussed above reflects a possible situation that would be against the argument.

(...) I believe that knowing the unit price can reveal important information about the commercial strategies of companies, artificially reducing the uncertainty associated with competition.

With this, it is important to consider the four main findings of a recent OECD study[29] on the effect of greater transparency in drug prices:

- Current efforts toward greater price transparency are *"slowly accelerating."*
- There is no clarity or consensus among countries and stakeholders on the objectives of greater price transparency, or on what information should be publicly accessible.
- There is little evidence on the likely consequences of increased price transparency around the world.
- There was substantial disagreement among the experts consulted on how transparency could affect the functioning of markets.

Therefore, we need to find the balance between transparency and confidentiality of certain information. In addition, when we talk about transparency, we should be very explicit about what we mean; whether it's about financial variables, the process itself, or decision-making.

And as a final thought, the combination of industrial economics and health economics offers us a theoretical solution to the problem that concerns us here: at a global level, a system of[30] *value-based differential pricing* could become an efficient and equitable system if we manage to increase global ac-

And as a final thought, the combination of industrial economics and health economics offers us a theoretical solution to the problem that concerns us here: at a global level, a system of *value-based differential pricing* could become an efficient and equitable system if we manage to increase global access to these therapies.

cess to these therapies. More specifically, we would have a situation where:

i) *Relative* prices between countries reflect differences in income, with higher prices in higher-income countries, and where higher income is a proxy for more inelastic demand[31];

ii) Absolute prices in each country are determined based on their willingness to pay – and reflecting the 'value' of the treatment from the point of view of the particular country.

In addition, and at least in the short/medium term, it would be interesting for these new very disruptive therapies to go beyond their unit cost (without denying the importance of this variable, of course). At the national level, we could complement it with robust health technology assessment systems, where in situations of great (clinical) uncertainty with unmet medical needs, the use of controlled entry agreements will be encouraged, making payments based on results in clinical practice. And with the possibility of adding financial agreements in a hybrid model. While these agreements are beyond the scope of this article, they are important for how to fund these therapies both now and in the future.

[1] The latest report available here: https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf

[2] More information is available here: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_es

[3] In economic terms, this effect can be defined as the '*free-riding effect*'.

[4] An argument sometimes used by the industry – and I think wrongly – that the prices of medicines are high due to the high costs of R+D, which has led other agents to demand evidence in this regard. But that's another topic.

[5] For more information: https://www.who.int/europe/groups/the-novel-medicines-platform#:~:text=At%20the%2072nd%20session%20of,the%20WHO%2FEurope%20Access%20to

[6] World Health Organization. Improving the transparency of markets for medicines, vaccines, and other health products (FOOTNOTE). Draft resolution proposed by Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta, Portugal, Russian Federation, Serbia, Slovenia, South Africa, Spain, Sri Lanka, Uganda, Seventy-second World Health Assembly, Agenda item 11.7, A72/A/CONF./2 Rev.1. 2019. p.2. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

[7] Initiatives in Spain in the medicines market include the publication of pharmaceutical expenditure series, minutes with (some) justification on financing decisions, the appearance of VALTERMED – not without complications and challenges still to be resolved, such as the duplication of processes – for medicines with high medical and economic impact, and the publication by the CAPF of several documents with its recommendations to improve the evaluation system. Pricing and financing.

[8] The LTAIBG establishes and regulates the right of access to public information by natural and legal persons, as well as the complaint procedure before the Transparency and Good Governance Council (CTBG).

[9] Article 14.1 of the LTAIBG places limits on the right of access to public information (Art. 14.1 LTAIBG). In addition, the Law on Public Sector Contracts allows only the total price of the contract to be published, without a breakdown of the units acquired, and the Law on Guarantees and Rational Use of Medicines and Medical Devices (LGURMPS) provides in its article 97.3 for the confidentiality of all information on the *"technical, economic and financial aspects"* provided by pharmaceutical companies to the Ministry of Health.

[10] More information on R+D costs at: SiRM, L.E.K. Consulting & RAND Europe, The financial ecosystem of pharmaceutical R&D: An evidence base to inform further dialogue, 2022. Rennane S, Baker L, Mulcahy A. Estimating the Cost of Industry Investment in Drug Research and Development: A Review of Methods and Results. INQUIRY: The Journal of Health Care Organization, Provision, and Financing. 2021;58. Schlander, M, Hernandez-Villafuerte, K, Cheng, C-Y, Mestre-Ferrandiz, J, Baumann M. 2021. How much does it cost to research & develop a new drug? A systematic review and assessment. PharmacoEconomics.

[11] See, for example, Mestre-Ferrándiz J, Nuño-Solinís R, del Llano Núñez-Cortés A, del Llano Señarís J. 2023. Biomarkers as a driver of Precision Medicine in Oncology. Gaspar Casal Foundation. ISBN: 978-84-7360-886-2.

[12] It is also important to note that another agent to take into account would be pharmacies/hospital pharmacies.

[13] Abellán et al. (2023) provide an overview of the following models of price regulation: value-based pricing; International reference prices; Risk-sharing agreements; control of benefits; and Cost-plus (Abellán, JM, Espín, Mestre-Ferrandiz, J., Oliva, J. 2021. Price regulation and financing of new medicines: elements for debate in Spain. AES Documents No. 2. July. Barcelona: Association of Health Economics. 2021. ISBN 978-84-09-31994-7. Available here: http://www.aes.es/Publicaciones/Politicas-Precios.pdf).

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[16] WHO guideline on country pharmaceutical pricing policies, second edition. Geneva: World Health Organization; 2020.

[17] For more literature on this aspect of price convergence, or not, through PRIs, see Barrenho E and Lopert, R. 2022. Exploring the consequences of greater price transparency on the dynamics of pharmaceutical markets. OECD Health Working Papers No. 146.

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[21] Ministry of Health, Consumer Affairs and Social Welfare. 2018. S/ Ref.: File 33408 (2018 hospital consumption data).

[22] Ministry of Health, Consumer Affairs and Social Welfare. 2018. S/ Ref.: File 33408 (2018 hospital consumption data).

[23] European Commission. Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements. Communication from the Commission, 2011/C 11/01. 2011. p. 17. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0720

[24] US Federal Trade Commission. Amendments to the Minnesota Government Data Practices Act regarding health care contract data. 2015. Available: https://www.ftc.gov/legal-library/browse/advocacy-filings/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care

[25] This case is especially relevant for Spain, if we take the different health plans as analogous to countries.

[26] OECD. 2021. Recommendation of the Council on Fighting Bid Rigging in Public Procurement, OECD/LEGAL/0396. p. 8. Available: https://www.oecd.org/daf/competition/RecommendationOnFightingBidRigging2012.pdf.

[27] OECD. 2023. Recommendation of the Council on Fighting Bid Rigging in Public Procurement. Available: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0396

[28] National Appellate Court, JUDGMENT no. 117/2023, PROCEDURE: Ordinary 2/2023-B. PO ORDINARY PROCEDURE 0000036 /2022.

[29] Barrenho E & Lopert, R. 2022. Exploring the consequences of greater price transparency on the dynamics of pharmaceutical markets. OECD Health Working Papers No. 146.

[30] Danzon, P.M., Towse, A.K. and Mestre-Ferrándiz, J. 2013. Value-based differential pricing: Efficient prices for drugs in a global context. Health Economics.

[31] The economic theory that reflects this inverse relationship in different markets between the elasticity of demand for a product and its price is due to *"Ramsey prices"*.

Jorge Mestre Ferrándiz

THE CONTRACTUALIZATION OF THE REIMBURSEMENT PRICE PROCEDURE AND THE PROTECTION OF CONFIDENTIALITY: AN IMPERATIVE LEGAL REFORM

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RESUMEN: La regulación legal vigente de la financiación pública de los medicamentos es claramente insuficiente, confusa e insegura. Sigue anclada en un modelo antiguo, basado en la fijación unilateral por el Estado del precio, y no refleja la realidad actual del proceso, que es eminentemente bilateral y negociado. Asimismo, no contempla la complejidad y variedad de las condiciones especiales de financiación de los medicamentos innovadores. Este hecho genera múltiples disfunciones administrativas y jurídicas, entre las cuales resulta especialmente relevante la defectuosa protección de la confidencialidad de los acuerdos que resultan de la negociación comercial entre el Estado y los laboratorios. En este artículo se plantea que la reforma del sistema de financiación pública actualmente en curso debería avanzar en el reconocimiento de la realidad negociada del procedimiento de precio de reembolso y en la garantía de la confidencialidad de los acuerdos alcanzados entre las partesa.

PALABRAS CLAVE: Financiación pública; precio de reembolso; confidencialidad; transparencia.

ABSTRACT: The current legal regulation of public financing of medicines and reimbursement prices is clearly insufficient, confusing and insecure. It is still anchored in an old model, based on unilateral price setting by the Government, and does not reflect the current reality of the process, which is eminently bilateral and negotiated. Likewise, it does not take into account the complexity and variety of the special financing conditions for innovative medicines. This fact generates multiple administrative and legal dysfunctions, among which the defective protection of the confidentiality of the agreements resulting from the commercial negotiation between the Government and the companies is particularly relevant. This article argues that the reform of the public financing system currently underway should make progress in recognizing the negotiated reality of the reimbursement price procedure and in guaranteeing the confidentiality of the agreements reached between the parties.

KEYWORDS: Public financing; reimbursement price; confidentiality; transparency.

1. INTRODUCTION: THE CURRENT LEGAL MODEL OF PUBLIC FINANCING OF MEDICINES

Historically, laws have given the Government the power to unilaterally fix the price of drugs. Such regulation has existed in Spain since industrial drugs began to be imposed in the 30s of the 20th century, as opposed to handmade drugs, and especially since the civil war.

Specifically, the universal attribution to the Government of the competence to fix the prices of all industrial medicines was carried out in the Decree of February 6, 1939 (BOE no. 41, February 10, 1939; p. 783) which created the Consejo Superior de Sanidad (attached to the Ministry of the Interior) and modified the *Reglamento de Especialidades Farmacéuticas* of 1924, regulating this function and the procedure for the authorization, registration and pricing of medicines.

Consequently, many years before the existence in Spain of the social security system and public financing of medicines, their retail price was already totally administratively intervened. Government control over prices was intended to prevent speculation in this market and to facilitate patients' access to medicines.

The powers on price intervention is contained in the Law of Bases of National Health of November 25, 1944, in force until the General Health Law of 1986, whose Base 16, attributes this power to the General Directorate of Health, from which several regulations were issued regulating the procedure for setting industrial prices. All of them are based on the method of addition of costs. The authorized retail price of a drug would be the result of adding a reasonable economic benefit for the producer to the costs of placing a specialty on the market.

In the post-1978 constitutional period, the fundamental milestones in the regulation of drug prices have been, essentially, the following: (i) Law 14/1986, General Health Law, which essentially maintains the traditional generalized intervention regime based on the addition of costs; (ii) Law 25/1990, on Medicines, direct antecedent of the current regulation, which does not alter the fundamental principle of intervention, although it establishes a very relevant rule which consists of the fact that the industrial price would have the character of *maximum price*, allowing downward competition; (iii) Law 66/1997 accompanying the PGE for 1998, which liberalizes the prices of drugs not financed by the SNS, which constitutes, at least conceptually, a notable change of paradigm with respect to the model of universal price intervention that has existed since 1939; (iv) Law 29/2006, i.e., which excludes from price intervention both drugs not financed by the SNS and drugs not subject to medical prescription; and finally (v) Royal Legislative Decree 1/2015, of July 24 (**"LM"**), which incorporates all the mechanisms for rationalizing pharmaceutical spending developed during the economic crisis of recent years (contained mainly in RDL 4/2010; RDL 8/2010; RDL 9/2011; RDL 16/2012; RDL 28/2012; and Law 10/2013), together with their implementing regulations to which we will refer below.

The legal model of administrative intervention on the price of drugs currently in force is extremely confusing. It is the result of the intertwining of a long legislative tradition based on *universal* price *intervention* (of all medicines marketed in Spain) and the system of public financing of drugs, which is much more recent in time. The reality is that the public financing of drugs has become the backbone of the current regulations, making the whole system orbit around this regulation. The legislation has abandoned the principle of *universal intervention* in the price of medicines and concentrates on regulating only public financing (*reimbursement price*).

Thus, as a general rule, it can be said that everything that is outside the scope of public financing, i.e., drugs not included in the ***SNS Pharmaceutical List*** (“*prestación farmacéutica del SNS*” o *Reimbursed Medicines List*)* , as well as the private market for financed drugs, is essentially *liberalized*. In other words, *there is* little or *no intervention*.

This major legislative transformation has been taking place gradually and, to a certain extent, imperceptibly. In Spain, as is the case in many of our neighboring countries, the weight of the public sector in overall pharmaceutical spending is overwhelming, so that, for practical purposes, for a substantial part of the drugs, especially innovative and more costly treatments, the “*publicly financed price*” is equivalent to their “*price*”. The confusion of the two concepts is very frequent in practice.

The legal regulation of this matter is essentially contained in Title VIII of the LM relating to “*...the public financing of drugs and medical devices...*”. A label under which legal norms of different historical origin, never well consolidated and scarcely systematic, converge and generate endless problems of application and interpretation.

The basic starting point of the legal regulation is the ***principle of selective and non-indiscriminate financing*** of drugs proclaimed in art. 92.1 of the LM. This precept establishes that “*The inclusion of drugs in the financing of the National Health System is made possible through selective and non-indiscriminate financing, taking into account general, objective and published criteria...*”.

This legal principle means that not all drugs that obtain a national or EU marketing authorization are automatically financed in Spain. Only those that are specifically *selected* and included in the “*pharmaceutical list*” of the SNS by means of the corresponding resolution of the Ministry of Health are.

Thus, as a general rule, it can be said that everything that is outside the scope of public financing, i.e., drugs not included in the *SNS Pharmaceutical List (“prestación farmacéutica del SNS” o Reimbursed Medicines List)*, as well as the private market for financed drugs, is essentially liberalized. In other words, *there is* little or *no intervention*.

Article 92 of the LM establishes a series of criteria on which the decision on the inclusion of a drug in public financing must be based. These are “...a) *severity, duration and sequelae of the different pathologies for which they are indicated, b) specific needs of certain*

groups, c) therapeutic and social value of the drug and its incremental clinical benefit, taking into account its cost-effectiveness, d) rationalization of public spending on pharmaceutical services and budgetary impact on the National Health System, e) existence of drugs or other therapeutic alternatives for the same conditions at a lower price or lower cost of treatment (and) f) degree of innovation of the drug".

These criteria are rather vague (and also somewhat reiterative) and, in fact, leave the decision on the inclusion of any drug in the pharmaceutical list completely open. The regulation empowers the National Government to develop these criteria in greater detail (both in this article and in article 94.1), but this has never been specified in the regulations.

However, together with these general criteria, Art. 92 LM also establishes a series of **general exclusions** that affect certain categories of drugs. This precept states that "*...in any case, the pharmaceutical list will not include medicines not subject to medical prescription, medicines that are not used for the treatment of a clearly determined pathology, nor products for cosmetic or dietetic use, mineral waters, elixirs, dentifrices and other similar products. Medicines indicated for the treatment of syndromes and/or symptoms of minor severity will not be financed either, nor those which, although authorized in accordance with the regulations in force at the time, do not respond to current therapeutic needs, this being understood as an unfavorable benefit/risk balance in the diseases for which they are indicated*". The essential rule is that drugs not subject to medical prescription are not subject to public financing.

Another relevant point of the legal regulation is that the decision on the inclusion of a drug in the pharmaceutical list of the SNS is made simultaneously with the decision on the setting of its price and financing conditions. This is clear from art. 92.1 LM, although historically this was not always the case. Nowadays, the resolutions of the Ministry of Health that decide on the inclusion of a drug in the pharmaceutical list also contain, in the same document, a pronouncement on the price and financing conditions.

Well, although the legal regulation of the criteria and limits for the inclusion of drugs in the public financing system is found in art. 92 of the LM, this same Law contains another precept (art. 94) related to **"*price setting*".** This article of the LM is unintelligible if one does not take into account the historical genesis of this regulation, to which we have alluded above.

It is worth remembering that in Law 25/1990, of December 20, 1990, on Medicines, the origin of the current LM, there was an entire title (Title VIII) entitled "*On the intervention of drug prices"* which established a complete regulation of the administrative procedure for setting the prices of all medicines *(*i.e., *universal price intervention).* The now repealed Article 100 of Law 25/1990 established the following*: "The Ministry... will establish the maximum national industrial price for each medicine when authorizing it and registering it in the Register*". In other words, all drugs without exception, whether financed or not, had their price administratively intervened. The price was fixed by a resolution of the Ministry of Health at the time of obtaining the national code.

However, as mentioned above, this is no longer the regulatory model. In the current LM there is no longer a title relating to "*... intervention in drug prices ...*". There is only a regulation on the "*public financing of drugs*". For this reason, paragraph 5 of article 94 of the LM, in contrast to what was previously established in article 100 of Law 25/1990, states that the Interministerial Commission on Drug Prices (**"CIPM"**), attached to the Ministry of Health, is responsible for "*...setting, in a rea-*

soned manner and in accordance with objective criteria, *the* ***prices for financing*** *the National Health System for drugs and medical devices for which a medical prescription is required, which are dispensed in Spanish territory".*

In fact, the last paragraph of this section of Art. 94 of the LM provides that "*... when these same products are not financed, if they are dispensed in national territory, the provisions of paragraph 4 shall apply*", regarding the **notified price** system.

In summary, within the complexity of the aforementioned legal precept, it is relatively clear that the perimeter of administrative intervention on the industrial prices of drugs in Spain is nowadays circumscribed (unlike what happened in our historical laws) to **drugs financed** by the SNS. In Spain, the Administration does not set the price of drugs, but rather their publicly financed price.

Finally, the LM regulates the (obligatory) coexistence of drugs financed in the public market (in the NHS) and in the private market. Section 6 of Art. 94 of the LM establishes that "*...in any case, drugs and medical devices that it is decided may be financed by the National Health System may also be marketed for prescription outside the same...*". However, in these cases of ***public-private duality*** in the commercialization circuit, it establishes that "*... As a general rule, the price of financing by the National Health System will be lower than the industrial price of the medicine applied when it is dispensed outside the National Health System...*". It is not possible, therefore, (at least as a "*...general rule...*") to market at a higher price to the public sector than in the private drug market.

It follows from this legal regulation that financed drugs have a *double price*: the public financing price (the financed industrial price or PVL) and the notified industrial price, for those cases in which the drug is marketed outside the SNS. In practice, in the resolutions currently issued by the Ministry of Health regarding public financing, two types of agreements are distinguished: (i) "*... To set the maximum industrial price of the presentations of the drug...*" and (ii) "*...To set the no-*

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tified industrial price for when it is to be dispensed outside the SNS".

2. THE FORMAL PROCEDURE FOR SETTING THE PRICE AND CONDITIONS OF PUBLIC FINANCING OF MEDICINES: AN AMALGAM OF RULES OF DUBIOUS VALIDITY AND APPLICATION

Once it has been clarified that universal intervention in the price of drugs has disappeared in our pharmaceutical law and that "*...price setting ..*" is limited to the specialties included in the pharmaceutical list of the SNS, the essential question is to know how this administrative procedure is regulated in the current legislation. And, above all, how it is actually carried out in practice.

As a starting point, we must point out that the LM sheds little light on all these issues, since the regulation it contains on the procedure for "*... price fixing ...*", contained in Article 94, is very brief. It is really very fragmentary and limited. In fact, it is surprising that such a relevant chapter of national public expenditure (around 22,000 million euros in 2023, including expenditure through pharmacies and public hospital pharmaceutical expenditure), in the control of which the administrative procedure for setting the price of public financing has a determining impact, has such a sparse, confusing, contradictory and insecure regulatory framework.

In relation to the procedure for setting the financing price, the most relevant rule of the LM is found in paragraph 2 of article 94*: "In order to* ***market*** *a drug in Spanish territory****, it will be essential to*** *have processed the offer of the drug to the National Health System. The same procedure will be followed if*

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there are substantial variations in the conditions of authorization of the drug".

This is a very controversial rule, a source of many interpretative disputes. In essence, it means that the NHS must always have the *opportunity* to include any newly authorized drug (or indication) in public financing. And that this *opportunity* must materialize before the drug is marketed ("*... it will be essential to* ***have processed*** *...*"). This legal provision raises doubts as to whether or not it is necessary for the price and financing procedure to have been completed or whether it is sufficient for it to have been initiated. Doubts are also raised by the fact that the maximum legal deadlines for issuing the resolution on public financing have elapsed without the Administration having issued a decision. In any case, the legal expression used in this precept "*... having processed the offer ...*" leads one to think that the administrative procedure for public financing is initiated at the request of a party (of the laboratory holding the marketing authorization), when, however, this is not the general rule.

The reality is that the procedure for the public financing of drugs is normally initiated ex officio. This is expressly contemplated in an important regulation (although of very low rank) which is the ***Instruction of December 13, 2002****, of the Undersecretariat of Health, which coordinates the administrative procedures related to marketing authorization and financing with public funds of medicines for human use*. As it happens very often in our pharmaceutical law, secondary rules regulate very relevant issues. This is one of those cases.

The Instruction of December 13, 2002, establishes that in the resolution granting the marketing authorization for a medicine, "*... the Director of the Spanish Drug Agency will communicate to the corresponding laboratory that, on the same date and based on the principle of administrative coordination, the resolution is transferred to the General Directorate of Pharmacy and Health Products, so that the aforementioned management center proceeds, ex officio, to resolve on the provisions of article 94.1, first paragraph, of Law 25/1990...".* That is to say, on public financing.

The DGCCSF "*... within three days from the date of the Agency's communication, will adopt an agreement to initiate a procedure aimed at deciding on the inclusion or exclusion of the authorized medicine, or of the authorized indications, from the pharmaceutical list of the Social Security, charged to the funds of the latter or to State funds allocated to health...*".

The Instruction foresees the case that, in the period between the date of notification of the marketing authorization and the date of notification of the agreement to initiate the procedure, the laboratory submits a request for price fixing to the DGCCSF. In such a case "*... this directive center will arrange its accumulation to the procedure to resolve on the inclusion or exclusion of the authorized medicine ...*" and the laboratory concerned will be notified.

In short, the administrative procedure on public financing (generally referred to in industry jargon as *the reimbursement price procedure*) is normally initiated ex officio through collaboration between the AEMPS and the DGCCSF. However, it can also be initiated at the request of the laboratory, either simultaneously at that time or at a later time in the event that public financing was initially rejected.

Beyond this rule regarding the initiation of the procedure, Art. 94 LM merely indicates that the decision corresponds to the Interterministerial Commission on Drug Prices (**"CIPM"**), attached to the Ministry of Health. It reads as follows: "*...It is the responsibility of the Interministerial Commission on Drug*

Prices, attached to the Ministry of Health ... to ***set, ... the prices*** *for financing the National Health System...*", (art. 94.5). A regulatory statement that is not legally accurate either, since, strictly speaking, the administrative resolution deciding the inclusion of the drug in the pharmaceutical list and setting the financing price is formally adopted by the unipersonal body to which the CIPM is attached, which is currently the General Directorate for the Common Portfolio of Services of the National Health System and Pharmacy (**"DGCCSF"**).

Section 8 of article 94 adds to the above that "*In order to make decisions, the Interministerial Commission on Drug Prices will take into consideration the reports prepared by the Advisory Committee for the Financing of the Pharmaceutical List of the National Health System"*. A body that is regulated in some detail in Article 95 of the LM, although its real relevance in the process of adopting the singular decisions on financing and pricing is quite limited.

At the substantive level (i.e., as regards the criteria or parameters used to set the financing price), Art. 94 of the LM is not much clearer either. It offers very few criteria for determining the public financing price. In fact, these criteria are practically reduced to a single one, expressed in the third paragraph of art. 94.1: "*The Interministerial Commission on Drug Prices will take into consideration the* ***cost-effectiveness*** *and* ***budgetary impact*** *analyses***".** To this it adds that "*... the return mechanisms (linear discounts, price review) for innovative drugs will be taken into consideration*".

Surprising as it may seem, this is all the regulation that exists in the LM with respect to the criteria for determining the price of public financing. It is all reduced, therefore, to the criterion of *cost-effectiveness* of the drug and the *budgetary impact* that the entry of the new drug into the pharmaceutical list would imply for the SNS. The current legal regulations do not establish any other additional criteria that could serve as a guide for the administrative decision, nor anything -absolutely nothing- on the possibility of establishing, together with the price, other **special conditions for public financing** of the drug (such as expenditure ceilings, decreasing prices, risk-sharing agreements, etc.), mechanisms that are currently, as we all know, the general rule in the agreements of the CIPM and the DGCCSF.

This scant regulation in the LM is not compensated by a good, complete and detailed development regulation, but rather the opposite. There are no provisions for the regulatory development of the LM on the procedure for the inclusion of drugs in the pharmaceutical list of the SNS or on the setting of the publicly financed price. All the existing regulations refer to the old Law 25/1990 (substantially different from the LM), so their premises and principles do not coincide. In fact, although these regulations have not been formally repealed, there are (very) serious legal doubts as to whether they are still in force. A bleak picture, therefore, from the perspective of legal certainty.

Among the regulations that have not been formally repealed, but whose validity is doubtful, the first to be mentioned is **Royal Decree 271/1990, of February 23, 1990**, *on the reorganization of price intervention for medicines for human use* (**"RDP"**). Even if it could be inferred from its reading that it has been implicitly repealed, what is evident is that it is in manifest *administrative disuse*. That is, in a lack of effective application by the Ministry of Health.

The RDP has the old interventionist language on prices (principle of universal price intervention), which has disappeared more recent legal regulation. Article 1.1 states that "*The laboratory sale price or industrial price of medicienes will be subject to intervention and will*

be fixed by the Ministry of Health and Consumer Affairs, in accordance with what is established by the Government Delegate Commission for Economic Affairs". As explained, this is no longer the case in Spain. The price of drugs is no longer universally intervened.

The explanatory memorandum of the RDP explains the traditional basis for (general) administrative intervention on the industrial prices of drugs, which has now disappeared. It refers to the rigidity of demand and the monopolistic tendency of this market and states that "*...in the study of the market for medicines it is necessary to consider the degree of concentration of the industry which, although it is difficult to evaluate, has a certain structure occupying dominant positions, especially in the different therapeutic subgroups; however, it should be noted that, due to constant innovation, the structure of competition is heterogeneous and that consumers are protected by the fact that in most cases substitute products are available. On the demand side, drugs are prescribed by doctors and reimbursed to a large extent by the Social Security, patients only pay part of the price and their participation in consumption is not conditional on payment, resulting in a demand with very little elasticity...*". Hence the need for price intervention by the public authorities.

The RDP regulates in its articles a pricing method based on the ***addition of costs***. In essence, it is very similar to the one that was inaugurated in Spain in development of the 1944 Law of Bases of National Health by means of the Order of January 11, 1945. Article 3 of the RDP describes what is known as ***Method-90***, according to which "*...the industrial price of the specialty will be fixed by adding to the total cost or cost price of the specialty the percentage corresponding to the business profit...*".

According to this Method-90, the cost price is calculated by the analytical application of the "*full cost*", including research and technological development. The unit cost thus obtained represents the cost of manufacturing the product, incorporating the allocations corresponding to commercial and administrative expenses incurred during the period.

For the calculation of the cost, several variables that have a direct impact on it are theoretically taken into account: level of activity, evolution of the company's costs and sales volumes, estimates of sales of the new specialty and the impact on structural costs arising from the manufacture of the new product. For its part, according to the RDP, the business profit for each specialty "*...shall be set at a percentage, determined by a technical report on the economic-financial situation of the company. This percentage will be within a range established annually by the Government's Delegate Commission for Economic Affairs, taking as a reference base the economic situation of the pharmaceutical industry as a whole and the economic policy forecasts*".

In order to ensure that the industrial price calculated is congruent with respect to similar products on the market, the following will act as "...correctors within the established profitability band..." "*...**the therapeutic usefulness provided by the new product**, scientifically proven...*", together with the proportionality criterion that prevents the cost of the treatment from being disproportionate with respect to other alternatives.

According to this RDP, "*...through the general application of these criteria, unjustified or unnecessary costs will be avoided, such as those arising from overpricing above market prices of active substances, excessive payments for licensing of brands or technology or promotional or advertising expenses not appropriate to the characteristics of the product, as well as those expenses not necessary for the development of the normal activity of the Company, so that the final*

price of the drug is calculated based on its ***real cost, in an objective*** *and transparent* ***manner****…*".

Together with the RDP (relating to administrative intervention on prices), there are two other legal rules from the same period that were issued to regulate the process of inclusion of drugs in the pharmaceutical list: (i) **Royal Decree 83/1993, of January 22, 1993**, which regulates the selection of drugs for the purposes of their financing by the National Health System (**"RD 83/1993"**) and (ii) the **Order of April 6, 1993,** which implements Royal Decree 83/1993 (**"OM1993"**). These are two regulations implementing the former Law 25/1990 that have not been formally repealed, so there are serious doubts as to whether they are in force or not. This is a problem from the point of view of the legal certainty of these procedures.

Art. 2 of RD 83/1993 establishes a series of general exclusions for pharmaceutical list of the SNS. These are very similar to those now indicated in art. 92.2 LM (although not identical). With regard to the specific exclusions, the criteria of this regulation also basically coincide with those established in art. 92.1 LM.

On a strictly procedural level, Art. 3.1 of RD 83/1993 establishes that "*…At the time of authorization and registration of a medicine, a decision will be made as to whether it is included in or excluded from the Social Security pharmaceutical list*. Section 2 contemplates the decision of non-inclusion in the following terms: "*The decision not to include the medicines referred to in the previous number must be reasoned, the applicant will be informed and will state the appropriate appeals and the deadlines for filing them*".

OM1993 is also very relevant in practice, since its sole purpose is to regulate the **administrative procedure for *non-financing*** and the procedure for **exclusion** from the pharmaceutical list. Two fundamental procedures for laboratories, which often give rise to legal disputes.

The OM1993 provides that once "*…the procedure for non-inclusion of the specialty has been initiated, the applicant will be notified so that he/she can make the allegations and provide the evidence he/she deems appropriate within a period of thirty days and, if necessary, make the appropriate modifications that could determine the inclusion of the specialty". (…) "Once the procedure has been instructed and after hearing the interested party, the appropriate resolution will be issued by the Directorate General of Pharmacy and Medical Devices. The resolution will be issued within a maximum period of* ***one hundred and eighty days*** *from the initiation of the procedure, must be reasoned, will be adopted simultaneously with the authorization and registration of the specialty and will be notified to the applicant*". The exclusion procedure is regulated in similar terms.

In all this set of regulations from the 1990s, never formally repealed, but of dubious validity, a very curious and perhaps surprising fact stands out in today's eyes: there is no specific regulation of the public financing price procedure. In fact, under Law 25/1990, when there was a universal price intervention system, the *price* of drugs was the same as the publicly financed *price* if the drug was included in the pharmaceutical list of the SNS. Unlike what happens today, the decision on public financing and the setting of the price were taken separately and independently.

All authors who have studied the pricing model in Spain agree on the *administrative disuse* in which these regulatory norms of the 1990s have derived, if they had ever really been applied.

Law 29/2006 (origin of the current LM) replaced the cost addition method by the **international comparison of prices in the EU**, stating that "…in *addition to the criteria set*

In all this set of regulations from the 1990s, never formally repealed, but of dubious validity, a very curious and perhaps surprising fact stands out in today´s eyes: there is no specific regulation of the public financing price procedure.

forth in article 89.1, the average price of the drug in the Member States of the European Union that, without being subject to exceptional or transitional regimes on industrial property matters, have incorporated the corresponding Community legislation into their legal system..." (art.90) *will also be taken into account*. This provision also states that the CIPM "*...shall take into consideration the* ***reports on the therapeutic usefulness*** *of medicinal products...*" prepared by the AEMPS. For the preparation of these reports (which would later be called Therapeutic Positioning Reports or **TPRs**), it would rely on a network of external collaborators made up of independent experts of recognized scientific prestige.

The only legal regulation of that time (1990s) that remains clearly in force is one from the European Union. This is Council Directive 89/105/EEC of 21 December 1988 [...]

In short, Law 29/2006 carried out a *tacit repeal* of Metodo-90, although without *formally repealing* the RDP of RD 83/1993 and the OM 1993. These old rules in disuse have not been replaced by a modern and finished regulatory regulation on the public financing of drugs, despite the fact that several attempts have been made to that effect in recent years.

The only legal regulation of that time (1990s) that remains clearly in force is one from the European Union. This is **Council Directive 89/105/EEC of 21 December 1988** *relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of na-*

It is an old regulation, somewhat outdated in its language, but fully in force and mandatory.

tional health insurance systems (**"Directive 89/105"**). It is an old regulation, somewhat outdated in its language, but fully in force and mandatory.

Directive 89/105 is one of those typical directives issued in the 1980s for the construction of the internal market and the elimination of national barriers and obstacles to the free movement of goods. In its explanatory part it states the concern about the existence of national legislative disparities that "... *may hinder or disturb intra-Community trade in medicinal products, thus directly affecting the functioning of the* ***common market in medicinal products***...". Its sole objective is to remove such obstacles.

Art. 1 of the Directive states that "... *any national measure, whether by law, regulation or administrative action, intended to control the prices of medicinal products for human use or to* ***restrict the number of medicinal products covered by national social security systems***, *shall comply with the requirements of this Directive*".

Despite its misleading name, the Directive is limited to establishing two types of time limitations: (i) to the duration of pricing procedures (in those States where there is a principle of universal price intervention, as was the case in Spain in 1988); and (ii) to the duration of procedures aimed at deciding on the inclusion of a drug in a "... *list...*" of medicinal products financed by the national public health system (reimbursement price procedures).

In relation to public financing procedures, Art. 6.1 of the Directive states that "... *any decision regarding an application for inclusion of a medicinal product in the list of medicinal products recognized by the social security system...*" shall be taken and communicated to the applicant "... *within* ***90 days*** *of receipt of the application...*".

When the procedure for inclusion in the *list of financed drugs* (which would become our pharmaceutical list) is accompanied by a pricing procedure (in "... *a* ***single administrative procedure*** ..."), the deadline will be extended by a further 90 days. In other words, 180 days.

The summary of what has been said so far is as follows: The current legal regulation has abandoned the *principle of universal* price *intervention* and limits pricing only to financed drugs (i.e., those included in the pharmaceutical list). Not all pharmaceutical innovation is financed (*principle of selective financing*). The administrative decision on the inclusion (or non-inclusion) of a drug in the pharmaceutical list and the determination of its financing price (commonly known as the *reimbursement price*) are regulated in the LM in a very brief manner. In fact, the LM limits itself to establishing that both decisions are made simultaneously (art. 92.1), unlike what happened in the past, and to establishing general criteria for the selection of financed drugs (art. 92.2) and specific criteria for inclusion (art. 92.1). Regarding the financing price, the LM simply limits itself to establishing *cost-effectiveness* and *budgetary impact* as criteria for its determination (art. 94.1), abandoning the legal method of *cost addition* that traditionally existed in Spain and on which the 1990 Medicines Law and its implementing legislation were based. Consequently, all the regulatory development regulations that we currently have regarding

the price of financing (the RDP, RD 83/1993 and the OM1993) are not adapted to the LM and are in manifest *administrative disuse*. The only legal regulation, apart from the LM, that is clearly in force on the subject of the price of financing is Directive 89/105, which establishes (in essence) a maximum period of 180 days for the adoption of the administrative decision on the inclusion in the pharmaceutical list and the fixing of the price of financing.

3. THE PRACTICAL REALITY OF THE PUBLIC FINANCING PROCEDURE FOR MEDICINES

This is the description of the current regulation of the procedure for the public financing of drugs. Now, the main questions that arise are the following: Does this legal regulation correspond to the practical reality? Are we really dealing with administrative acts resulting from the exercise of a unilateral administrative power? Are other public financing conditions administratively set in addition to the maximum price of each drug? Are these special conditions regulated in any regulation? Are the maximum deadlines for resolution by the Spanish Ministry of Health met? And, if not, are there any legal consequences if these deadlines are not met?

People working in the legal field of this sector or in the institutional or market access teams of pharmaceutical laboratories know the answer to these questions. It seems quite clear that the practical reality of the public financing procedure for pharmaceutical innovation differs substantially from its normative regulation.

Starting with the most obvious, the maximum time limits established in Directive 89/105 (180 days) are systematically not complied with. However, this is not only the case in Spain, but also in most EU member states.

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Analogous to what we indicated above with respect to the RDP, it could be said that Directive 89/105 is in general *administrative disuse* in Europe.

Data from EFPIA's latest **W.A.I.T.** (*Waiting to Access Innovative Therapies*) Report published in June 2024[1] show that the average time to access pharmaceutical innovation in Europe, i.e. the time between the innovative drug obtaining Marketing Authorization (EMA) and its inclusion in the *reimbursement list*, is **531 days** for all new drugs. For oncology drugs, this average time is **559 days**. This WAIT study concerns new medicines authorized between 2019 and 2022 and includes 36 States (27 EU States, in which Directive 89/105 applies and 9 non-EU Member States).

Data from EFPIA's latest W.A.I.T. *(Waiting to Access Innovative Therapies)* Report published in June 2024 2 show that the average time to access pharmaceutical innovation in Europe, i.e. the time between the innovative drug obtaining Marketing Authorization (EMA) and its inclusion in the reimbursement list, is 531 days for all new drugs. For oncology drugs, this average time is 559 days.

The differences between countries are, in any case, considerable. Of the large EU states, only Germany (47 days) and Denmark (109) are within the parameters of Directive 89/105. All the other states are far behind: the Netherlands (321), Italy (358), France (461), Ireland (493). England (now outside the EU) has 299 days. Spain is in a particularly negative band in this comparative study, with **613 days** for innovation in general and **701** for oncology drugs. In other words, it is at the tail end of the large EU countries.

According to the WAIT Report, between 2019 and 2022 the EMA granted authorization to 167 new drugs. Of these, by 2024 a total of 103 had been incorporated in Spain into the pharmaceutical list of the SNS, i.e. 62%. On this point (the so-called innovative drug ***availability ratio***) Spain has a good ranking in Europe and is in the highest band. The EU average is 43%. Italy 77%, France 63% and the Netherlands 54%. Only Germany, with its regulatory specificities, has a significantly higher ratio (88%). The problem of the Spanish model lies, therefore, in the **time taken to process** the procedures and not in the extent to which the drugs are available in the SNS.

With respect to the duration of reimbursement price procedures in Spain, FARMAINDUSTRIA itself qualifies the results of the WAIT Report, pointing out that "*If instead of taking into account the date of European authorization ... the time from the moment the company expresses its interest in marketing in Spain (obtaining the national code) is counted, the time* ***is reduced to 551 days***[2]." In Spain, it takes laboratories approximately one hundred days on average to apply for the

marketing of drugs (national code) and, consequently, for the public financing procedure to be initiated.

In any case, even if the time of the request for the national code to the AEMPS were taken into consideration for these purposes and the bias introduced in the statistical data by the cases in which the drug is not initially included by the CIPM in the pharmaceutical list and a new procedure is subsequently initiated at the request of a party were corrected, it is obvious that in Spain the maximum period of 180 days established in Directive 89/105 is systematically not complied with.

This failure to meet the deadlines is relevant from the point of view of the State's pharmaceutical policy and strategy, but it is also, or could become, relevant from a legal point of view.

Thus, among lawyers specializing in this area, there is an intense debate on the extent to which the rule of **positive administrative silence** applies in public financing procedures, particularly in the case of procedures initiated at the request of a party. Although there are judicial precedents[3] that seem to exclude positive silence in these procedures, the issue is far from being definitively closed.

There are also legal doubts as to whether the exceeding of the maximum time limits for deciding on the public financing of drugs can lead to the pharmaceutical Authority being **held liable for** having deprived the beneficiaries of the SNS of access to a pharmacological treatment. In other words, a case of *loss of therapeutic opportunity*, recognized by the jurisprudence of our Courts of Justice.

Another very clear element of dissociation between current regulations and practical reality in public financing procedures is the imposition, together with the price, of *special conditions, restrictions or singular reservations*.

For several years now, it has been increasingly common for DGCCSF resolutions on public financing of innovative drugs to restrict it to certain indications or categories of patients. It is also increasingly common for reimbursement price decisions to contain ***special* financing *conditions***, mainly with mechanisms to limit public spending on the new drug or to remunerate the laboratory based on health *outcomes* (*payments for results* or *risk-sharing agreements*).

EFPIA's latest WAIT Report, cited above, analyzes the percentage of new drugs authorized (2019-2022) for which **access restrictions** have been established by national authorities. Such "...*restrictions*..." are understood to be mainly those that are linked to certain categories of patients or to certain types of indications (i.e., those resolutions that distinguish, for the same drug, between **funded and *non-funded* indications**) or that establish unique visa or authorization mechanisms. According to the WAIT Report, in Spain, resolutions with this type of restriction **account for 52% of the total number** of publicly funded resolutions, and this percentage has remained fairly stable over the last few years. In Italy the percentage of restricted financing is 20%, in France 35% and in England 49%. The data for Spain on this point are therefore relatively normal.

As for special financing conditions, their typology is very varied and detailed comparative studies on their degree of use are not available, since a good part of these conditions remain – logically – within the sphere of confidentiality of the financing agreements.

According to data published in the industry press[4], almost all of the DGCCSF's current decisions on public financing of medicines (around 95%) contain mechanisms for "... *annual review of sales and prices now fixed*...". In turn, between 20% and 30% of all DGCCSF resolutions on public financing (in 2023 there were 193 CIPM public financing decisions, of

According to data published in the industry press, almost all of the DGCCSF's current decisions on public financing of medicines (around 95%) contain mechanisms for *"annual review of sales and prices now fixed..."*. In turn, between 20% and 30% of all DGCCSF resolutions on public financing (in 2023 there were 193 CIPM public financing decisions, of which 58% were positive) contain special financing conditions.

which 58% were positive) contain **special financing conditions**.

These special financing conditions are increasingly varied, complex and creative, but in general, they are grouped into two broad categories: (i) those that aim to **limit or contain spending** on the financed drug, within which we find (a) *price-volume* systems, (b) maximum cost per patient systems, and (c) spending ceiling systems (whether these are national, territorial and mixed); and (ii) those that establish the remuneration of laboratories based on ***health outcomes***, such as *risk-sharing agreements* (RCAs). This last modality (ARC), which theoretically should be the most widespread in pharmaceutical innovation, is, however, in practice in clear decline with respect to the mechanisms of mere financial containment of expenditure, mainly due to the greater complexity of its design (since it is necessary to establish objective metrics for measuring health outcomes and sophisticated control mechanisms). In any case, it continues to be a common formula for certain classes of drugs with a high budgetary impact and a small number of recipients, such as gene therapies, for example.

The establishment of special conditions is nowadays a common practice in public financing procedures, but, however, it lacks legislative support. There is only a slight mention to the establishment of "*...financing conditions...*" in the first paragraph of art. 92.1 of the LM. However, neither this Law nor its implementing regulations regulate these special mechanisms of cost control and ***public-private collaboration*** through risk sharing (the risk of the efficacy of the pharmacological risk), much less their limits or operational rules. These special conditions are simply designed and negotiated *ad hoc* and articulated on the occasion of the different pricing and financing procedures.

In this context, and based on the practical reality described above, the big question we

have to ask ourselves is whether the public financing procedure for medicines can really continue to be considered today as a unilateral administrative procedure derived from the exercise of an administrative power.

4. ARE WE REALLY DEALING WITH A UNILATERAL PROCEDURE RESULTING FROM THE EXERCISE OF AN ADMINISTRATIVE POWER?

In reality, it is not really possible today to sustain this approach. It certainly was in the past, when the prices of all drugs were subject to a price intervention mechanism, but it is not possible today. The current system of public financing is not unilateral. It is the result of an open negotiation between the parties (the Goverment and the pharmaceutical laboratory) that concludes with an agreement between them on whether the drug enters public financing in Spain and under what economic conditions for the SNS.

This statement is risky from a legal point of view, insofar as it does not correspond either to the provisions of the LM or to the implementing legislation, which remain anchored in the old interventionist regulations stemming from the Decree of February 6, 1939 and the Medicines Regulations of 1924. The historical regulations were based on the premise that the Government has the unilateral power to fix and control the price of all medicines. In other words, the Government intervenes in the market. This power was limited to setting the maximum PVP and was exercised in a regulated manner, i.e., subject to an administrative procedure and certain well-defined legal criteria (the aggregation of costs and industrial profit, as mentioned above). As has been indicated, there are still reflections of this regulation in the regulations from the 1990s (the RDP, RD 83/1993 and OM993).

The current LM, although it has changed substantially on this point with respect to the 1990 Law, still maintains a language and specific precepts that evoke that old "...*price intervention*...". Article 92.1 of the LM still leads us to think that we are dealing with a unilateral procedure. It speaks of an "...***express resolution***..." of the Ministry of Health in which it will decide on public financing and set "...*the conditions of financing and price*..." within the scope of the SNS. Art. 94 LM refers to the "...***setting of prices***..." (which evokes a unilateral nature) and its articles include continuous references to this and to the "...***decision making***..." by the CIPM.

However, if we look at the heart of the matter, in the current LM the (real) role of the Government is very different from what it was historically. The Government does not act so much as a ***market regulator*** as a representative of the SNS. That is, as a ***"purchaser"*** of the drugs. What the Government actually does, through the bodies of the Ministry of Health, is to negotiate with the laboratories the economic conditions for the "*acquisition*" of drugs: both those that *will be* "*purchased*" by hospital pharmacy services and those that will be "*reimbursed*" when they are dispensed through pharmacies. The Government, therefore, does not unilaterally fix the price of drugs, as it did in the past. It negotiates the conditions of *acquisition* with the laboratories. Thus conceived, the publicly financed price (maximum price for the entire SNS) is a sort of *price-framework*. It resembles, with all due respect, the price resulting from a framework agreement in a negotiated procedure.

Beyond the legal regulation, there are several official documents that reflect the actual functioning of the public financing procedure in the terms we are describing, such as, for example, the "*Information document on the financing and pricing of drugs in Spain*", published by the Ministry of Health in May 2022. In these documents, it is natural-

The Government, therefore, does not unilaterally fix the price of drugs, as it did in the past. It negotiates the conditions of acquisition with the laboratories. Thus conceived, the publicly financed price (maximum price for the entire SNS) is a sort of price-framework. It resembles, with all due respect, the price resulting from a framework agreement in a negotiated procedure.

ly made explicit that, within the framework of this procedure, the laboratory submits its *financing proposal* (**offer**) to the Ministry. A proposal that often contains both a price and possible special financing conditions (price/volume, cost limitation proposals, etc.), which form the basis for subsequent negotiation.

The laboratories' proposal is analyzed by the DGCCSF technicians who submit their opinion to the CIPM. The DGCCSF actually performs a double analysis: on the one hand (i) an essentially **scientific-technical** evaluation of the therapeutic value of the new drug, of its "*...incremental clinical benefit...*" and its comparison with other pharmacological treatments (which is based on the so-called, and controversial, ***Therapeutic Positioning Reports***, IPT)[5]; on the other hand (ii) an evaluation of a **pharmaco-economic** nature, which should not be intermingled with the previous one, as has been declared by jurisprudence[6], in which several factors are decisive: comparison with the cost of other existing therapeutic alternatives, comparison of the proposed price with the existing international price, cost-benefit and, above all, the budgetary impact that the financed drug could have.

However, contrary to what might be inferred from a superficial reading of the LM, the scientific-technical and pharmaco-economic analysis of the drug does not lead to a unilateral decision by the Administration to set the financing price, but is **part of the bilateral negotiation** between the Ministry and the laboratory. In this negotiation, as is well known, there are proposals, counter-proposals, meetings, new alternative proposals and, finally, an agreement (or disagreement). And this agreement, **undoubtedly bilateral**, is the one that is finally embodied in the DGCCSF's public funding resolution. Obviously when it is positive.

The official resolution of the DGCCSF does not adequately reflect either in its format or in its wording the **materially bilateral nature** of this legal transaction. It continues to take the form of a unilateral resolution (as this is what still follows from the regulation of this procedure in the LM) and even includes an appeal footnote in which the means of challenging the resolution are made explicit.

However, if we consider the material content of the DGCCSF resolution, it must be admitted that it is difficult to classify it as a typical unilateral administrative act: these resolutions often incorporate obligations that are not conceivable within a scheme of unilateral pricing power.

It is impossible for an administrative act (resulting from the exercise of unilateral authority) to impose, for example, an expenditure ceiling on a laboratory, which entails a duty to supply a drug free of charge after a certain number of units. How can the Administration unilaterally impose on a laboratory the duty to supply a drug free of charge? It is also complicated to conceive of a unilateral administrative act establishing a risk-sharing agreement (RSA), for example, reducing or eliminating payment to the laboratory if certain health or survival results are not achieved.

Conceptually, these types of legal obligations (these special financing conditions) **cannot be imposed unilaterally** by the Administration. Drug prices, especially if we were in a universal intervention system, could be set unilaterally by the Administration. However, the special financing conditions are obviously of **a materially contractual**, **bilateral and synallagmatic nature**. And, good proof of this is that the laboratory formally agrees to the reimbursement price resolutions of the DGCCSF, before they are adopted and notified with legal effects.

In this context, full of elements of uncertainty, what we should ask ourselves is whether it would be advisable for our legal regulation on public financing of drugs to evolve towards *contractualization*. In other words, whether it would be desirable to bring the regulations governing these procedures closer to the **materiality of the legal business underlying** the resolutions of the DGCCSF.

In other words, whether it would be desirable to bring the regulations governing these procedures closer to the materiality of the legal business underlying the resolutions of the DGCCSF.

5. THE CONTRACTUALIZATION OF PRICE AND FINANCING CONDITIONS AND THEIR EFFECTS ON THE PROTECTION OF CONFIDENTIALITY

The absence of an adequate correlation between the legal regulation (still based on the idea of a unilateral power of the Government) and the practical reality of the public financ-

ing procedure is a source of numerous legal problems, as all of us who practice law in this field are well aware.

We have already referred to one of them, which is the problem of positive administrative silence (which would obviously be meaningless in a *contractualized* scenario). There is also the question of the challengeability of public funding resolutions, both by the laboratory concerned and by third parties, which would take a substantial turn in the event that regulatory progress is made towards a ***conventional*** (agreed) ***funding*** model.

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The configuration of the financing procedure as the exercise of an administrative power, that is, as a unilateral act of public authority, and the "...*resolutions*..." of the DGCCSF as formal administrative acts reflecting the exercise of such power, explains the reluctance to accept the possibility that such decisions may be kept confidential, even when this is in the clear public interest.

The authorities and agencies responsible for ensuring transparency and the right of access to public documents (in our case the Council for Transparency and Good Governance, CTBG, regulated by Law 19/2013, of December 9), as well as the Courts of Justice that control their decisions, often express reluctance to exempt the transparency of the administrative act that provides for the public financing of a drug, its price and financing conditions.

It is difficult for these bodies to understand and accept, and this is clear from reading the CTBG resolutions and multiple court rulings, that a decision on the price of a drug, supposedly adopted unilaterally by the Administration on the basis of an objective technical methodology based on a scientific-clinical evaluation of its therapeutic usefulness and on pharmaco-economic analyses carried out by experts from the Ministry of Health, can be harmful to the economic and commercial interests of the laboratories if it is publicly disclosed. The doctrine of the CTBG and our Courts of Justice has been explained in detail in previous works[7].

However, everyone should accept as a matter of course that the **agreements resulting from a commercial negotiation** between the Government and a laboratory could in-

clude a commitment to confidentiality of all or some of its clauses.

In fact, this is exactly what has happened recently in the commercial negotiations concluded in between the European Commission/Member States and the laboratories for the financing of the purchase of vaccines and drugs for the fight against COVID 19 in the *Advanced Procurement Agreements* (APA) and *Joint Procurement Agreements* (JPA) in 2020, 2021 and 2022, which included multiple confidential clauses (which remain confidential today). These include those relating to the *purchase price* of the drugs.

The General Court of the EU ("GC of the EU") has issued several judgments confirming the validity of confidentiality clauses included in pan-European public procurement contracts for vaccines and medicinal products concluded by the European Commission. And it has recognized that the European Commission's decision to keep such clauses confidential is in accordance with EU law. This Resolution is the result of a request for information from a German journalist who demanded to know different documentation related to the purchase of vaccines, including the price of the vaccines.

The judgment of the GC of 7 September 2022 in case T-448-21 and T-651/21 resolved a case in which the European Commission refused access to these contracts requested under Article 4 of EU Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents. The EUAT upheld the Commission's decision to maintain the confidentiality of certain clauses of these contracts on the grounds that their disclosure "... ***could affect the competitive position of the manufacturer***...". According to the TFEU it is justified "...*to consider the redacted information in question as sensitive commercial information, sufficient to indicate the existence of a reasonably foreseeable and not purely hypothetical risk that disclosure of that information* ***would undermine the protection of the commercial interests*** *of the Covid-19 vaccine manufacturers concerned*". The same doctrine is expressed in the TGUE judgment of 12 October 2022 in case T-524/2.

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A few months ago, the TGUE ratified its doctrine on this matter in the **Judgment of 17 July 2024** in case T-689-21 (case *Margrete Auken and others v European Commission*). In this case, five Members of the European Parliament (no less) filed a legal challenge

against a Decision of the European Commission (2022/1038 of 15 February 2022) limiting access to the APAs of COVID 19 vaccines of five pharmaceutical laboratories.

From our point of view, the *contractualization* of the public financing procedure, that is, the legal recognition that we are dealing with a **free commercial negotiation** between parties and not with the exercise of a unilateral administrative power of intervention on prices, would explain and justify the recognition –in parallel– of the need to preserve the confidentiality of certain agreements reached.

The very reasonable argument that both the Ministry of Health and the pharmaceutical laboratories maintain before the CTBG and the Courts of Justice would reach its full meaning if we start from the premise that we are dealing with a commercial negotiation. Laboratories operate in a highly competitive international environment in which they adapt their prices to the specific characteristics of the market (population, GDP and payment capacity). They thus offer prices that are commercially adapted to the different national health systems and which can only be realized if there are guarantees of confidentiality. Otherwise, the alternative would be to renounce the market or delay entry into the market so as not to prejudice negotiations in other jurisdictions.

Spain benefits from advantageous economic conditions for public funding compared to those applied in other European jurisdictions only on the premise that it adequately guarantees confidentiality. This reasoning is more naturally acceptable if one legally recognizes the reality that the public funding procedure materially involves a bilateral commercial negotiation between the Government and the laboratory.

If we assume this basic approach, it seems clear that the **legislative reform of the public**

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drug financing system currently underway should have among its main axes the *contractualization* of the model. In other words, the introduction of the **principle of *conventional financing*** or ***agreed financing***.

This idea was already timidly reflected a few years ago in the "*Draft Royal Decree regulating the financing and pricing of drugs and medical devices and their inclusion in the pharmaceutical list of the national health system*", processed by the Ministry of Health in 2015 (**"Draft RD 2015"**)[8] , which would not be approved. However, both the CNMC[9] and the Council of State reported on it.

The Draft RD 2015 was a rather extensive (71 articles) proposal for a regulatory standard for the development of the LM, which jointly regulated the procedure for the public financing of drugs and medical devices. It was a scarcely innovative and insufficient draft in its substantive approaches, although it tried to reflect somewhat more realistically the practice of the public financing procedure.

In relation to what concerns us here, the Draft RD 2015 was continuist. It maintained

If we assume this basic approach, it seems clear that the legislative reform of the public drug financing system currently underway should have among its main axes the contractualization of the model. In other words, the introduction of the principle of *conventional financing or agreed financing*.

the current scheme of the public financing procedure as an exercise of unilateral administrative power. Art. 2.1 stated that "*The public financing of drugs and medical devices requires their inclusion in the pharmaceutical list of the National Health System* ***by means of a prior and express resolution*** *of the competent body of the Ministry of Health (...) by which its inclusion is resolved,* ***the financing conditions*** *are* ***determined*** *and the* ***maximum industrial price*** *of financing in the National Health System* ***is fixed*** *for each of the presentations*".

However, it contained a Chapter III on "*Special reserves and special conditions for the financing of medicines*", which was quite novel. Article 14.1.a) defined "*special reserves*" in public financing as "*The measures or set of measures applied (...) in order to verify their adequate use, paying special attention to drugs subject to restricted medical prescription, of use reserved for certain specialized means, as well as those that pose special safety problems or are limited to the pharmacological treatment of certain population groups considered to be at risk...*".

Art. 14.1 b) defined "*special financing conditions*" in the following terms: "*These are the* ***conditions agreed****, following a favorable report from the Interministerial Commission on Drug Prices****, between the competent body for pharmaceutical list*** *of the Ministry of Health, (...)* ***and the holder of the marketing authorization for*** *the drug (...)".* In other words, the Draft RD of 2015 already incorporated a clear *contractualization* of the special financing conditions.

Furthermore, paragraph 2 of this same precept established the formal terms in which this bilateral agreement should be implemented: "*...it is the responsibility of the aforementioned body, following a favorable report from the Interministerial Commission on Drug Prices, to* ***formalize with the holder of the marketing authorization*** *for the drug (...),* ***the agreement*** *establishing, where appropriate, special conditions applicable to the financing, which will be previously incorporated and as an annexed document, to the corresponding resolution of inclusion of the drug in the pharmaceutical list of the National Health System".*

Article 15.2 of the Draft Royal Decree 2015 regulated the possible types of special financing conditions. These were basically the following: (a) the conditioning of the inclusion in the pharmaceutical list of the National Health System to compliance with the obligation to communicate the updated situation of the drug in other markets; (b) the submission to periodic or fixed-date reviews of the price and/or financing conditions; (c) the conditioning of the inclusion in the pharmaceutical list of the National Health System to compliance with certain commitments in R&D&I; (d) financing formulas linked to health results, when there is uncertainty about the results and these are measurable; (e) the establishment of maximum expenditure ceilings for the drug; and (d) others that may be established in accordance with the applicable legal provisions (i.e., any other agreements between the parties on the financing conditions).

Although this regulation was far from perfect, it clearly stated that the special financing conditions cannot be legally configured as a unilateral imposition by the Administration. They must be articulated as a **free commercial agreement** between parties, embodied in a document that would be annexed to the resolution on public financing.

In my view, this approach could be a correct starting point here, although it should be more ambitious and extend to the entire public financing procedure, not just to special conditions. Strictly speaking, as we have indicated above, all public financing today, including both the price and the indications financed and the special conditions, is the

product of a comprehensive commercial negotiation. The entire negotiation must therefore take the form of a **Public Financing Agreement** between the NHS and the laboratory, of a commercial nature. These clauses must have legally guaranteed confidentiality when the parties so determine within the framework of the negotiation.

The reform of the public financing system for medicines, incorporating a mechanism agreed between the parties as the core of the model, must therefore be accompanied by a provision that protects the clauses or conditions declared confidential by the parties.

[*] Translation note: We use "*Pharmaceutical List*" or "*Pharmaceutical List of the SNS*" to translate "*Prestación Farmacéutica*" o "*Prestación Farmacéutica del SNS*". This expression refers to the official list of drugs that the Government has decided to finance with budgetary resources from the National Health System. It can also be translated as "*Reimbursed Medicines List*".

[1] EFPIA (IQVIA); "*The Patients W.A.I.T. (Waiting to Access Innovative Therapies)*"; June 2024. Accessible at https://efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf

[2] FARMAINDUSTRIA; *Press release on WAIT Report*; June 2024.

[3] The most relevant judicial precedents in this matter are two: (i) Ruling no. 57/2010, January 22, 2010, of the Eighth Section of the Administrative Chamber of the Superior Court of Justice of Madrid [ECLI:ES:TSJM:2010:1548]. No. 57/2010, of January 22, 2010, of the Eighth Section of the Administrative Chamber of the Superior Court of Justice of Madrid [ECLI:ES:T SJM:2010:1548] regarding the drug VIVACE 30 mg/10 mg tablets, 28 tablets, from the laboratory CHIESI; and (i) Ruling no. 403/2021, of July 1, 2021 [ECLI:ES:TSJM:2021:7678]. regarding the drug COPAXONE® from the laboratory TEVA.

[4] A. MOZETIC and L. SÁNCHEZ-CALERO; "*Trends in drug financing in Spain 2023: consolidation over 2022*"; *DIARIOFARMA;* 17 April 2024.

[5] On the question of the nature of the Therapeutic Positioning Reports (TPR), the ruling of the 8th Section of the Contentious-Administrative Chamber of the National Court of Appeals of 26.06.2023 (appeal: 0000123/2021) in which it resolves the appeal filed by FARMAINDUSTRIA against the agreement of February 3, 2020 (updated on July 8, 2020), of the Permanent Pharmacy Commission of the Interterritorial Council of the National Health System (SNS) approving the "*Plan for the consolidation of the Therapeutic Positioning Reports (IPT) of the drugs of the National Health System*".

[6] Vid. Judgment of the Administrative Chamber of the Audiencia Nacional of 26.06.2023 cited in the previous note.

[7] A. DORREGO DE CARLOS; *La transparencia en la fijación del precio de los medicamentos y en los contratos de suministro hospitalario*"; Cuadernos de Derecho Farmacéutico, CEFI; núm. 66, Julio-Septiembre 2018.

[8] Ministry of Health; "*Proyecto de Real Decreto, por el que se regula la financiación y fijación de precios de medicamentos y productos sanitarios y su inclusión en la prestación farmacéutica del sistema nacional de salud*"; September 18, 2015.

[9] CNMC; IPN/CNMC/023/15 "*REPORT ON THE DRAFT ROYAL DECREE REGULATING THE FINANCING AND PRICE-FIXING OF MEDICATIONS AND HEALTH CARE PRODUCTS AND THEIR INCLUSION IN THE PHARMACEUTICAL SUPPLY OF THE NATIONAL HEALTH SYSTEM*"; November 19, 2015.

Alberto Dorrego de Carlos

JUDGMENT OF THE GENERAL COURT OF 17 JULY 2024 ON THE SCOPE OF THE EXCEPTION FOR THE PROTECTION OF COMMERCIAL INTERESTS IN THE CONTEXT OF A REQUEST FOR ACCESS TO THE ADVANCE PURCHASE AGREEMENTS FOR COVID-19 VACCINES

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FECHA DE RECEPCIÓN: 18 OCTUBRE 2024

FECHA DE ACEPTACIÓN Y VERSIÓN FINAL: 30 OCTUBRE 2024

RESUMEN: El Tribunal General, con fecha 17 de julio de 2024, ha dictado una sentencia de un impacto notable en la que analiza en detalle la adecuación del uso de la excepción de la protección de los intereses comerciales en el contexto de una solicitud de acceso a los acuerdos de compra anticipada de vacunas contra el COVID-19. La solicitud es amplia e incluye información sobre cuestiones de precio. El Tribunal General, en línea con la posición mantenida por la Comisión, desestima los motivos de impugnación de los demandantes relativos a un uso incorrecto por la Comisión de dicha excepción de la protección de los intereses comerciales, particularmente en lo que aspectos de precio se refiere, concluyendo que la expurgación de este tipo de información por la Comisión está bien motivada y fundamentada.

PALABRAS CLAVE: precio; confidencialidad; transparencia; información sensible; estrategia comercial.

ABSTRACT: The General Court, dated 17 July 2024, has issued a judgment of notable impact in which it explores in detail the appropriateness of the use of the protection of commercial interests exception in the context of a request for access to advance purchase agreements for COVID-19 vaccines. The request is broad and includes information on price issues. The General Court, in line with the position held by the Commission, rejects the applicants' grounds of challenge relating to the Commission's misuse of the protection of commercial interest exception, particularly with regard to price aspects, concluding that the Commission's refusal to disclose this type of information is well-founded and well-reasoned.

KEYWORDS: price; confidentiality; transparency; sensitive information; commercial strategy.

1. INTRODUCTION

The purpose of this article is to analyze the recent and relevant judgment of the Fifth Chamber of the General Court of the European Union (hereinafter, "*General Court*") of 17 July 2024 in case T-689/21 (hereinafter, "*Judgment*")[1].

This Judgment of the General Court is issued in the context of a request by six Members of the European Parliament (hereinafter, the "*six MEPs*") for access to the advance purchase agreements for COVID-19 vaccines. The European Commission (hereinafter, the "*Commission*") settled the request by granting partial access to these advance purchase agreements. The six MEPs, unhappy with the Commission's decision for partial access, filed the relevant appeal with the General Court. A significant portion of the applicants' grounds for appeal concern the insufficient reasoning and justification provided by the Commission in using the exception for the protection of the commercial interests of pharmaceutical companies to refuse part of the request and to withhold certain information deemed sensitive, including aspects related to pricing (price per dose, delivery price, total price or cost, or advance payments or down payments).

The General Court, after a detailed analysis of the parties' positions and applying in a serious manner the rules known to all actors regarding access to information held by institutions/authorities vs. the protection of commercial interests of the interested parties, dismisses most of the appeal and upholds the Commission.

As mentioned, the purpose of this article is to analyze the aforementioned Judgment, although focusing on the aspects related to the request for access to price information in a broad sense and how the General Court deals with the exception for the protection of commercial interests in a request for access to sensitive information in a context as important as that of the advance purchase agreements for COVID-19 vaccines.

2. JUDGMENT OF THE GENERAL COURT

2.1. Background

For context, it is worth quickly reviewing the background of the case:

- On 14 April 2020, the Council of the EU adopted Regulation (EU) 2020/521[2] and activated the urgent assistance mechanism under Regulation (EU) 2016/369[3] to finance expenditure necessary to address the COVID-19 pandemic.

- On 17 June 2020, the Commission published the *'EU Strategy for COVID-19 Vaccines'*[4], highlighting as one of its pillars ensuring the sufficient production and supply of vaccines through advance purchase agreements with pharmaceutical companies.

- By a brief dated 20 January 2021, six MPEs, under Regulation (EC) 1049/2001[5] on access to public information held by certain EU institutions (hereinafter, "*Regulation (EC) 1049/2001*"), requested access to the advance purchase agreements for COVID-19 vaccines entered into between the Commission and pharmaceutical companies (including both, those already concluded at that time and those that might be concluded after the request).

- Following various communications, on 15 February 2022, the Commission settled the request by granting partial access to a total of thirteen documents, justifying that access to the documents could not be full due to privacy and integrity pro-

tection and the **protection of the commercial interests of the pharmaceutical companies**, that is, it relied on the exception under Article 4(2), first indent, of Regulation (EC) 1049/2001, which allows the Commission **to refuse access to documents or information whose disclosure would harm "*the commercial interests of a natural or legal person, including intellectual property*"** (hereinafter, the "*Decision*").

- Upon notification of the Commission's Decision, the six MEPs filed the relevant appeal with the General Court, seeking the annulment of the Decision based on various grounds, most of them related to improper use by the Commission of the exception for the protection of the commercial interests of pharmaceutical companies.

2.2. The Commission's position and how the General Court deals with the case

In the context of the above-mentioned request, the Commission, amongst other information, **redacted from the advance purchase agreements price-related aspects and payment terms, including price per dose, price upon delivery, total price or cost, or advance payments or down payments (having access to this information made it possible in some cases to establish the price per dose)**.

With regard to price-related aspects, the applicants primarily questioned two aspects:

- Insufficient reasoning and justification for the Decision to explain the redaction of price-related aspects based on the exception for the protection of commercial interests; and

- Insufficiency of the Decision in balancing the public interest and the interests of the pharmaceutical companies in maintaining the confidentiality of such information.

2.2.1. *Insufficient reasoning and justification for the exception for the protection of commercial interests in the context of price information*

As mentioned, the applicants challenge, both from the perspective of reasoning and justification, the arguments put forward by the Commission regarding the use of the exception for the protection of commercial interests of pharmaceutical companies to redact price-related information from the advance purchase agreements.

The Commission points out that **the redacted information contains sensitive elements from a commercial perspective** and that the disclosure of such information:

- **Could harm the competitive position of the pharmaceutical companies** in the global market for the manufacturing and marketing of COVID-19 vaccines; and

- Would allow third parties to draw conclusions about the commercial strategies and pricing structures of these companies, giving competitors the option to use that information to plan their own strategies, which **could not only seriously jeopardize ongoing and future negotiations with other international buyers but also put the execution of the agreements in question at risk**.

An example of the above is the following excerpt from the Judgment:

> "*(...) the Commission stated that, according to the case-law,* ***commercially sensitive information relating, in particular, to the commercial strategies of the undertakings concerned or to their commercial relations was protected by the first indent of Article 4(2) of Regulation***

No 1049/2001. *Moreover,* ***the potential commercial risks, the prices charged and the thresholds of financial covenants concluded in the framework of a sensitive contract could also be commercially sensitive****, in particular for contracts which are still being implemented. In this instance,* ***disclosure of such passages from the advance purchase agreements would clearly place the undertaking concerned at a disadvantage vis-à-vis its competitors, since the level of financial risk accepted by that undertaking and information on its pricing strategy would thus be brought to those competitors' attention.*** *In those circumstances,* ***the Commission considered that certain financial aspects of the agreements should remain protected under the exception relating to the protection of commercial interests****."*

The General Court ruled in favor of the Commission, both in terms of reasoning and justification. In this regard, it stated that:

- The Commission provided **detailed explanations about the nature of the redacted information and how the disclosure of such information could harm the commercial interests of the pharmaceutical companies**, reaching the conclusion that the reasoning of the Decision allowed the applicants to understand the specific reasons that led the Commission to redact this information; and

- **The Commission rightly considered that the disclosure of the information in question could provide the pharmaceutical companies' competitors and third-party buyers with commercially sensitive information about the commercial and pricing strategies and structures of the companies**, reaching the conclusion that such explanations were well-founded and **that they fall within the concept of a reasonably foreseeable and not merely**

The Commission rightly considered that the disclosure of the information in question could provide the pharmaceutical companies' competitors and third-party buyers with commercially sensitive information about the commercial and pricing strategies and structures of the companies, reaching the conclusion that such explanations were well-founded and that they fall within the concept of a reasonably foreseeable and not merely hypothetical risk regarding harm to the protection of commercial interests.

hypothetical risk regarding harm to the protection of commercial interests.

In view of the above, the General Court dismissed this ground of appeal.

2.2.2. *Insufficient balancing of the public interest in relation to the exception for the protection of commercial interests in the context of price information*

The applicants argue that the Commission did not properly balance the commercial interests of the pharmaceutical companies against the public interest in health that transparency promotes. In their view, there is an overriding public interest that justifies the full disclosure of the advance purchase agreements. Among other reasons, they invoke public confidence in the role played by the Commission in acquiring vaccines, the use of public funds, or public confidence in the vaccines themselves.

Particularly, regarding the disclosure of price aspects, the applicants argue that "*is necessary in order to restore public trust in the joint procurement of vaccines and to explain the different vaccine choices of the Member States and the difficulties encountered with deliveries*" and that "*is important for the public to have trust in the vaccines and in the Commission's investments of public funds and so that the public can analyse them and draw conclusions on the joint procurement of vaccines and possible profits made by the undertakings concerned.*"

While the Commission agrees with the applicants on the importance of public confidence in its actions regarding the acquisition of vaccines:

- It emphasizes that, at the time of the Decision, the health crisis was ongoing **and that the right of access to documents is not a general and absolute right**;

It emphasizes that, at the time of the Decision, the health crisis was ongoing and that the right of access to documents is not a general and absolute right;

It recalls that general considerations, including those concerning the protection of human health, are not sufficient to justify an overriding public interest; and

It points out that it has not identified any public interest that outweighs the public and private interests protected by Article 4(2), first indent, of Regulation (EC) 1049/2001, i.e., commercial interests.

- It recalls that **general considerations, including those concerning the protection of human health, are not sufficient to justify an overriding public interest**; and

- It points out that **it has not identified any public interest that outweighs the public and private interests protected by Article 4(2), first indent, of Regulation (EC) 1049/2001, i.e., commercial interests**.

Before addressing this issue, the General Court, in line with the Commission's position, recalls that:

- "***It is for the party requesting access to refer to specific circumstances to establish an overriding public interest which justifies the disclosure of the documents concerned***"; and

- "***General considerations cannot be used to justify access to the requested documents; access requires that the principle of transparency should (...) raise an issue of particularly pressing concern which prevails over the reasons justifying the refusal to disclose the documents in question***", among other reasons for the protection of commercial interests, as is the case here.

Coming back to the considerations regarding price, the General Court finds that the applicants:

- Do not explain how public confidence in the acquisition of vaccines is strengthened by the disclosure of sensitive financial aspects, **which can be used against pharmaceutical companies in their negotiations with third-country buyers and even against the Commission and Member States in future purchase agreements**;

- Do not explain how prices per dose can alone reveal the underlying reasons for Member States' decisions regarding the vaccines used in their COVID-19 vaccination campaigns; and

- Do not justify how the disclosure of clauses related to advance payments and down payments helps to strengthen public confidence in vaccines and public investments, since **the sensitive financial elements of the purchase agreements in question have no relation to the effectiveness or safety of COVID-19 vaccines.**

That said, it is worth noting a comment from the General Court, which adopts an argument from the Commission, stating **that** "***administrative activity does not require such extensive access to documents as that required by the legislative activity of an EU institution***", drawing the conclusion that, "*in the present case, the agreements at issue form part of an administrative activity.*"

All of the above leads the General Court to dismiss this ground of appeal as well.

3. CONCLUSION

This is a very important Judgment that largely **consolidates the position held by the Ministry of Health and the pharmaceutical industry in recent years, namely that all matters related to pricing constitute sensitive commercial information and are protected by the exception for the protection of commercial interests**.

It is important not only because of the substance and how the General Court deals with the various issues raised, but also because **it settles them by applying the rules widely known to all actors**, including the pharmaceutical industry, the Ministry of Health, the Transparency and Good Governance Council, and even the courts.

This is a very important Judgment that largely consolidates the position held by the Ministry of Health and the pharmaceutical industry in recent years, namely that all matters related to pricing constitute sensitive commercial information and are protected by the exception for the protection of commercial interests.

This is not an isolated ruling on a very specific issue that suggests that it occurred in a context where these rules do not apply or do not apply as strongly; rather, **these rules are very present, and the Judgment touches on almost all the elements that have been on the table for the past few years and are still there today**.

Proof of this is that the General Court, as explained above, dismisses all the applicants' grounds for access to price-related information, and recalls at various points in the Judgment that the concept of commercial interests, although not defined in Regulation (EC) 1049/2001, is more of an exception to the general rule. In this regard, it states that:

- "*In order to justify refusal of access to a document the disclosure of which has been requested, it is not sufficient, in principle, for that document to fall within the scope of a commercial activity, but it is for the institution concerned to explain how disclosure of that document could specifically and actually undermine the commercial interests and to demonstrate that the risk of the interest being undermined is reasonably foreseeable and not purely hypothetical*";

- "*The examination which the institution must undertake in order to apply an exception must be carried out in a specific manner and must be apparent from the reasons for the decision*"; *and*

- "*It must be noted that it is not possible to regard all information concerning a company and its business relations as requiring the protection which must be guaranteed to commercial interests under the first indent of Article 4(2) of Regulation No 1049/2001*".

However, it also points out that "***that protection may cover commercially sensitive information, such as information relating to the commercial strategies of the undertakings, their sales figures, market shares or customer relations,***" **including, as has been proven, information regarding the price**.

Having said this, we are dealing with a very well worked Judgment, in a fundamental matter, such as vaccines against COVID-19, in which the General Court applies with criteria and seriousness aspects on which on many occasions there have been erratic approaches.

[1] Judgment of the Fifth Chamber of the General Court of the European Union of 17 July 2024, EUR-Lex - 62021TJ0689 - EN - EUR-Lex (europa.eu).

[2] Regulation (EU) 2020/521, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0521&qid=1729228533126.

[3] Regulation (EU) 2016/369, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0369-20200201&qid=1729233708624.

[4] EU Strategy for COVID-19 Vaccines, https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1597339415327&uri=CELEX%3A52020DC0245.

[5] Regulation (EC) 1049/2001, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001R1049&qid=1729233801111.

Álvaro Abad Fernández de Valderrama

EXCEPTIONS TO PRICE TRANSPARENCY FOR MEDICINES: ADDRESSING THE CHALLENGE OF PROVING FUTURE HARM: Commentary to the Ruling of the Swiss Federal Administrative Court (Bundesverwaltungsgericht) on July 27, 2023

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FECHA DE RECEPCIÓN: 28 OCTUBRE 2024

FECHA DE ACEPTACIÓN Y VERSIÓN FINAL: 31 OCTUBRE 2024

RESUMEN: Este artículo revisa las reflexiones de la sentencia del Tribunal Federal de lo Contencioso-Administrativo (Bundesverwaltungsgericht) de Suiza de 27 de julio de 2023, relativa a una solicitud de acceso a información pública sobre condiciones de financiación y precio de medicamentos innovadores, y, en particular, el modo en que el Tribunal pondera el interés general de la transparencia con los posibles perjuicios que se derivarían del acceso público a dicha información. El interés de la sentencia radica en su aproximación a la carga de la prueba de dichos posibles perjuicios, cuando se trata de daños futuros, y en el peso que atribuye a la opinión fundada de las autoridades sanitarias sobre la probabilidad de que efectivamente se materialicen en caso de otorgarse el acceso.

PALABRAS CLAVE: : transparencia del precio de los medicamentos; acceso a información sobre precios de medicamentos; ponderación de intereses; juicio de proporcionalidad; intereses económicos y comerciales.

ABSTRACT: This article reviews the reflections of the July 27, 2023, ruling by the Swiss Federal Administrative Court (Bundesverwaltungsgericht) on a request for access to public information about the financing terms and pricing of innovative medicines. It specifically analyzes how the Court balances the public interest in transparency with the potential harm that could arise from granting public access to this information. The ruling's significance rests in its approach to the burden of proof for potential future harm and the weight it places on the informed assessments of health authorities regarding the likelihood of these harms materializing if access is permitted.

KEYWORDS: medicines price transparency; access to medicines price information; weighing of interests; proportionality test; reasonable test-economic and commercial interests.

1. INTRODUCTION

As is well known, Spanish legislation –aligned with European Union law principles and the highest international standards on transparency and good governance– broadly recognizes citizens' right to access public information. Law 19/2013, of December 9, on Transparency, Access to Public Information, and Good Governance (the "LTBG") represents a significant milestone in guaranteeing access to information regarding the performance of public administrations, accountability, and citizen participation.

The LTBG is structured around two main pillars: (i) active publicity, which imposes an obligation on public administrations to proactively disclose relevant information about their organization, operations, and activities without prompting (including administrative acts and resolutions, contracts, agreements, and subsidies, among others); and (ii) the right to access public information, which (in principle) allows any citizen, without needing to justify a legitimate interest, to request and obtain information from public administrations, except in exceptional cases where maintaining the confidentiality of the information is warranted based on specific legally established grounds.

One potential limitation to this right of access is the necessary protection of legitimate economic and commercial interests (per Article 14.1.h LTBG).

The tension between applying transparency principles and safeguarding legitimate economic and commercial interests has been particularly pronounced in the health sector. It is widely recognized that this sector has long embraced transparency, even prior to the adoption of the LTBG. Regulatory demands and the sector's impact on public health and expenditure have driven the pharmaceutical industry to actively publish, disclose, and sub-

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mit to public scrutiny detailed, up-to-date information about its activities, products, and relationships with other stakeholders. Public disclosure of ongoing clinical trials and their results, as well as comprehensive data on the composition, safety, and efficacy of pharmaceutical products, is mandatory. Additionally, the industry's commitment to transparency has led to the adoption of voluntary codes of conduct requiring the disclosure of financial interactions (transfers of value) with healthcare professionals and organizations, with widespread adherence by pharmaceutical operators in Spain and across Europe.

Despite this robust commitment, there remains one area where the pharmaceutical industry asserts a vital need for confidentiality: the pricing and financing conditions of medicines and the actual prices applied in transactions with the Administration. Both the pharmaceutical industry and the Spanish Ministry of Health have repeatedly cautioned that indiscriminate disclosure of this information would not only harm the legitimate economic and commercial interests of private companies but also run counter to the public interest.

In summarizing a history spanning several years, it should be noted that, when responding to requests for access to information on the pricing and financing conditions of innovative medicines, the Spanish Ministry of Health has consistently and steadfastly advocated for confidentiality. Initially, the Ministry's responses were often brief, merely citing applicable legal provisions without thoroughly analysing the applicability of the exception related to protecting legitimate economic and commercial interests. As a result, several decisions denying access were annulled by the courts, which found that the Ministry had not sufficiently justified the need to keep this information confidential.

In recent years, however, the Ministry of Health has provided increasingly detailed ex-

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planations for its refusals. These justifications emphasize not only the legitimate economic and commercial interests of the pharmaceutical companies but, more critically, the economic and commercial interests of the Spanish state itself.

Summarising, once again, the reasoning of multiple decisions, the Spanish Ministry of Health has argued that public disclosure of the agreed price and financing conditions for a medicine would imply revealing data of an economic nature relevant to the business of a commercial entity, which could be used by its competitors to its detriment. But it also reasons that a decontextualized disclosure of information on the content of the price resolution for a medicine in Spain could have a significant impact on the determination of the price of the same medicine in other Member States of the European Union, as it is common for other countries to base their pricing systems on those of neighbouring countries, which would affect the pricing policy of the company in question in other markets, once again harming its economic and commercial interests.

More importantly– and likely the key issue– the Ministry has explained that unrestricted third-party access to financing prices of medicines in Spain would place the Administration at a considerable disadvantage in price negotiations, thereby undermining its ability to secure more competitive prices and, in turn, potentially harming the Spanish healthcare system. As the Ministry points out, neighbouring countries "*take great care not to disclose the advantages they obtain in drug financing negotiations, recognizing that confidentiality enables them to achieve greater savings compared to countries that do not maintain such secrecy*." The Ministry concludes that sharing such information with other Member States would empower them in their negotiations, to Spain's detriment, by reducing Spain's leverage to secure lower prices. This line of reasoning is reflected across several decisions, but perhaps the clearest example is the report dated November 20, 2019, prepared by the Ministry of Health at the request of the State Attorney's Office of the National Court. This report was issued as part of a contentious-administrative appeal against a resolution[1] by the Spanish Council for Transparency and Good Governance (**"CTBG"**) directing the Ministry

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to disclose detailed price information for certain oncological medicines[2].

These arguments have not always been upheld by the CTBG or the courts when evaluating this issue. While some CTBG rulings have aligned with the Ministry of Health's stance[3], in more recent decisions, the CTBG has argued against restricting access to drug price information in Spain. The CTBG's position is based primarily on the view that there is insufficient evidence demonstrating that disclosure would indeed harm the economic and commercial interests of companies or the Spanish Administration itself.For example, in Resolution 1076/2021 concerning a request for access to information on the financing conditions and price of a novel gene therapy, the CTBG concluded:

> "*The complainant is correct in arguing that it has not been precisely specified how access to the administrative decision would harm the economic and commercial interests of the pharmaceutical company, especially given that the authorization and price negotiation process has already concluded*" (emphasis added).

In the same vein, a recent ruling of the Spanish Central Court for Contentious Administrative Proceedings no. 9 of July 11, 2023 stated:

> "*Nor is it accepted that providing the information would affect economic and monetary policy, affecting public interests, in that it would impede access to cheaper medicines. Such arguments are viewed as generic statements lacking sufficient evidence and are considered speculative*" (emphasis added).

In essence, we encounter a classic (and unresolved) legal issue: the proof of future harm. The main obstacle for the CTBG and the courts to consider the application of the exception invoked by the Spanish Ministry of Health (and the pharmaceutical industry) lies in the necessity of providing concrete and specific evidence of the damage to commercial and strategic interests, both public and private, that would result from disclosing the information, so that these consequences are not –as we have seen– merely "*speculative*".

In a way, we are faced with the same challenge faced by thousands of plaintiffs in tort

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claims (both contractual and non-contractual) when it comes to meeting the courts' demands for proving lost profits for which they seek compensation. It is well known that case law is extremely stringent regarding the requirement to substantiate lost profits. Courts have consistently maintained that mere speculative expectations of profit must be excluded from compensation, as they pertain to uncertain realities and outcomes. Only profits deemed highly probable are eligible for claims. The Spanish Supreme Court, in a classic ruling dated November 30, 1993 (RJ 1992\9222), to which the vast majority of rulings handed down subsequently by that body systematically refer, ruled that:

> *"Determining lost profits or frustrated profits presents numerous challenges, as it is fraught with the vagueness and uncertainties inherent to hypothetical concepts. To address these issues, legal doctrine asserts that the mere possibility of realizing a profit is insufficient. There must be a certain* ***objective probability resulting from the normal course of events*** *and the special circumstances of the specific case, and our jurisprudence is guided by a* ***cautious and restrictive approach*** *for the estimation of loss of profits, repeatedly stating that it must* ***be rigorously proven that the advantages were not obtained, without these being doubtful or contingent and only based on mere hopes***" (emphasis added).

In summary, the challenge of proving events that have yet to occur–an issue that frequently arises in the context of lost profits and claims for damages– is also the central issue faced by those advocating for the confidentiality of prices and financing conditions in Spain.

In this context, ruling A-2459/2021 of July 27, 2023 of the Swiss Federal Administrative Court (Bundesverwaltungsgericht) (the "**Ruling**"), offers valuable insights and perspectives that we will discuss in detail below.

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2. KEY POINTS OF THE RULING OF THE SWISS FEDERAL ADMINISTRATIVE COURT (BUNDESVERWALTUNGSGERICHT) A-2459/2021 OF JULY 27, 2023

2.1. Background

On August 28, 2020, a journalist applied to the Federal Office of Health of the Swiss Confederation (Bundesamt für Gesundheit - BAG)

for access to certain documents relating to autologous CAR-T cell therapy, including, inter alia, "*the actual amount of remuneration paid*" for such therapies. The Federal Office informed the journalist that it could only grant him restricted access, and that the amount of the confidential remuneration, the amount of the confidential discount and the estimated total costs of CAR-T cell therapy and their calculation would not be disclosed in order to protect commercial confidentiality. In response, the applicant filed a request for conciliation with the Federal Data Protection and Information Commissioner, who recommended granting full access. However, the Federal Office upheld its position, asserting that disclosing the redacted information would compromise its ability to ensure the safe supply of new, innovative, and high-priced therapies. It argued that such disclosure would impede the implementation of official measures aimed at providing high-quality, appropriate, and cost-effective healthcare to the Swiss population.

On May 25, 2021, the journalist lodged an appeal with the Swiss Federal Administrative Court against the Federal Office's decision, requesting that he be granted access to the documents, without censorship, including the price actually reimbursed and the calculation of the estimated total costs of CAR-T therapy.

Both the Federal Office of Health and the pharmaceutical companies involved, which were joined as co-defendants, argued in favour of maintaining the confidentiality of the information. The Federal Office specifically justified the need to keep the therapy prices confidential with the following reasoning:

> "*In the case of new, innovative and high-priced therapies, security of care at affordable prices can only be ensured if confidential price agreements can also be implemented. The publication of price agreements and/or specific reimbursement amounts would undermine the corresponding protective measures. The use of confidential price agreements would serve to ensure that the Swiss population receives new, innovative and high-priced therapies at a high level of quality and cost-effectiveness. Pending approvals of tariff agreements are specific official measures worthy of protection. If the confidentiality of the corresponding price information were not guaranteed, marketing authorisation holders would no longer agree to set discounted net prices. As a consequence, either excessive prices would have to be accepted, or access to new and innovative therapies would no longer be guaranteed or would be guaranteed only with a considerable delay* […]. *If information from the authorisation procedure were to be disclosed, it would be impossible for OKP to cover new, innovative and high-priced therapies* […]. *If the confidentiality of confidential pricing information is not protected, this would also seriously hamper new tariff agreements with confidential net prices as well as the extension of existing ones. It would clearly not be in the interest of the OKP to hinder or even prevent the economic assumption of the costs of certain innovative and high-priced therapies, and it would contradict the objective of access to high quality care*" (emphasis added).

For its part, the applicant denies the plausibility of such damage, arguing, in essence, the following:

> "*The applicant argued that disclosure would not affect the implementation of the price agreements, which had already been concluded, and that information was not requested on current or future negotiating positions, but only on concluded negotiations, since the price agreements had already been concluded and approved by the authority. The authority had assumed purely speculatively that access*

to the requested data could hinder the extension of existing contracts or make other tariff agreements more expensive or delayed. Nor was it possible to draw conclusions about future negotiating positions on the basis of past remunerations and discounts. The scientific community has realised that secret price agreements with pharmaceutical companies do not lead to lower prices and faster availability of therapies. The federal government can also authorise effective, appropriate and affordable therapies with price transparency" (emphasis added).

Recognizably, the debate closely mirrors the discussions previously articulated in the Spanish context.

In this instance, the Swiss Federal Administrative Court unequivocally supported the Federal Office's position and rejected the journalist's appeal for access to information. The Court reasoned that disclosing data on drug prices could significantly jeopardize public interests. The significance of the ruling extends beyond the Court's thorough examination of both parties' arguments; it also includes the Court's insights into procedural matters, particularly regarding the burden of proof and how it is evaluated.

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2.1.1. *The principle of transparency does not necessarily take precedence over the principle of confidentiality in cases of uncertainty*

As explained by the Swiss Federal Administrative Court, the purpose of the Swiss Freedom of Information Act is to promote transparency with regard to administrative mandate, structure and activities. Therefore, the principle of publicity under Swiss law establishes a presumption in favour of free access to official documents by all persons. However, this access may be restricted, postponed or denied in certain cases where there are overriding public or private interests that justify it. The effectiveness of exemption clauses depends on the harm in case of disclosure being of a certain importance and on there being a serious risk of the harm occurring. So far, nothing differs from the principles applicable in Spain.

However, the approach does diverge in how in the interest in transparency is balanced against other legitimate interests that may be affected by the disclosure of the information.

First, the Court acknowledges that the fundamental principle is that the burden of proof lies with the denying authority to demonstrate that the presumption of free access to information can be rebutted by meeting one or more of the legal exceptions. However, this does not negate the conclusion that authorities possess a degree of discretion in determining whether any of the conditions warranting the denial of access to information apply. This discretion is grounded in the general principle that authorities enjoy a "*wide margin of interpretation*" regarding indeterminate legal clauses that encompass multiple exceptions.

Nor is there an overarching rule stipulating that, because they have been configured as exceptions, the cases in which a request for access to public information should be rejected must be interpreted restrictively. On the contrary:

> "*In cases of exception, it must be examined on a case-by-case basis whether the interest in secrecy outweighs the interest in transparency* [...]. *There is no principle that dictates that, in cases of doubt, priority should be given to the principle of openness, nor is there a counter principle to the opposite effect. On the contrary, for each possible exception applicable, the question of whether transparency or confidentiality should be respected must be analysed on a case-by-case basis, on the basis of the proportionality test set out above*" (emphasis added).

In summary, both interests–transparency and secrecy–are evaluated on equal terms, without preconceived notions. Furthermore, in the absence of compelling arguments or evidence demonstrating the potential harm to the interests protected by each principle, neither interest is required to take precedence over the other.

Indeed, the Ruling emphasizes that not only must those advocating for the application of the exception–namely, the Federal Office and the pharmaceutical companies–provide clear and specific details regarding the extent of the potential harm to their respective interests. The information claimant is also required to substantiate their argument by demonstrating why the confidentiality of drug prices does not serve the interests of the Swiss population, thereby challenging the positions of the Federal Office and the companies. It is insufficient for the claimant to merely assert, as has occasionally occurred in Spain, that the opposing parties have failed to adequately prove the hypothetical harm they claim or to suggest that their concerns are merely speculative.

2.1.2. *Proof of future harm. Validity of assumptions, suppositions, or hypotheses based on the circumstances of the specific case*

In relation to the always complex question of proving future harm, the Swiss Federal Administrative Court explains that the exception set out in Article 7(1)(b) of the Swiss Freedom of Information Act –which allows an authority to deny access to information that "*hinders the achievement of the objectives envisaged*" by the authority in taking measures within its competence– could apply whenever there is a high probability that the disclosure of information would wholly or partially frustrate the success of the measures taken by the Federal Office to ensure access to therapies at reasonable prices. It is assumed that "*the threat of infringement of the respective public or private interests as a consequence of granting access does not have to occur with certainty, but neither must it appear merely conceivable or (remotely) possible*" (emphasis added).

The standard to be applied in assessing (rather, predicting) whether or not such hindrance will occur is, in the Court's view, necessarily more flexible in cases where it is more difficult to associate a particular consequence

with the facts. The Court recognises that "*The longer and more complex the causal chain, the more difficult it will generally be to predict with the requisite high degree of probability that the success of the measure or the measure itself will be wholly or partially impaired as a result of the granting of access*". In such cases:

> "*The exception may also apply in less obvious cases if it can be presumed with a high degree of probability based on the circumstances that the success of a measure would be frustrated in whole or in part by the disclosure of information* [...]. *The wording, legislative history or materials and purpose of the provision also suggest the application of Art. 7(1)(b) of the Information Act in less obvious cases, if it can be presumed with a high degree of probability based on the circumstances that the success of a particular official measure –or even the measure itself– would be frustrated in whole or in part by the disclosure of the information used to prepare it*" (emphasis added).

Thus, when assessing the likelihood of future events, the Court's approach is that such a forecast:

"*Cannot be based solely on 'concrete' facts, but must necessarily also be based on assumptions, suppositions or hypotheses formed on the basis of the circumstances of the particular case*" (emphasis added).

2.1.3. *The relevance of the competent authority's judgement in determining the likelihood of injury*

As previously noted, the Swiss Federal Administrative Court acknowledges in its Ruling that the health authority possesses a broad margin of interpretation concerning the exceptions to the general principle of transparency. This recognition stems not only from the understanding that these exceptions are indeterminate legal concepts whose interpretation falls within the purview of the relevant authority, but also from the Court's acknowledgment of the health authority's role as the primary expert on the subject and its privileged knowledge of the reality of the markets.

The Court underscores that the health authority, tasked with ensuring cost-effective healthcare delivery, possesses specialized knowledge of market dynamics that equips it to evaluate whether price transparency could negatively impact Swiss patients' access to new therapies. Additionally, the authority is well-versed in the reference pricing systems employed by other countries, enabling it to provide an informed assessment of the potential consequences of disclosure in the international market where marketing authorization holders operate. This expertise reinforces the authority's capacity to make informed decisions regarding the balance between transparency and the safeguarding of public health interests. In particular:

> "*The authority referred to international developments with understandable arguments. The reference price system of the fixed reference countries influences the level of remuneration in other countries and thus the market in which marketing authorisation holders offer their services to combat rare and serious diseases. In so far as the appellant argues that the risk to the maintenance of the service has not been sufficiently demonstrated and is, moreover, unlikely in view of the possibility of transparent pricing models, it must be pointed out that such a forecast is future-oriented and cannot be based solely on 'concrete' facts, but must necessarily be based on assumptions, presumptions or hypotheses formed from the circumstances of the individual case (see E. 7.1 in fine above). In the view of the Federal Administrative Court, the instance body, as a specialised authority, has specific knowl-*

edge of the market and, with reference to the current international practice of confidential price agreements, has convincingly demonstrated that disclosure of the net prices actually reimbursed in Switzerland would very likely jeopardise the care of seriously affected and therapy-dependent patients. The assumption of the instance body that the marketing authorisation holders would revert to list prices or at least temporarily withdraw from the Swiss market is easily understandable" (emphasis added).

Without expressly mentioning it, here the Court is applying a line of argument that clearly evokes the principle of technical discretion of the Administration, recognised to a greater or lesser extent in all European legal systems. When rules refer to indeterminate legal concepts or circumstances involving a margin of appreciation, there may be a certain presumption of the correctness of the administration's criterion, especially in matters requiring specialised technical knowledge. This does not logically prevent administrative action from being, as it should, subject to judicial review, but to a certain extent it confines the scope of this control to cases in which there is a manifest error, a clear lack of reasoning, or an unreasonable or arbitrary application of the rule. The fact that there is an inevitable margin of discrepancy does not suffice to override the reasoned and motivated criterion of the specialised body of the Administration.

3. FINAL COMMENT

Although it may seem evident, the primary conclusion drawn from the Ruling is that both the Spanish and Swiss health authorities concur that public access to information on drug prices could significantly undermine the public interests they aim to protect, particularly by hindering negotiations and the attainment of better economic conditions.

[...] the primary conclusion drawn from the Ruling is that both the Spanish and Swiss health authorities concur that public access to information on drug prices could significantly undermine the public interests they aim to protect, particularly by hindering negotiations and the attainment of better economic conditions.

They are not alone in this stance, as we have had the opportunity to comment in the past[4]. However, these are only examples; if we take into account the statements of the Swiss Federal Council, which the Ruling reproduces, practically all countries are aware of the importance of maintaining the confidentiality of drug prices.

Indeed, the Court refers to statements by the Federal Council (the Swiss government) in a report issued on February 17, 2021, in which it stated that:

> "*However, for high-priced medicines, foreign authorities, health insurers or regions often establish pricing models in the form of confidential discounts, rebates, volume limits or pay-for-performance models. The actual prices reimbursed are subject to confidentiality. The prices taken into account in the price comparison abroad are not actually paid in almost any country*" (Federal Council Report of February 17, 2021, cited in the Ruling) (emphasis added).

The Ruling exemplifies a thorough analysis of the parties' positions and the reasonableness of their respective arguments. Regardless of individual opinions on the ultimate conclusion, it is clear that this issue has been treated with the seriousness that a legal debate of such significance warrants. The Ruling dedicates over twenty pages to examining the existing regulatory framework in Switzerland, the financing system, and specific pricing agreements. It addresses each party's arguments individually and provides a well-reasoned response. This level of detailed reflection is particularly pertinent, considering that legal operators often experience understandable frustration when courts superficially dismiss well-founded arguments of the parties, including those of the health administration itself.

From the material point of view, the careful and measured approach to the evidentiary issues is also noteworthy. In particular, in a matter such as the one at hand, it would seem reasonable in Spain to adopt a more flexible (and realistic) approach to proof of future harm, taking into account its particular complexity. Similarly, it would seem appropriate to give the well-founded opinion of the health authority (in our case, the Ministry of Health) the weight it deserves as an authoritative argument (*magister dixit*), relying on its capacity and knowledge of regulatory and market dynamics that likely surpasses the specialization of judges and the CTBG. The insights offered in the Ruling present a much-needed perspective that should be taken into account when shaping transparency policies related to drug pricing in our country.

From the material point of view, the careful and measured approach to the evidentiary issues is also noteworthy.

[1] CTBG Resolution 262/2019, of July 8.

[2] As stated by the Ministry of Health in this report, "*EU countries use the prices financed in other Member States, when they are made public, to achieve price reductions in their public systems. This creates a situation where marketing authorisation holders for a particular*

medicine are unwilling to make concessions (price reductions) in a given country (e.g. in countries with a less prosperous economic situation) if the prices in that country are made public, as this would force them to apply the same advantages in countries with better economic situations. As a result, many countries –including our own– avoid publishing these prices as a measure to protect national interests, since only by keeping these prices secret can they ensure that they get a better deal. In other words: giving third parties access to the prices at which medicines are financed in Spain would mean a loss of credibility for our Administration, and would entail a negotiating disadvantage when it comes to obtaining more competitive prices (which could be achieved taking into account our more disadvantaged economic-financial situation than other neighbouring countries, due to our high public deficit and lower per capita income). Consider that neighbouring countries –e.g. the United Kingdom and France– take great care not to reveal the advantages they obtain in their drug financing negotiations, in the knowledge that this allows them to obtain greater savings compared to countries that do not guarantee the confidentiality of the negotiations. [...] *It is therefore clear that it would be contrary to Spain's interests to make available to other Member States information that would help them in negotiating prices in their respective countries, but which would be detrimental to obtaining savings in Spain*". (emphasis added).

[3] *Vid.* by way of example Resolution 478/2019, handed down in case 32710. In this Resolution, the CTBG considers it justified to maintain the confidentiality of information on the price of medicines because of the possibility it offers to "*maximise patient access to innovative medicines*" and to allow "*each country to obtain the best possible price according to its circumstances (public coverage, co-payments, economic capacity...)* [...] *in balance with the necessary economic return for pharmaceutical companies"*. Thus, he adds, "*if there were no confidentiality at the European level, prices would tend to equalise in a single value that could be relatively low for the richest countries, but too high for those with less economic capacity*", which "*could complicate access for those with fewer resources*".

[4] COCINA ARRIETA, B. Resolution of the Irish Information Commissioner of 13 April 2018 on the application of transparency rules to the pricing of publicly funded medicines. *Cuadernos de Derecho Farmacéutico*, no. 69. Madrid: CEFI, 2019. In this resolution, the Information Commissioner considers that granting access to confidential information about the price conditions offered by pharmaceutical companies would "*seriously prejudice the financial interests of the State*", justifying the refusal to provide the requester with that information under Irish transparency act.

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TRANSPARENCY AND CONFIDENTIALITY IN THE ACQUISITION OF COVID-19 VACCINES: JUDGEMENT 3935/2024 OF THE NATIONAL HIGH COURT

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FECHA DE ACEPTACIÓN Y VERSIÓN FINAL: 11 NOVIEMBRE 2024

RESUMEN: El 25 de junio de 2024, la Audiencia Nacional emitió una sentencia sobre la transparencia en los precios de adquisición de medicamentos. El procedimiento trae cause de la solicitud del del Consejo de Transparencia y Buen Gobierno (CTBG) a la Agencia Española del Medicamento (AEMP) de información extensa sobre los acuerdos de reventa y donación de vacunas bioNTech/Pfizer. La sentencia confirma que el derecho a la transparencia y acceso a la información tiene límites definidos por otros intereses protegidos por la ley, subrayando que estos han de ser ponderados caso por caso, para determinar qué interés debe prevalecer. En este caso, la Audiencia Nacional reconoce que la divulgación de la información solicitada por el CTBG podría perjudicar las internacionales de España y menoscabar la confidencialidad de los procesos de toma de decisión de la Administración, sin que concurra ningún interés superior que lo justifique.

PALABRAS CLAVE: Derecho acceso a la información; límites; precio de medicamentos; negociaciones; doctrina.

ABSTRACT: On 25 June 2024, the National High Court issued a ruling concerning transparency and confidentiality in medicine procurement prices. The proceedings originated from the Council of Transparency and Good Governance's (CTBG) request for extensive information on the resale and donation agreements of BioNTech/Pfizer vaccines to the Spanish Medicines Agency (AEMPS). The ruling confirms that, although the right to transparency and access to information is very broad, it is limited by legally protected interests, which must be weighed on a case-by-case basis to determine which should prevail. In this particular case the National High Court recognized that disclosing the information requested by the CTBG could harm Spain's international relations and undermine the confidentiality of the Administration's decision-making processes, without any overriding interest to justify such harm.

KEYWORDS: Access to information; limits; medicines prices; negotiations; doctrine.

1. SUMMARY OF THE CONFLICT

On 25 June 2024, the Seventh Section of the Administrative Chamber of the National High Court issued a very interesting judgment ("*Judgement*") that sheds some light on the complex and prickly issue of transparency in the purchase prices of medicines, and its limits.

The judgment resolves the appeal brought by the Ministry of Health/Spanish Medicines and Medical Devices Agency ("AEMPS") against judgment number 58/2023 of 24 March of the Central Contentious-Administrative Court of the National High Court which dismissed the appeal brought by the AEMPS against the resolution number 823/2021 of 8 April 2022 issued by the Council for Transparency and Good Governance on resale and donation agreements of BioNTech/Pfizer vaccines ("*Resolution*").

The procedure stems from a request by the Council for Transparency and Good Governance ("CTBG") to the AEMPS to provide the following information/documentation:

a) Copy of the AEMPS agreement for the resale of BioNTech/Pfizer vaccines to Andorra,

b) List of each and every one of the agreements and/or arrangements reached by the Government of Spain to resell or donate vaccines, detailing whether it was a resale or donation, indicating the date, number of doses, brand of vaccine, country and amount to be paid to the Government of Spain, and

c) A copy of each of these agreements or arrangements

The Ministry of Health, through the AEMPS, partially complied with the CTBG's request and provided the following documentation/information:

a) Number of vaccine doses resold to Andorra, indicating that the price was the same as the purchase price, and therefore the resale was not for profit, and

b) A link to a list of vaccine donations made to American countries.

However, it refused to provide the rest of the information on the grounds that it was covered by the exceptions or limits provided for in articles 14.1 c) and 14.1 k) of Law 19/2013, of 9 December, on transparency, access to public information and good governance ("LTAIBG"). That is, the Ministry of Health/AEMPS considered that providing this information to the CTBG would be detrimental to Spain's external affairs (article 14.c) of the LTAIBG) and would affect the confidentiality or secrecy required in decision-making processes (article 14.k) of the LTAIBG).

1.1. The CTBG's resolution

In response, the CTBG in its Resolution considered that the limitations alleged by the Ministry of Health/ AEMPS to refuse the requested information were not applicable as no reasonable or sufficient justification was provided.

Specifically, and in relation to the limitation provided for in article 14.1 k) of the LTAIBG, which refers to the need to protect the confidentiality or secrecy of decision-making or negotiation processes, the CTBG considered that providing a copy of donation agreements or vaccine resale agreements with third countries does not reveal secret or confidential information on the negotiation process that took place to reach said agreement or arrangement.

Similarly, the CTBG considered that the exception provided for in letter c) of article 14.1

of the LTAIBG, i.e., affecting or damaging Spain's foreign affairs, could not be accepted, given that the Ministry of Health had merely alleged that the disclosure of the terms of said agreements or resale or donation agreements could affect future negotiations without specifying the precise way in which they could be affected or damaged. The CTBG also considered that the disclosure of the final text of the agreement or resale agreement could hardly affect or harm future foreign affairs, especially when the existence of these agreements is already known to the public, as well as the number of doses resold to Andorra.

1.2. Appeal against the CTB's resolution

The Ministry of Health/AEMPS appealed the Resolution on the grounds that providing copies of agreements for the resale or donation of vaccines with third countries would damage Spain's foreign affairs, as well as its strategic and negotiating interests, as it would clearly harm future negotiations by generating mistrust towards Spain from third countries which would see that the full content of agreements or arrangements reached with Spain could be potentially be published without said countries being able to express their opinion.

The Central Contentious-Administrative Court of the National High Court upheld the CTBG's position at first instance and considered that the AEMPS had not duly accredited the alleged harm or effect on external affairs, nor on the confidentiality of the negotiation (decision-making process). The court considered that the appellant (AEMPS) had simply limited itself to arguing a potential, hypothetical and future harm, without proving the causal link between said disclosure and the alleged harm (i.e., that the harm test had not been passed), and that therefore, in the absence of a statement of reasons, the limits set out in letters c) and k) of article 14.1 of the LTAIBG could not be applied.

1.3. Appeal against the first instance judgement

The Ministry of Health/AEMPS appealed the first instance judgment, claiming that the harm to the confidentiality of the negotiations and to Spain's foreign affairs in the event of disclosure of the information requested had been sufficiently proven. The CTBG, opposed the appeal again, arguing once again that the damage had not been proven, and yet, the existence of a public interest in the knowledge of this information was evident, stressing transparency as an appropriate instrument of accountability for the use of public money and considering that if a test is carried out between possible damage (not proven) and the public interest in accountability, the latter should prevail. The CTBG took advantage of the opposition to the appeal to argue that the Supreme Court's jurisprudence on the limitations to transparency provided for in Article 14 of the LTAIBG is repetitive and consistent in establishing that the possibility of the existence of harm is not enough, but that there must also be no overriding interest that justifies the granting of transparency. The CTBG also points out that transparency is articulated as one of the guiding principles of the State's External Action, in application of the provisions of article 2.1.f) of Law 1/2014 of 25 March on the State's External Action and Foreign Service.

Having heard and analyzed the positions of the parties, the National High Court resolved the appeal filed by the Ministry of Health/AEMPS, upholding the appeal and revoking the first instance judgment and upholding the contentious administrative appeal initially filed by the Ministry of Health/AEMPS against the Resolution.

2. THE LIMITS OF THE RIGHT TO TRANSPARENCY AND ACCESS TO INFORMATION

This judgment confirms the doctrine set out in the judgment of the Litigation Chamber of the High Court of 22 December 2023, which upheld the appeal 60/2023 filed by the AEMPS against the lower court's judgment upholding the CTBG's decision to deliver the price of COVID-19 vaccines, as well as that of the General Court of the European Union itself, in its judgments of 6 April 2022 (T-506/21), 7 September 2022 (T-448/21) and 10 October 2022 (T-524/21).

This doctrine could be summarized as follows: the right to transparency, as an instrument of control on public spending, is a broad right that does not need to be justified in order to be exercised because it protects a public interest (i.e., to know how our rulers spend public resources, which are ultimately the resources of the citizens). However, this right, despite being broad and not needing to be justified, is not unlimited; on the contrary, it has well-defined limits. Which are said limits? Well, those other interests that must be protected and which are included in article 14 of the LTAIBG. Thus, when the right to transparency comes into conflict with these other interests, the so-called harm test must be applies in order to decide which of the two should prevail (as stated in the Explanatory Memorandum of the LTAIBG itself).

This means that the two rights must be weighed against each other, and it must be assessed whether it is proportionate to limit the general public interest sought by transparency in order to safeguard the right protected by the limit in Article 14 (in this case the right to protect Spain's foreign affairs and the right to protect the confidentiality of decision-making processes).

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2.1. The protection of international affairs

In relation to the protection of international affairs, it seems quite obvious that if it were confirmed that from now on all trade agreements concluded with the Spanish State could eventually be subject to disclosure and publication, other States would be wary and would possibly adopt defensive and restrictive measures, something that would ultimately damage and affect Spain's negotiating position. On the other hand, it is important to note that these agreements could contain (as was precisely the case here) confidential information of third parties (as in this case is the purchase price of vaccines negotiated and agreed by the European Commission with BioNTech/Pfizer), whose rights would be affected without being able to remedy it.

[...] it seems quite obvious that if it were confirmed that from now on all trade agreements concluded with the Spanish State could eventually be subject to disclosure and publication, other States would be wary and would possibly adopt defensive and restrictive measures, something that would ultimately damage and affect Spain's negotiating position.

This means that the two rights must be weighed against each other, and it must be assessed whether it is proportionate to limit the general public interest sought by transparency in order to safeguard the right protected by the limit in Article 14 (in this case the right to protect Spain's foreign affairs and the right to protect the confidentiality of decision-making processes).

Without diving into the details of the characteristics of the Joint Purchase Agreements (legal instrument used by the European Commission for the procurement of Covid-19 vaccines for all EU Member States), it is clear that the confidential nature of the terms of the Joint Purchase Agreements was one of the key elements that allowed the acceleration of the negotiation and procurement of vaccines for the citizens of all Member States. This confidentiality protected the interests of the European Commission, of all EU Member States and of the pharmaceutical companies supplying the COVID-19 vaccines (in this case Pfizer). Henceforth, it is clear that, if the agreement to resell the vaccines to Andorra for the same purchase price were to be published and the purchase price of the Pfizer vaccines negotiated by the European Commission for all the Member States were to become known, the confidentiality not only of Spain and the pharmaceutical company, Pfizer, but also of the other Member States, would be affected. Nor does it escape anyone's notice that, if such a scenario were to occur, Spain's foreign affairs would be severely affected. If, in the future, a situation were to arise that would require recourse to this type of legal instrument (hopefully not due to a health crisis such as the one caused by COVID-19), would the European Commission be willing to negotiate the acquisition and price of strategic medicines and allow Spain to benefit from such negotiations, knowing the impact on confidentiality that could eventually arise? The answer seems obvious. Quite simply, no.

If, in the future, a situation were to arise that would require recourse to this type of legal instrument (...)), would the European Commission be willing to negotiate the acquisition and price of strategic medicines and allow Spain to benefit from such negotiations, knowing the impact on confidentiality that could eventually arise? The answer seems obvious. Quite simply, no.

Transparency as an instrument of control and accountability over the use of public money by those in power is undoubtedly a useful and necessary instrument, but as provided for in the LTAIBG itself and confirmed by the National High Court in the Judgment, it must have its limits, since otherwise it can easily go from being a necessary instrument of accountability in democratic systems to a burden that causes irreparable harm. Thus, and in relation to the limitation provided for in article 14.1c) of the LTAIBG, when applying the harm test, it is confirmed that the right to transparency does not pass this test, as in this case, transparency would be more harmful than beneficial. Thus, in the case at hand, the Judgment confirms the existence of a causal link between the granting of access to infor-

mation (transparency) and the harm to the protected legal interest (protection of international affairs - article 14.1c)), without there being any overriding interest that could justify the disclosure of the information.

2.2. The guarantee of confidentiality or secrecy in decision-making processes

On the other hand, and in relation to the protection of the confidentiality of negotiations or decision-making processes (limit provided for in article 14.1k) of the LTAIBG), we see that if confronted with the right to transparency, it does not pass the harm test either. Although the CTBG and the first instance ruling considered that the fact of knowing the final result of a negotiation (final text of the vaccine donation or resale agreements) does not reveal sensitive information on the decision-making process or on the negotiations that took place to reach these agreements, the National High Court does not consider this to be the case.

The National High Court is right in understanding that while for an average external observer, knowing the final text of an agreement does not reveal much information about the terms of the negotiations that took place to reach this agreement, it is clear that for entities that are engaged in the same business (in this case pharmaceutical companies and medicines purchasing organizations), knowing the final text of the agreement allows them to know how and what was negotiated and what the decision-making process was like, something that is precisely confidential and secret and therefore recognized as one of the limits to transparency. This confirms the interpretation of the National High Court as set out in the judgment of 22 December 2023 in the appeal 60/2023, when it indicates, for the purposes of assessing whether or not the limit to the right of access and disclosure of certain information (transparency) is applicable, that the "*decontextualized disclosure*" of certain information (such as, in this case,

This confirms the interpretation of the National High Court as set out in the judgment of 22 December 2023 in the appeal 60/2023, when it indicates, for the purposes of assessing whether or not the limit to the right of access and disclosure of certain information (transparency) is applicable, that the *"decontextualized disclosure"* of certain information (such as, in this case, the acquisition cost of the COVID-19 vaccines acquired through the Commission's Procurement Agreements), *"could have a serious impact on the determination of the conditions in the formalization of this type of contract"*.

the acquisition cost of the COVID-19 vaccines acquired through the Commission's Procurement Agreements), "*could have a serious impact on the determination of the conditions in the formalization of this type of contract*".

2.3. The harm test

It is particularly encouraging to see how the National High Court brings clarity and common sense to a subject as delicate as the transparency of the prices at which the National Health System purchases medicines or financed prices. We should not underestimate the importance of transparency as an instrument of control of the actions of our rulers, especially in relation to the control of public spending. However, it is clear that applying it absolutely and indiscriminately can do more harm than good. To this end, the limits provided for in article 14 of the LTAIBG itself must be observed and applied in accordance with the harm test. This means comparing both rights in order to assess which should prevail in each case, taking into account the consequences that transparency could have for the subjects and sectors affected, not in general terms for an average observer and in a decontextualised manner, but for the sector affected and the subjects that carry out their activity in it. Thus, the disclosure of the final purchase price of vaccines, in isolation, may provide little information to the average citizen about the negotiation process used to reach this agreement (price), but it would reveal economic information on the subject of the business (price of the medicine) that could be used by other countries or other parties involved (competitors) to the detriment of future negotiations.

We should not underestimate the importance of transparency as an instrument of control of the actions of our rulers, especially in relation to the control of public spending. However, it is clear that applying it absolutely and indiscriminately can do more harm than good.

Once again, the Court confirms the existence of a causal link between the granting of access to information (transparency) and the harm to the protected legal interest (protection of the confidentiality of the Administration's negotiation processes - article 14.1k)), without there being any overriding interest that could justify the disclosure of the information.

This is particularly interesting, because numerous CTBG resolutions (all of which are being appealed and reviewed) have insisted that knowing the final result, the final text of an agreement (in this case those for the resale and/or donation of vaccines against COVID-19, but also in other cases in relation to agreements on the price and financing of medicines) does not reveal confidential information about the negotiation process involved in reaching that result, insisting that an average observer could not know what was the decision-making process involved

in reaching the agreement or arrangement. The National High Court insists that, in order to assess this aspect, the impact of an average observer accessing this information in an isolated and decontextualized manner should not be taken into account, but rather the impact and use that could be made of this information in the future by other affected parties or bodies involved in the same sector.

Once again, the Court confirms the existence of a causal link between the granting of access to information (transparency) and the harm to the protected legal interest (protection of the confidentiality of the Administration's negotiation processes – article 14.1k) –, without there being any overriding interest that could justify the disclosure of the information.

The National High Court insists that, in order to assess this aspect, the impact of an average observer accessing this information in an isolated and decontextualized manner should not be taken into account, but rather the impact and use that could be made of this information in the future by other affected parties or bodies involved in the same sector.

Finally, it should be noted that the National High Court recalls, in line with what was agreed by the General Court of the European Union in its judgments of 6 April 2022 (T-506/21), 7 September 2022 (cases T-448/21 and 651/21) and 10 October 2022 (T-524/21) that the provision of confidential information (purchase price of the vaccines) would affect the confidentiality of a third party (pharmaceutical laboratory, Pfizer in this case) without even giving it the opportunity to intervene or express its position, thus affecting the negotiating position of the body responsible for the purchase (the European Commission in this case) in future similar processes, where the manufacturing laboratories would take into consideration the potential impact on the confidentiality of their negotiations.

3. CONCLUSION

The Judgment under analysis sheds some light on an highly controversial issue that many have attempted to decontextualize, on the basis of an alleged absence of limits to the right to transparency and access to information, with the National High Court reminding us that the fact that it is not necessary to give reasons for the exercise of this right does not, in any case, mean that there are no limits, which must be analyzed and weighed on a case-by-case basis and taking into account the specifics and context of each case.

Paula González de Castejón

[...] with the National High Court reminding us that the fact that it is not necessary to give reasons for the exercise of this right does not, in any case, mean that there are no limits, which must be analyzed and weighed on a case-by-case basis and taking into account the specifics and context of each case.

APPLICATION OF THE SPANISH TRANSPARENCY ACT IN RELATION TO MEDICINES (2013-2023)

Joan Carles Bailach de Rivera

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2023 Report

Spanish Law 19/2023, of 9 December, on transparency, access to public information and good governance [*Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno*] (the "*Transparency Act*") was approved in 2013. The Transparency Act establishes and regulates the right of individuals and legal entities to access public information, as well as the procedure for complaining to the Spanish Transparency and Good Governance Council (CTBG).

The public authorities that receive access-to-information requests are obliged to resolve them. If they fail to do so within the established period (in which case the request is considered denied) or the requester does not find the response satisfactory, a complaint can be filed with the CTBG or directly apply for a judicial review.

Complaints before the CTBG replace any administrative proceedings/appeals, and its resolutions are binding for public authorities.

The CTBG's resolutions can be appealed before the Administrative Chamber of the National Court.

Since the Transparency Act was approved, numerous requests have been made related to information on medicines (among others, ex-factory prices, P&R decisions, purchase price paid by hospitals).

In relation to ex-factory prices or P&R resolutions, the Ministry of Health's stance has been to reject access to this information based on the following:

Giving access to reimbursement prices of medicines in Spain would hinder the MoH's negotiating position to obtain more competitive prices based on Spain less privileged economic-financial situation compared to other countries.

- Giving access to reimbursement prices of medicines in Spain would hinder the MoH's negotiating position to obtain more competitive prices based on Spain less privileged economic-financial situation compared to other countries.

- Public reimbursement of medicines comes after a negotiation process with the pharmaceutical companies on which costs of manufacturing the medicine, profit margin and the therapeutic utility of the product are assessed. Data on companies costs and margins are confidential and their publication could seriously affect companies capacity to compete effectively, given that it is information relating to, among others, costs of products, storage and transformation; commercial costs; sales forecasts, market shares, economic analysis and pharmacological costs. All this information is under trade secret protection, and its disclosure could seriously affect economic and commercial interests of impacted companies.

- Section 97(3) of the Spanish Medicines Act establishes the confidentiality of all information on *"technical, economic and financial aspects"* provided by pharmaceutical companies to the Ministry of Health.

The CTBG's stance on this has been erratic. However, in recent years, it has established a clear position in favour of giving access to information such as ex-factory prices, P&R resolutions or purchase prices based on the following grounds:

- The confidentiality warranty under section 97(3) of the Medicines Act only affects the information that pharmaceutical companies provide during negotiations but does not affect P&R resolutions.

- The ex-factory price is information that contributes to generate a public debate on the use of public resources.

- Pharmaceutical companies have not proved what impact would have on their economic and commercial interests the provision of access to ex-factory prices and P&R decisions.

To date, most of CTBG's decisions that have been appealed before the courts have been overturned based on formal grounds.

However, with regard to the position taken by the courts, three judgments should be highlighted:

Data on companies costs and margins are confidential and their publication could seriously affect companies capacity to compete effectively, given that it is information relating to, among others, costs of products, storage and transformation; commercial costs; sales forecasts, market shares, economic analysis and pharmacological costs. All this information is under trade secret protection, and its disclosure could seriously affect economic and commercial interests of impacted companies.

- Supreme Court Judgment of 8 March (315/2021). This judgment confirmed the CTBG and MoH's duty to give audience to MAHs when access-to-information requests are made in relation to them.

- Judgment of the Administrative Chamber of the National Court of 30 March (55/2020). This judgment confirmed MoH's position of denying access requested on prices of all medicines paid by public hospitals in 2018. The Ministry of Health argued that providing such information would cause clear, real and effective harm to the economic and commercial interests of pharmaceutical companies (section 14(1)(e) of the Transparency Act). Furthermore, the MoH also justified that granting access to ex-factory prices of medicines in Spain to third parties would hinder MoH's negotiating position to obtain more competitive prices. The Court ratified MoH's position and endorsed the refusal to provide the requested information.

- Judgment of the Administrative Chamber of the High Court of Justice of the Canary Islands of 28 March 2023 (119/2023). This judgment ratified the position maintained by the MoH that pharmaceutical companies have a legitimate interest in relation to the reimbursement price of their medicines, as this is based on of confidential information. The High Court of Justice ruled that disclosing this information could seriously hinder the company's capacity to compete and that this price should be considered a trade secret subject to protection. Furthermore, it stated that the Spanish Public Sector Contracts Act does not require the publication of the unitary price of the medicines purchased, and that it is acceptable to publish only the total price of the contract, without a breakdown of the units purchased.

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CONFIDENTIALITY OF THE EX-FACTORY PRICE OF MEDICINAL PRODUCTS. GREATER AND MORE SUSTAINABLE ACCESS

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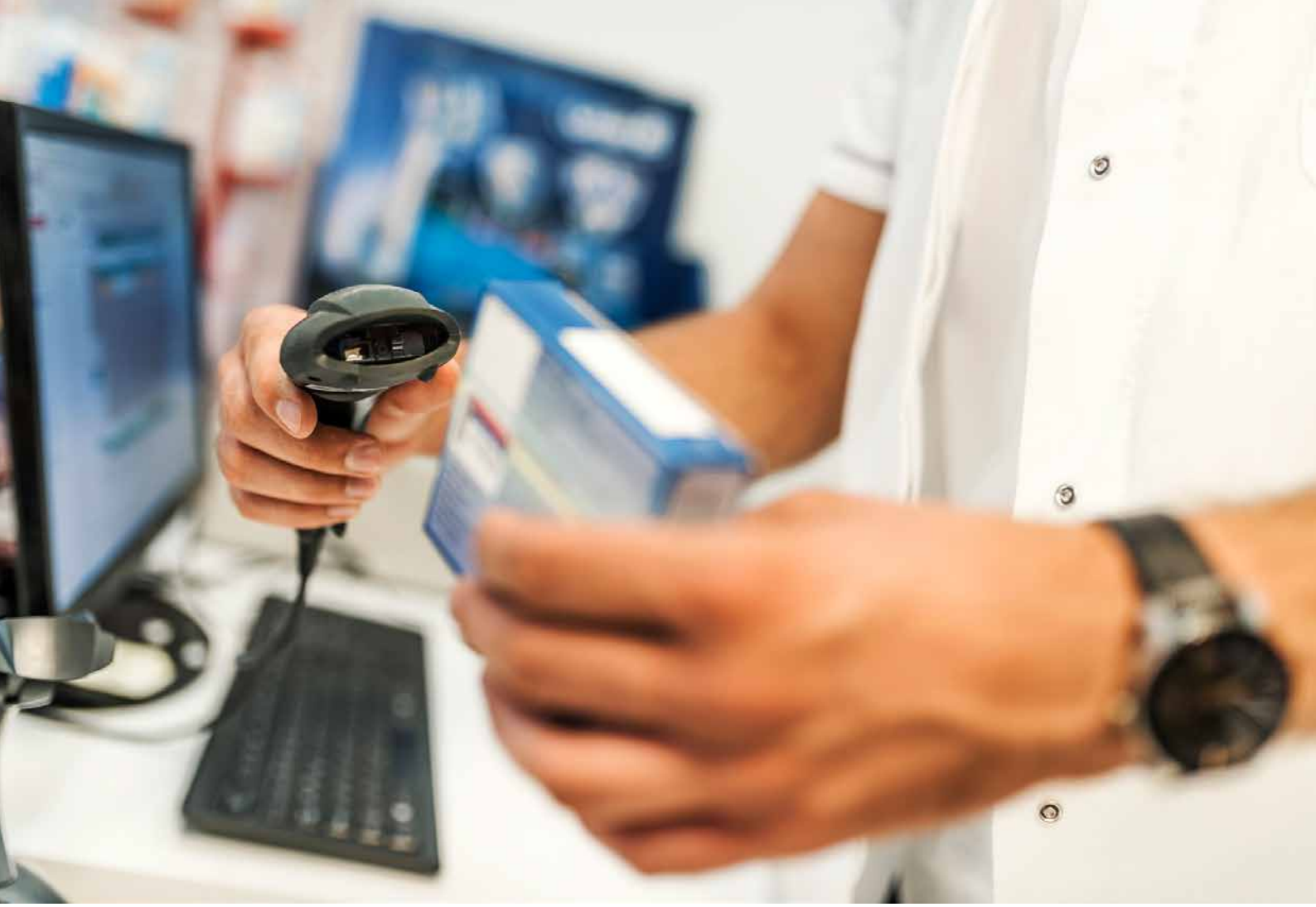

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RESUMEN: Este artículo analiza la relación entre la confidencialidad del precio y las condiciones de financiación de los medicamentos y el acceso por parte de los usuarios del Sistema Nacional de Salud a estos. Se analiza también la postura mantenida por la Comisión Europea en relación con el mantenimiento de la confidencialidad del precio de las vacunas contra el COVID-19 a los efectos de garantizar un correcto suministro de estas en la Unión Europea. Finalmente, también se analiza la posibilidad de mantener confidencial el precio unitario de los medicamentos.

PALABRAS CLAVE: Ley de Transparencia; confidencialidad;transparencia; precio medicamentos; licitaciones públicas; vacunas COVID-19.

ABSTRACT: This article analyses the relationship between the confidentiality of the price and financing conditions of medicinal products and the access of users of the National Health System to these medicinal products. It also analyses the position maintained by the European Commission in relation to maintaining the confidentiality of the price of COVID-19 vaccines in order to guarantee the correct supply of these vaccines in the European Union. Finally, the possibility of keeping confidential the unit price of medicinal products is also analysed.

KEYWORDS: Transparency Law; Confidentiality; transparency; price of medicines; public tenders; COVID-19 vaccines.

1. INTRODUCTION

The pharmaceutical provision of the National Health System (NHS) includes medicinal products and medical devices and the set of actions aimed at ensuring that patients receive in a way that is appropriate to their clinical needs, in the doses required according to their individual requirements, for the appropriate period of time and at the lowest possible cost for patients and for the community[1].

The inclusion of medicinal products in pharmaceutical services is not carried out in a general and indiscriminate manner, but rather follows a model of selective financing based on the therapeutic usefulness and the need to improve the health of citizens. As a complementary measure to the decision on public funding, the Ministry of Health is carrying out the intervention on the price of medicinal products and medical devices, with the aim of ensuring the sustainability of the health system.

According to the latest available data published[2] by the Ministry of Health in 2019, 1,391 presentations of medicinal products were included in the public financing of the NHS, reaching more than 21,383 presentations financed by public funds in total. In 2021, according to data[3] from the Ministry of Finance and Public Function, the total cost of pharmaceutical provision of medicinal products and medical devices amounted to €20,500 million. Consequently, and in view of the need to include new innovative medicinal products with a high budgetary impact, the Ministry of Health has chosen to establish in some cases new financing formulas that allow innovative medicinal products to be included under affordable economic conditions. In this sense, after an analysis of the agreements of the Interministerial Commission on Medicinal Pro duct Prices (CIPM) published by the Ministry of Health on its website[4], we can reach a clear Conclusion: in recent years, there has been a significant increase in agreements for the inclusion of medicinal products in the pharmaceutical provision of the NHS that incorporate shared risk clauses. In particular, during 2020-2022, for example, we can observe different agreements for the inclusion of medicinal products subject to expenditure ceilings, pay-for-result or pay-by-volume agreements.

Inclusion agreements with the establishment of individual reservations –such as the application of a visa–, the establishment of automatic price review clauses or clauses establishing a maximum cost per patient are also not uncommon.

All these measures are aimed, on the one hand, at promoting access to new medicinal products in the public pharmaceutical sector; and, on the other hand, to maintain the necessary financial sustainability of the NHS.

A key element in achieving these measures is the necessary confidentiality of the specific economic conditions agreed between the Ministry of Health and the pharmaceutical companies offering the new medicinal products. Without this confidentiality, it would not be possible to access new medicinal products on terms that are affordable and contribute to maintaining the financial sustainability of the NHS.

In this regard, it is also important to maintain the confidentiality of the unit price for the acquisition of medicinal products in public tenders, especially in those procedures negotiated for reasons of exclusivity in which, as we will explain, public hospitals can negotiate better economic conditions with companies.

At this point, we must consider the impact of Law 19/2013, of 9 December, on transparency, access to public information and good governance (LTAIBG) on the pharmaceutical sector.

2. THE DETERMINATION OF THE EX-FACTORY PRICE OF MEDICINAL PRODUCTS IS NOT ARBITRARY

Before proceeding to explain the impact of the entry into force of the LTAIBG, we consider it necessary to make a brief excursus on the procedure for determining the price of medicinal products in order to understand how this price is established. And all this because the price of medicinal products is not determined randomly or arbitrarily. On the contrary, it is determined in a regulated manner and following the procedures that are determined in the regulations in force.

In this regard, it is necessary to set out the rules governing the inclusion of a medicinal product in the pharmaceutical provision of the NHS and the setting of its maximum marketing price.

Firstly, the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015 (LGURMPS), establishes in Article 92 that the inclusion of medicinal products in the financing of the NHS is made possible through selective and not indiscriminate financing, taking into account general, objective and published criteria. In particular, Article 92(1) LGURMPS establishes the criteria for the inclusion of a medicinal product in the pharmaceutical provision of the NHS, such as the therapeutic and social value of the medicinal product and its incremental clinical benefit, taking into account its cost-effectiveness, the rationalisation of public expenditure, the degree of innovation or the existence of medicinal products or other therapeutic alternatives; among others.

In addition, paragraph 8 of the same article 92 LGURMPS clearly establishes that for the decision to finance new medicinal products, in addition to the corresponding cost-effectiveness and budgetary impact analysis, *"the innovation component will be taken into account, for undisputed therapeutic advances by modifying the course of the disease or improving its course, the prognosis and therapeutic outcome of the intervention and its contribution to the sustainability of the NHS if, for the same health outcome, it contributes positively to the Gross Domestic Product".*

Secondly, and with regard to the specific administrative procedure for the inclusion of a medicinal product, we must look at the provisions of Royal Decree 271/1990 of 23 February 1990 on the reorganisation of price intervention for proprietary medicinal products for human use (Royal Decree 271/1990). In order to illustrate the nature of the information that pharmaceutical companies must provide during the listing procedure; we believe it is relevant to point out the provisions of Article 3 thereof:

> *"Art. 3. Procedure for setting the prices of newly marketed proprietary medicinal products.*
>
> *1. Newly marketed pharmaceutical specialities shall require, as an essential requirement, the prior establishment of the laboratory's selling price, from which, by aggregating the items corresponding to distribution, the retail price which must necessarily appear on the dispatch packaging may be obtained.*
>
> *2. The manufacturing companies shall provide, together with the initial application, the technical, accounting and financial documentation necessary for the preparation of the economic report, which shall serve as the basis for*

setting the price of the new medicinal product. The Administration may carry out verifications as may be necessary to verify the documentation provided.

In the event that the applicant company is part of a group that carries out other activities in addition to those related to medicinal products, or carries them out outside Spain, additional information may be required to verify the internal transactions carried out within the group of companies and related to the pharmaceutical activity.

3. The prices of newly marketed specialities shall be set following the completion of an individualised dossier, the content of which shall necessarily meet the following criteria:

The industrial price of the speciality shall be fixed by adding to the total cost or cost price of the speciality the percentage corresponding to the business profit.

The cost price shall be calculated by means of the analytical application of the "full cost", including that of research and technological development. The unit cost thus obtained represents the cost of manufacturing the product, incorporating the apportionments corresponding to commercial and administrative expenses incurred in the period.

In order to calculate the cost, the following variables that have a direct impact on it will be taken into account: Level of activity, evolution of the Company's costs and sales volumes, estimates of the sales of the new speciality and the incidence that arises in the structure costs due to the manufacture of the new product.

The company profit for each speciality shall be set at a percentage, determined by a technical report on the economic-financial situation of the company. This percentage shall be within a range established annually by the Government's Delegate Commission for Economic Affairs, taking as a reference point the economic situation of the pharmaceutical industry as a whole and the economic policy forecast.

In order for the calculated industrial price to be congruent with respect to similar products on the market, the therapeutic usefulness of the new product, scientifically proven, together with the criterion of proportionality that prevents the cost of the treatment from being disproportionate to other alternatives, shall act as correctors within the established profitability band.

By means of the general application of these criteria, unjustified or unnecessary costs will be avoided, such as those arising from overpricing above market prices of active substances, excessive payments for licensing of brands or technology or promotional or advertising expenses not appropriate to the characteristics of the product, as well as those expenses not necessary for the development of the normal activity of the Company, so that the final price of the medicinal product is calculated in accordance with its real cost, in an objective and transparent manner".

In accordance with the provisions of Royal Decree 271/1990, the following variables that have a direct impact on the medicinal product will be taken into account in the calculation of the full cost of the medicinal product: level of activity, evolution of costs and sales volumes of the Company, estimates of sales of the new specialty and the impact on structural costs arising from the manufacture of the new product.

The business profit for each specialty will be set at a percentage determined by a techni-

cal report on the economic and financial situation of the pharmaceutical Company. This percentage will be included within a band established annually by the Government's Delegate Commission for Economic Affairs, taking as a reference base the economic situation of the pharmaceutical industry as a whole and the short-term Economic Policy Forecasts.

In view of the above, we can conclude that the ex-factory price established for medicinal products is neither arbitrary nor random, but is the result of a regulated procedure, and the use of objective criteria set out in the regulations. In other words, the price is a reflection of the costs of research, development, manufacturing, distribution and the business margin.

At this point, the authors of this article would like to point out that it is very simple, and it is done by certain groups on a regular basis, to question the prices of certain medicinal products with a high budgetary impact. However, it is never mentioned that these prices are maximum, and discounts can be made at the time of purchase by hospitals. Moreover, it is never highlighted that many of these medicinal products, which may indeed be considered to have a high budgetary impact, carry with them high research, development and marketing costs. And all this, without taking into account that many of these products are orphan medicinal products[5] that are intended to treat a condition that does not affect more than 5 people per 10,000. For this reason, it should also be noted that the return of these medicinal products is limited given that their target population is also limited.

3. AND WHY IS IT NECESSARY TO KEEP THE PRICE OF MEDICINAL PRODUCTS CONFIDENTIAL?

Well, the answer to this question is twofold. On the one hand, maintaining the Confidentiality of medicinal products prices means looking after the public interest.

The Ministry of Health has maintained a clear stance on this issue in recent years. In 2019, the then The Directorate General of Pharmacy at the Ministry of Health prepared a report[6] on the guarantee of confidentiality in the procedure for including medicinal products in the pharmaceutical provision of the NHS.

In that report, the The Directorate General of Pharmacy at the Ministry of Health pointed out that the competence relating to the fixing of prices and their inclusion in the provision of public pharmaceuticals is a specific competence to each Member State of the European Union. In this sense, the Ministry of Health acknowledges, EU countries use prices financed in other Member States, when they are made public, to achieve price reductions in their public systems. This scenario, according to the Ministry of Health, generates a situation in which the holders of the marketing authorisation for a specific medicinal product are not willing to offer more favourable economic conditions to countries with a less prosperous economic situation, in the event that these were made public, since this would force them to apply those same advantages in countries with better economic situations.

As a result, the Ministry of Health states that many Member States "*avoid publishing these prices as a measure to protect national interests, since only by maintaining the secrecy of these prices do they ensure the achievement of better conditions*". In other words, giving third parties access to financing prices in Spain would entail a negotiating disadvantage for the Ministry of Health when it comes to obtaining more competitive prices (which could be achieved taking into account Spain's most disadvantaged economic-financial situation compared to other neighbouring countries, due to the high public deficit and lower per Capita Income).

This scenario, according to the Ministry of Health, generates a situation in which the holders of the marketing authorisation for a specific medicinal product are not willing to offer more favourable economic conditions to countries with a less prosperous economic situation, in the event that these were made public, since this would force them to apply those same advantages in countries with better economic situations.

In short, it is contrary to the public interest to make available to other Member States information that would help them in their negotiation of the prices of medicinal products with the laboratories, but the disclosure of which would be detrimental to the achievement of savings - and would hinder access to new medicinal products - in Spain.

On the other hand, maintaining confidentiality means protecting the legitimate economic and commercial interests of pharmaceutical companies. The Ministry of Health points out that, during the price negotiation procedure, pharmaceutical companies provide information on product, supply and processing costs (raw materials, labour costs, licences, etc.); business costs (personnel, transportation); Information relating to sales forecasts, market shares, economic analysis and pharmacological costs.

In relation to this information, the Ministry of Health recognises that all of this data is of confidential knowledge and its publication could seriously affect the ability of companies to compete. Moreover, all this information is covered by professional secrecy and its disclosure could seriously affect the economic and commercial interests of the companies concerned.

In addition, the Ministry of Health points out that, the legislator, aware of this situation, declared that all this information should be confidential, including this in the article 97.3 of the LGURMPS.

Indeed, given the nature of the information to be provided for the determination of the price, it is not surprising that the LGURMPS itself establishes a guarantee of absolute confidentiality. The terms of Article 97 LGURMPS are categorical with respect to the issue at hand:

"*Article 97. Economic information.*

1. For the purposes of pricing, pharmaceutical laboratories shall provide the Ministry of Health, Social Services and Equality with all information on technical, economic and financial aspects. The Ministry may carry out checks on the information provided.

2. In the event that the company is part of a group that carries out other activities, in addition to those related to medicinal products, or carries them out outside Spain, the Ministry of Health, Social Services and Equality may require the information that allows the allocation to be known in order to determine the expenses allocated to the pharmaceutical activity in Spain.

3. The information obtained by the General State Administration pursuant to this article shall be confidential.

4. The Ministry of Health, Social Services and Equality shall submit an annual report to the Government Delegate Committee for Economic Affairs on its actions in the field of prices."

This position of the Ministry of Health has been fully endorsed by the Administrative Chamber of the National High Court which, in its judgment of 30 March 2021, confirmed the position of the Ministry of Health according to which providing the requested information would entail obvious, real and effective damage to the economic and commercial interests of pharmaceutical companies and to the public interests.

4. THE EUROPEAN COMMISSION'S POSITION ON COVID-19 VACCINES

Following the line of argument defended by the Spanish Ministry of Health, the European Commission has recently ruled on the need

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to maintain certain levels of confidentiality in relation to the price of medicinal products. For example, with regard to the purchase price of COVID-19 vaccines, the European Commission has defended the confidentiality of the price of vaccines precisely under the argument that the public interest that should prevail is not indiscriminate transparency, but to ensure that the procurement of vaccines could be done under the best possible conditions.

Contracts for the purchase of COVID-19 vaccines are public and available to anyone interested on the European Commission's website[7]. All these contracts have one thing in common: the section on the unit cost of vaccines and their financing conditions is restricted and their information is not public.

The European Commission's argumentation for the need to maintain this confidentiality is as follows:[8]

> "*Contracts are protected for confidentiality reasons, which is warranted by the highly competitive nature of the global market.*
>
> *This is in order to protect sensitive negotiations as well as business related information, such as financial information and development and production plans.*
>
> *Disclosing sensitive business information would also undermine the tendering process and have potentially far-reaching consequences for the ability of the Commission to carry out its tasks as set out in the legal instruments that form the basis of the negotiations. All companies require that such sensitive business information remains confidential between the signatories of the contract. The Commission therefore has to respect the contracts it concludes with the companies.*".

The European Commission has also argued, in various written replies to Members of the European Parliament, that:

> "*The law protects the commercial interests of companies. Non-disclosure clauses are a standard feature of purchase agreements. They protect the legitimate interests of companies, which have invested heavily in research and production capacity. There are also rules that protect the bidding process. The disclosure of sensitive business information would weaken the EU's position in the ongoing negotiations, thereby undermining the beneficial effects of fair competition and the effectiveness of the single procurement process that has led to the best conditions for Member States and citizens.*"

In view of the above, we can conclude that the position held by the European Commission is fully aligned with the position held by the Ministry of Health, in the sense that the confidentiality of the price of COVID-19 vaccines facilitates greater access to these vaccines under the best economic conditions for Member States.

5. EFFECTS OF THE ENTRY INTO FORCE OF THE LTAIBG IN SPAIN IN RELATION TO THE CONFIDENTIALITY OF THE PRICES OF MEDICINAL PRODUCTS

With the approval of the LTAIBG in 2013, the right of access to public information was regulated for the first time in Spain in a general way. This law created the Council of Transparency and Good Governance (CTBG), a public body whose purpose, among others, is to safeguard the exercise of the right of access to public information. Within the framework of its competences, the CTBG is the body responsible for resolving complaints submitted in relation to the right of access to information, and its resolutions are mandatory for the Public Administrations that are subject to this Law.

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And what position has the CTGB maintained in relation to the confidentiality of the ex-factory price of medicinal products, the purchase prices by public hospitals or the resolutions themselves to include medicinal products in the pharmaceutical service?
In a chronological analysis of the CTBG's resolutions, we can conclude that it has maintained a position that is mostly in favour of granting access to all this information.

In a chronological analysis of the CTBG's resolutions, we can conclude that it has maintained a position that is mostly in favour of granting access to all this information.

Despite the fact that on some occasions the CTBG has defended that agreeing to the resolution to include a medicinal product would be detrimental to economic and commercial interests[9] (art. 14.1.h LTAIBG), the truth is that its latest resolutions are in favour[10] of granting access to this type of information.

In this sense, the CTBG currently defends that providing access to this information (i) does not affect the limit of the guarantee of confidentiality (art. 14.1.k) since the confidential Information that pharmaceutical companies provide during the inclusion process is not comparable to the resolutions to include a medicinal product in the pharmaceutical service; (ii) does not prejudice the economic and commercial interests of pharmaceutical companies; and that (iii) helps to "*promote an informed public debate on the problems of the current system of R+D and medical innovation and their impact on access to medicinal products and on the sustainability of health systems, inside and outside our country*".

In short, as can be seen, the position of the CTBG differs from the position held by the Ministry of Health and the European Commission. We believe that this position is not taking into account the impact on the public interest that access to this type of information would entail; The consequences of this would be a higher cost for medicinal products and, ultimately, a greater budgetary impact of the pharmaceutical provision of the NHS.

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6. MAINTAINING THE CONFIDENTIALITY OF THE UNIT PURCHASE PRICE OF MEDICINAL PRODUCTS IN PUBLIC TENDERS

On the other hand, we consider it necessary to make a series of reflections on the confidentiality of the purchase price of certain medicinal products by public hospitals. We are referring to those medicinal products that, for reasons of exclusivity or because they are the sole supplier in the NHS, are acquired through a negotiated procedure without advertising in according to Law 9/2017, of 8 November, on Public Sector Contracts (LCSP).

In this regard, it should be remembered that the ex-factory price is the maximum price at which the NHS will purchase a medicinal product; In other words, public NHS hospitals can acquire these medicinal products on more favourable economic terms after negotiating with pharmaceutical companies. For this reason, and by analogy to what has been established in the previous sections of this document, the confidentiality of the unit price for the acquisition of medicinal products by public hospitals is necessary in order to be able to make discounts and improve economic conditions in those Autonomous Communities with greater difficulties or with greater purchase quantities.

And all this, for two reasons.

Firstly, because the ex-factory price is the maximum price at which the NHS will purchase a medicinal product. In other words, the establishment of a Ex-factory price is the guarantee that no public hospital will pay more for a medicinal product than the previous maximum that the Ministry of Health establishes. This measure ensures equity in access to medicinal products by limiting the

"*cap*" or "*ceiling*" at which hospitals will purchase a medicinal product when negotiating with a pharmaceutical company.

And, secondly, because the LCSP allows the unit purchase price of a medicinal product (but not the total value of the contract) to be kept confidential.

From a literal interpretation of the provisions of the LCSP that regulate the content of the advertising of public contracts, it can be deduced that they allow the unit price at which a medicinal product is purchased not to be published. In this regard, it should be noted that the formalization of contracts must include the information contained in the Annex III LCSP, and point 7 of section 4 of subparagraph A) thereof provides that the *"nature and quantity or value of the supplies"* must be published in the tender notices. In the same vein, point 6 of section 6 of subparagraph A) of the same Annex III of the LCSP mentions the "*nature and quantity or value of the supplies*".

As can be seen, the regulation provides for the possibility of choosing to publish the quantity of supplies or the value of the supplies, but does not require the publication of both at the same time. Consequently, it is possible to publish only the quantities to be supplied under the contract, without making any reference to their valuation.

On the other hand, what is to be understood by the "*value*" of the contract if one chooses to publish this data? To answer this question, it is appropriate to refer to Article 101 LCSP, a provision that details what is to be understood by "*value*" with respect to a public contract. Thus, article 101 LCSP defines the "*value*" of the contract as the total amount of the contract, and not as the unit amount of the units of products to be supplied. It is true that it does so by referring to the "*estimated value*", but that is only because it is dealing with the preparatory phase of the award of the contract.

Therefore, the LCSP establishes a correspondence between the term "*value*" and the "*total*" amount of a contract, which is not unitary. We understand that this correspondence should also be applied to Annex III of the LCSP when it refers to the "*value of supplies*".

This interpretation is also supported by Article 189 of Royal Decree 1098/2001 which, when referring to the value of supply contracts, always refers to global values and not to unit supply prices.

Likewise, article 102.4 LCSP, when referring to the price of a contract (although Annex III of the LCSP speaks of "*value*" and not "*price*", it is interesting to check the relationship between the two terms), expressly accepts that the price of the contract is formulated in relation to all the services of the contract. and not in unitary terms.

Based on all this, we can conclude that the LCSP does not require the publication of the unit prices of a supply contract and that, therefore, the duty of publicity in the Contractor Profile regulated by the LCSP is fulfilled by referring to the total values of the contract or the lots awarded.

As mentioned above, the Administrative Chamber of the National High Court, in its Judgment of 30 March 2021, declared that the Resolution of the CTBG that considered to provide the "*breakdown of the medicinal products that make up hospital pharmaceutical expenditure for the year 2018, including (...) acquisition price and laboratory marketed, by each of the Autonomous Communities and other Public Administrations in an editable format (Excel or SCV)*" was not in accordance with the law.

7. CONCLUSIONS AND PROPOSALS

The advertising of the price of medicinal products is a complex debate due to the confrontation of competing interests. On the one hand, greater transparency and control of the actions of the Public Administration is entirely desirable, but on the other hand it is inevitable to note that in this area the application of the limits provided for, whether in European or national legislation, serves to protect not only the private interests of companies but especially the interests of public health systems in terms of obtaining the best possible conditions for the public health system when acquiring medicinal products.

Based on all this, we can conclude that the LCSP does not require the publication of the unit prices of a supply contract and that, therefore, the duty of publicity in the Contractor Profile regulated by the LCSP is fulfilled by referring to the total values of the contract or the lots awarded.

Consequently, we can affirm that not only does the LCSP allow not to publish the unit prices for the acquisition of medicinal products; Furthermore, the National High Court has established that unit prices cannot be accessed either via the right of access to public information (ex. LTAIBG).

Consequently, we can affirm that not only does the LCSP allow not to publish the unit prices for the acquisition of medicinal products; Furthermore, the National High Court has established that unit prices cannot be accessed either via the right of access to public information (ex. LTAIBG).

As we have pointed out in this article, maintaining the confidentiality of the price of medicinal products favours Spain's access to new treatments under cheaper conditions, which contributes to maintaining the financial sustainability of the NHS. By maintaining the confidentiality of the Ex-factory price of medicinal products, the NHS achieves greater discounts on the purchase prices of medicinal products by public hospitals over the Ex-factory price set by the Ministry of Health.

Maintaining the confidentiality of the ex-factory price of medicinal products is not incompatible with a fully transparent attitude of the Ministry of Health in relation to the inclusion of new medicinal products in the NHS. In this regard, we highlight the publication of the Therapeutic Positioning Reports for medicinal products by the Spanish Agency for Medicinal Products and Medical Devices, the greater information that is being included in the public agreements of the CIPM or the modifications established in the "*BIFIMED*" database on the status of the financing of medicinal products. All these actions are positive because they allow us to obtain the most relevant information on the inclusion of new medicinal products in the public pharmaceutical service; without prejudice to the maintenance of the confidentiality of the specific financing conditions and the ex-factory price.

For this reason, we consider it necessary for the Ministry of Health to continue carrying out actions that contribute to financial sustainability through the maintenance of the confidentiality of the ex-factory price of medicinal products and their economic conditions.

In this sense, we would like to conclude this article by proposing two lines of action that we consider to be positive:

First of all, we consider that the prior public consultation that was opened in July 2022 for the modification of the LGURMPS is an optimal opportunity to strengthen the confidentiality of the ex-factory price and the economic conditions of medicinal products. Among the various options that could be considered, we propose that the new LGURMPS includes the idea that the guarantee of confidentiality in article 97.3 covers both the information that the General State Administration obtains in any procedure for the inclusion of a medicinal product in the public pharmaceutical service, as well as the ex-factory price, the economic conditions of financing and the resolution of inclusion in the pharmaceutical benefit of the NHS.

Likewise, it would also be useful to include a specific chapter on access to information on pharmaceutical provision of the NHS, detailing the subjects entitled to it and/or the content and limits of the information that can be provided. Additional Provision 1 of the LTAIBG states that "*they shall be governed by their specific regulations (...) those matters that have a specific legal regime of access to information*". Jurisprudence (see, for example, Supreme Court Judgment 314/2021 of 8 March) has established that, in order to displace the application of the LTAIBG by virtue of its first additional provision, a legal rule must include its own specific regime that allows it to be understood that we are dealing with an alternative regulation due to the existing specialties in a given area or matter, thus creating an autonomous regulation in relation to the legitimate subjects and/or the content and limits of the information that can be provided. It would therefore be an excellent opportunity to establish a specific regime for access to information that is specifically designed and takes into account the idiosyncrasies of the pharmaceutical sector.

Given the long period required for a legislative amendment of this magnitude - it should be borne in mind that so far only prior public consultation has been carried out - we believe that this reform would be a me-

dium-long term measure of implementation. For this reason, we consider it necessary for the Ministry of Health to carry out additional actions in the short term to strengthen and guarantee the confidentiality of the ex-factory price of medicinal products and their financing conditions.

Secondly, and more immediately, we consider that the Ministry of Health should establish clauses of express confidentiality of the ex-factory price itself and the financing conditions in the same resolutions for the inclusion of a medicinal product in the pharmaceutical service. Such clauses would consist of specific and express wording declaring the confidentiality of the ex-factory price and the financing conditions.

This measure would be in line with the position held by the CTBG itself. In its Resolution 964/2021, of May 17, 2022, the CTBG itself, in relation to a request for access relating to the conditions for the acquisition of vaccines against COVID-19, stated that "*In the assessment of the justification provided for denying information on the cost of the operation, the undoubted fact that, irrespective of the Judgment that this may merit, the contracts signed by the European mission are subject to a duty of confidentiality. (...) In view of this, the disclosure of the costs by the Spanish State would entail a breach of that confidentiality, so that the application of the limits of Article 14 LTAIBG invoked must be considered justified*". For this reason, the establishment of express confidentiality clauses would strengthen the position of the Ministry of Health in limiting the right of access to public information of this specific information.

Finally, the maintenance of the confidentiality of the ex-factory price should also be compatible with the maintenance of the confidentiality of the unit purchase price of medicinal products by hospitals. There is no point in keeping the Ex-factory price confi-

Given the long period required for a legislative amendment of this magnitude - it should be borne in mind that so far only prior public consultation has been carried out - we believe that this reform would be a medium-long term measure of implementation. For this reason, we consider it necessary for the Ministry of Health to carry out additional actions in the short term to strengthen and guarantee the confidentiality of the ex-factory price of medicinal products and their financing conditions.

dential via LTAIBG if, applying public procurement regulations, the unit purchase price is publicized.

In this sense, and as we have explained, hospitals can and should advertise the *"value"* of contracts without specifying the unit price of medicinal products This maintenance of the *"confidential"* unit purchase price - not the total value of the contract - is fully aligned with public procurement regulations.

In this sense, and as we have explained, hospitals can and should advertise the *"value"* of contracts without specifying the unit price of medicinal products This maintenance of the *"confidential"* unit purchase price - not the total value of the contract - is fully aligned with public procurement regulations.

[1] https://www.sanidad.gob.es/estadEstudios/estadisticas/sisInfSanSNS/tablasEstadisticas/InfAnualSNS2020_21/INFORME_ANUAL_2020_21.pdf

[2] https://www.sanidad.gob.es/estadEstudios/estadisticas/sisInfSanSNS/tablasEstadisticas/InfAnualSNS2020_21/Informe_PrestacionFarmaceutica_2020-21.pdf

[3] https://www.hacienda.gob.es/es-ES/CDI/Paginas/EstabilidadPresupuestaria/InformacionAAPPs/Indicadores-sobre-Gasto-Farmac%C3%A9utico-y-Sanitario.aspx

[4] https://www.sanidad.gob.es/areas/farmacia/precios/comisionInteministerial/acuerdosNotasInformativas/home.htm

[5] Definition according to Regulation 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

[6] Report on the guarantee of confidentiality in the procedure for negotiating the financing prices of medicinal products, provided in the context of the administrative appeal brought before the Administrative Chamber of the National High Court (Appeal No.: 55/2020).

[7] https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en

[8] https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/questions-and-answers-covid-19-vaccination-eu_en

[9] *Vid.*, to that effect, Resolution 478/2019 of 26 September 2019 of the CTBG - Hyrimoz® case.

[10] *Vid.*, to that effect, Resolution 1076/2021 of 15 June 2022 of the CTBG - Luxturna® case.

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NEW DEVELOPMENTS IN RELATION TO TRANSPARENCY OF THE PRICE OF MEDICINAL PRODUCTS

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RESUMEN: Este artículo examina el impacto de la Ley de Transparencia, Acceso a la Información Pública y Buen Gobierno (LTAIBG) de 2013 en el sector farmacéutico. Se analizan las posturas del Ministerio de Sanidad, el Consejo de Transparencia y Buen Gobierno (CTBG) y la Comisión Europea en relación con la confidencialidad del precio y las condiciones de los medicamentos. También se analiza la STC 68/2021 y las posibilidades de declarar confidencial el precio unitario en las licitaciones públicas.

PALABRAS CLAVE: Ley de Transparencia; confidencialidad; transparencia; precio unitario medicamentos; licitaciones públicas.

ABSTRACT: This article examines the impact of the 2013 Law on Transparency, Access to Public Information and Good Governance (LTAIBG) on the pharmaceutical sector. It analyses the positions of the Ministry of Health, the Council for Transparency and Good Governance (CTBG) and the European Commission in relation to the confidentiality of the price and conditions of medicinal products. It also analyses the judgement 68/2021 of the Constitutional Court and the possibilities of declaring confidential the unit price in public tenders.

KEYWORDS: Transparency Act; confidentiality; transparency; medicinal product unit price; public tenders.

1. PUBLIC PROCUREMENT

1.1. Net price confidentiality

Since its approval in 2013, the Law on Transparency, Access to Public Information and Good Governance (LTAIBG) has had a significant impact on many sectors, including the pharmaceutical sector. Over the last few years, Fundación CEFI has made a significant effort to address the specific impact that the LTAIBG has had on this sector.

In addition to the obligations relating to the active disclosure of information by public administrations, the LTAIBG also incorporated the right of access to public information by individuals who wish to do so. In relation to the pharmaceutical sector, two pieces of information have been of greatest interest to third parties who have submitted requests for access to public information. On the one hand, the ex-factory price and the financing conditions of medicinal products established by the Ministry of Health when including them in the pharmaceutical provision of the National Health System (NHS); and, on the other hand, the unit prices for the purchase of medicinal products by public hospitals.

Throughout these 8 years, both the Ministry of Health, the Council of Transparency and Good Governance (CTBG) and the Spanish Courts have maintained an erratic position on this issue. Without prejudice to the fact that this debate is by no means closed, this article seeks to reach some conclusions on this issue in the light of the latest case law and administrative developments.

First of all, the Ministry of Health seems to have adopted a clear position on the matter, being against providing the ex-factory price of medicinal products in order to defend the public interest. This can be seen in the "*Report on the guarantee of confidentiality in the procedure for negotiating the prices for the financing of medicines*" prepared by the Directorate General of Pharmacy at the Ministry of Health and presented by the State Attorney in a legal proceeding. The Directorate General of Pharmacy used two arguments in this report to defend the need to maintain a certain degree of confidentiality regarding the price of medicinal products and to protect the secrecy of the information provided by pharmaceutical companies during the procedure to include a medicinal product in the pharmaceutical provision of the NHS.

On the one hand, the Directorate General of Pharmacy argued that the determination of the price of a medicinal product in the context of the pharmaceutical provision of the NHS involves an exercise of weighing the manufacturing costs, the company's profit margin and the therapeutic usefulness of the product. All these data, according to the Directorate General of Pharmacy, are privileged data, the publication of which could seriously affect the ability of companies to compete with each other. On the other hand, the Directorate General of Pharmacy defends the need to maintain certain levels of confidentiality in relation to the price of medicinal products because this is beneficial in terms of protecting public interests, given that confidentiality makes it possible to obtain optimal economic conditions, even better than those obtained in other countries.

The Administrative Chamber of the National High Court, in which this report was presented, ratified the position of the Ministry of Health and endorsed not providing the breakdown of medicinal products that made up the hospital pharmaceutical expenditure for 2018, including the number of units and their acquisition price.

This position of defending public interests seems to be in line with the position maintained by the European Commission in relation to the unit price of COVID-19 vaccines that were purchased centrally by the Mem-

(...) the European Commission justified that *"[T]his is in order to protect sensitive negotiations as well as business related information, such as financial information and development and production plans. Disclosing sensitive business information would also undermine the tendering process and have potentially far-reaching consequences for the ability of the Commission to carry out its tasks as set out in the legal instruments that form the basis of the negotiations".*

ber States. In this regard, the European Commission defended the confidentiality of the contracts, and of the unit price of the vaccines, on the grounds that the contracts are protected for confidentiality reasons "*which is justified by the highly competitive nature of this global market*". In this regard, the European Commission justified that "*[T]his is in order to protect sensitive negotiations as well as business related information, such as financial information and development and production plans. Disclosing sensitive business information would also undermine the tendering process and have potentially far-reaching consequences for the ability of the Commission to carry out its tasks as set out in the legal instruments that form the basis of the negotiations. All companies require that such sensitive business information remains confidential between the signatories of the contract. The Commission therefore has to respect the contracts it concludes with the companies.*".

Finally, this article also mentioned the Judgement N°. 68/2021, of 18 March, of the Constitutional Court, which resolved an appeal of unconstitutionality filed by the Government of Aragón against some articles of the Law on Public Sector Contracts (LCSP). Among others, the appellant considered that the second and third paragraphs of Article 154.7 LCSP violated the constitutional doctrine on the limits that basic legislation can regulate with respect to a matter.

Article 154.7 LCSP establishes that:

> "*Certain data relating to the conclusion of the contract may not be published when it is considered, with due justification in the file, that the disclosure of this information may (...) be contrary to the public interest or harm legitimate commercial interests of public or private companies or fair competition between them (...)*" (first paragraph). In its second paragraph, it states that "*prior*

to the decision not to publish certain data relating to the conclusion of the contract, the contracting bodies shall request the issuance of a report by the Council of Transparency and Good Governance referred to in Law 19/2013, of 9 December, on transparency, access to public information and good governance, which shall assess whether or not the right of access to public information prevails over the assets that are intended to be safeguarded by its non-publication, which shall be issued within a maximum period of ten days" and "*Notwithstanding the above, this report shall not be required by the Council of Transparency and Good Governance in the event that the contracting body has previously consulted on an identical or similar matter, without prejudice to the due justification for its exclusion from the file under the terms established in this section*" (third paragraph).

The Constitutional Court declared the second and third paragraphs of art. 154.7 LCSP to be contrary to the constitutional order of competences, given that the requirement that the report be requested from the CTBG is considered to be a detailed provision, which exhausts any possibility of regulation by the Spanish Autonomous Regions. However, the Court clarified that this declaration does not entail their nullity, given that they are applied at the state level without this having been the subject of controversy in the proceedings that gave rise to the ruling.

As stated in the article, the importance of this Judgement lies in the fact that it can be concluded that the regional contracting bodies are not obliged to request this report when they receive a request for non-publication of certain data relating to the conclusion of the contract. It is necessary to remember that the Government of Aragón did not appeal the first paragraph of Article 154.7 LCSP; that is, the paragraph that states that certain data may not be published when their disclosure could be detrimental to the commercial interests of the companies. As the following two paragraphs were annulled, it can be understood that this decision to make transparent, or not, is left to the discretion of the contracting bodies, without the need to resort to the regional bodies responsible for ensuring the transparency of the actions of the public administrations, as they are not legally empowered to do so.

Due to its proximity, since the publication of this article at the end of 2021, there have been no significant developments in the area of medicinal products price transparency. However, there are bound to be future developments affecting this issue. It will be very interesting to see, for example, if the Supreme Court has the opportunity to rule on the confidentiality of the ex-factory price of medicinal products and whether this is covered by article 97 of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. It will also be interesting to see how the regional contracting bodies apply the aforementioned Constitutional Court Judgement.

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NEW DEVELOPMENTS IN RELATION TO THE TRANSPARENCY OF THE PRICE OF MEDICINAL PRODUCTS

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RESUMEN: El presente artículo tiene como objetivo aportar algunas reflexiones sobre las últimas novedades en materia de transparencia del precio de los medicamentos de uso humano.
Este artículo analiza un informe del Ministerio de Sanidad que defiende mantener cierta confidencialidad en el precio de los medicamentos, así como la posición de la Comisión Europea respecto el precio de las vacunas contra el COVID-19. Por último, se analiza la sentencia del Tribunal Constitucional que declara inconstitucionales algunos preceptos de la Ley de Contratos del Sector Público.

PALABRAS CLAVE: Ley de Transparencia; Acceso a la Información Pública y Buen Gobierno; precio; financiación pública; confidencialidad; acceso a la información; Consejo de Transparencia y Buen Gobierno.

ABSTRACT: The purpose of this article is to provide some analysis on the latest developments in the area of price transparency of medicines for human use. This article analyses a report issued by the Ministry of Health that defends maintaining a certain degree of confidentiality in the price of medicines, as well as the European Commission's position on the price of vaccines against Covid-19. Finally, it analyses the ruling of the Constitutional Court declaring unconstitutional some precepts of the Public Sector Contracts Law.

KEYWORDS: Law on Transparency; Access to Public Information and Good Governance; price; reimbursement; confidentiality; access to information; Council of Transparency and Good Governance.

1. INTRODUCTION

The transparency of the price of medicinal products for hospital use is a highly relevant issue. The cost of the pharmaceutical provision of the National Health System (NHS), the confidentiality of the information that companies provide in the process that they must follow in order to have the maximum industrial price of their products approved, or the regulations that promote greater transparency in the actions of the Administration, are some of the factors that converge and that can sometimes reveal the existence of contradictory interests.

In recent years, Fundación CEFI has made a major effort to address the impact on the pharmaceutical sector of the entry into force and application of Law 19/2013, of December 9, 2013, on Transparency, Access to Public Information and Good Governance (LTAIBG).

In number 66 of this same publication, Alberto Dorrego[1] gave a very good presentation on the problems that the LTAIBG and Law 9/2017, of November 8, on Public Sector Contracts (LCSP) have generated around the confidentiality of the price of medicinal products, both in the context of administrative procedures for setting the price of financing, and in the context of negotiated procedures for the public purchase of innovative medicinal products protected by intellectual property rights.

Subsequently, in number 68 of the same publication, Jordi Faus, Mercè Maresma and Laura Marquès[2] argued that the rules governing medicinal products prices and antitrust law allow us to question how the rules on transparency should be applied, and that the objectives pursued by administrative decisions on setting the maximum price of a medicinal product transparent can be achieved without the need for pharmaceutical companies to waive the confidentiality of certain information.

Also, in number 72 of this publication, Pablo García Vázquez and Irene Moreno-Tapia Rivas[3], commented on Resolution Nº. 92/2019, of 19 December 2019, of the Basque Commission for Access to Public Information (CVAIP). This Resolution aroused particular interest as it was one of the first pronouncements on requests for access to the purchase price of medicinal products in the framework of public hospital tendering. The CVAIP decided to refuse access to the unit price per complete treatment of a medicinal product as well as to the number of treatments foreseen in the published tender. The CVAIP based its decision on the harm that disclosure of this information would cause, as it could affect the pricing policy followed by the bidding pharmaceutical company before other public Administrations.

This article aims to reflect on a number of new developments that have emerged in the last year in relation to the confidentiality or transparency of medicinal product prices.

We refer, firstly, to the Judgement of 30 March 2021 of the Administrative Chamber of the National High Court, which resolves an appeal filed against a Judgement of the Central Administrative Court number 6. The appealed Judgement confirmed a Resolution of the Council of Transparency and Good Governance (CTBG) that ordered the Ministry of Health to provide the interested party with the "*breakdown of the medicinal products that make up the hospital pharmaceutical expenditure corresponding to 2018, including information on the active ingredient, brand name, number of units, acquisition price and laboratory that markets, for each of the Autonomous Communities and other Public Administrations in an editable format (excel or scv)*". The Administrative Chamber of the National High Court overturns this Judgement, and in doing so relies on a report by the Directorate General of Pharmacy at the Ministry of Health that justifies the need to maintain the confidentiality of the price of

The Administrative Chamber of the National High Court overturns this Judgement, and in doing so relies on a report by the Directorate General of Pharmacy at the Ministry of Health that justifies the need to maintain the confidentiality of the price of medicinal products, a report that we will also discuss in this article.

medicinal products, a report that we will also discuss in this article.

Secondly, it seems relevant to comment briefly on the confidentiality policy that the European Commission has adopted in relation to the price of COVID-19 vaccines. Despite the advances in transparency that the European Commission has made with the publication of contracts and advance purchase agreements, information such as the price paid for them has remained confidential. In this article we will analyse the justification that the European Commission has used in this regard and what lessons can be learned from this justification.

Finally, we will comment on Judgement Nº. 68/2021, of 18 March, of the Constitutional Court, which resolves an appeal of unconstitutionality presented by the Government of Aragón against some articles of the LCSP. Among other contested precepts, the Government of Aragón considered that the second and third paragraphs of Article 154.7 LCSP violated the constitutional doctrine on the limits that basic legislation can regulate with respect to a matter. As will be developed

Despite the advances in transparency that the European Commission has made with the publication of contracts and advance purchase agreements, information such as the price paid for them has remained confidential.

below, Article 154.7 LCSP establishes that the contracting body, with justification and after a report from the CTBG, may decide not to publish certain data relating to a contract when its disclosure would be contrary to the public interest or could harm the commercial interests of the companies. The Constitutional Court has upheld the appeal by the Government of Aragón, declaring these precepts contrary to the constitutional order of competences as they are not of a basic nature, leaving the application of this article at the regional level in an uncertain situation. We will expand on this point and its practical consequences throughout this article.

2. IMPACT OF THE LTAIBG ON PRICE TRANSPARENCY FOR MEDICINAL PRODUCTS AND THE CURRENT SITUATION

2.1. The position of the Ministry of Health and progress in transparency

As established in Article 17.1 LTAIBG, the procedure for exercising the right of access to public information begins with the submission of a request addressed to the head of the administrative body or entity that holds such information. Once the request reaches the administrative body that must decide on it, the latter must first analyse whether the grounds for refusal set out in Article 18.1 LTAIBG apply. The rule states that requests shall be inadmissible if: (i) they refer to information in the process of preparation or general publication; (ii) those referring to auxiliary or support information; (iii) those relating to information whose disclosure requires prior redrafting; (iv) those addressed to a body that does not hold the information when the competent body is unknown; and (v) those that are manifestly repetitive or abusive in nature that is not justified by aim of transparency pursued by the LTAIBG.

Having ruled out the application of the aforementioned grounds for inadmissibility, the Administration must analyse the merits of the matter. Public information may comprise content or documents in the possession of the Administration that have been prepared or acquired in the exercise of its functions. In such cases, disclosure of such public information may affect the rights or interests of third parties. In conducting this substantive analysis, the Administration is obliged to allow third parties whose interests or rights may be affected by the request to participate in the process.

Once this interested third party has made its allegations, the Administration must decide to grant or deny access to the requested information by applying the criteria established in Articles 14 and 15 LTAIBG.

Article 14.1 provides that the right of access to public information may be limited where access to the information would harm, among other things, commercial and economic interests (14.1.h), professional secrecy and intellectual and industrial property (14.1.j), the guarantee of confidentiality or the secrecy required in decision-making processes (14.1.k). The application of these limits, however, must be duly justified and proportionate to their object and purpose of protection, and must take into account the specific circumstances of each case, especially the concurrence of an overriding public or private interest that justifies access to the requested information. Article 15 LTAIBG, for its part, establishes the guarantees related to the protection of personal data in requests for access to public information.

As Alberto Dorrego points out in his aforementioned article, after the entry into force of the LTAIBG, the Ministry of Health reacted to requests for information related to the price of medicinal products with a certain disdain, without taking care to build a solid argumentation about the need to maintain

certain levels of confidentiality in the process of adopting decisions on public funding and medicinal products pricing.

It was not until August 2019 that the Ministry of Health began to show a more solid legal reasoning[4] about the need to maintain a certain degree of confidentiality in matters related to the financing conditions of medicinal products. Thus, in response to a request for access to information requesting access to the price and reimbursement resolution for the medicinal product Hymiroz®, the Ministry of Health argued that the granting of this information should be limited because it would violate the economic and commercial interests of the pharmaceutical company offering the medicinal product to the NHS, as well as professional secrecy and intellectual and industrial property. Despite not granting the copy of the resolution on the financing and price of Hymiroz®, the Ministry of Health did grant partial access to the information requested, informing the notified price of the medicinal product in question.

Subsequently, and despite maintaining an erratic stance on some occasions, the Ministry of Health has maintained a similar reasoning in the face of similar requests for access to information[5].

2.2. The National High Court Judgement and the Directorate General of Pharmacy report, a first step towards the application of one of the legal limits foreseen for requests for access to public information?

A recent Judgement by the Administrative Chamber of the National High Court has shed some light on whether the Ministry of Health must provide the price of medicinal products when these are requested via the LTAIBG. In this case, the Judgement deals with the request that a citizen made to the Ministry requesting the "*breakdown of the medicinal products that make up the hospital pharmaceutical expenditure for 2018, including information on the active ingredient, brand name, number of units, purchase price and the laboratory that markets them, for each of the Autonomous Communities and other Public Administrations in an editable format (excel or scv)*".

In response to this request, the Ministry of Health denied access to the requested information, citing the application of the limit provided for in Article 14.1.k) LTAIBG, namely "*the guarantee of confidentiality or secrecy required in decisionmaking processes*". What the Ministry of Health did provide was a link to its website where data on the consumption of medicinal products in the hospital setting can be consulted, data which are published on a monthly basis.

In response, the interested party filed a complaint with the CTBG. In its decision, the CTBG urged the Ministry of Health to provide the rest of the information requested, considering that the limit invoked did not apply. According to the CTBG, the information requested fell within the concept of "*public information*" and this concept should be interpreted broadly.

The Ministry of Health appealed the decision by the CTBG before the administrative jurisdiction. The Central Administrative Court number 6, at first instance, dismissed the appeal. The State Attorney's Office lodged an appeal, alleging, among other arguments, that the appealed judgment erred in the assessment of the evidence with respect to the concurrence of the limit provided for in Article 14.1.k) LTAIBG. The Ministry of Health understood that the confidentiality of the price of medicinal products is recognised ex lege, and that this confidentiality had been accredited with the submission of a report prepared by the Directorate General of Pharmacy.

In its Judgement, the Chamber upheld the position maintained by the Ministry of Health

based on the idea that providing the requested information would entail evident, real and effective harm to the economic and commercial interests of the pharmaceutical companies. In its analysis of the issue, the Court took into consideration the report issued by the Directorate General of Pharmacy, and presented by the Solicitor General's Office, in which it argued that, in the procedure for setting the price of medicinal products, it is essential to keep the information available to each party confidential; information that should not be revealed in order to protect the public interest, which consists, in essence, of obtaining the best possible price when including the medicinal product in the public pharmaceutical provision in Spain.

At the time, after reading this Judgement, the authors of this article considered it important to know the content of this report, and we decided to request a copy of it, exercising our right of access to public information in application of the provisions of the LTAIBG. In response to this request, the Ministry of Health provided us with a document entitled "*Report on the guarantee of confidentiality in the procedure for negotiating medicinal products financing prices*" prepared by the Directorate General of Pharmacy, which the Solicitor General's Office had submitted to the legal proceedings in which the aforementioned Judgment was handed down.

This document details that the report had been drawn up at the request of the Solicitor General's Office, which wished to know in detail "*the procedure for negotiating the prices for financing medicinal products in order to justify the application of the limit of article 14.1.k) LTAIBG*". In response to this request, the Directorate General of Pharmacy considered it necessary to make a brief excursus on the prices of medicinal products and their projection in the European geopolitical environment.

The Directorate General of Pharmacy uses two arguments in its report to defend the need to maintain a certain confidentiality of the price of medicinal products and to protect the secrecy of the information provided by pharmaceutical companies during the procedure for the inclusion of a medicine in the pharmaceutical provision of the NHS.

(...) in the procedure for setting the price of medicinal products, it is essential to keep the information available to each party confidential; information that should not be revealed in order to protect the public interest, which consists, in essence, of obtaining the best possible price when including the medicinal product in the public pharmaceutical provision in Spain.

First, the Directorate General of Pharmacy argues that the determination of the price of a medicinal product in the context of the pharmaceutical provision of the SNS involves an exercise of weighing the manufacturing costs, the company's profit margin and the therapeutic usefulness of the product. All these data, according to the Directorate General of Pharmacy, are proprietary data, the publication of which could seriously affect the ability of companies to compete with each other. This information contains, among others, data relating to product, supply and transformation costs (raw materials, labour costs, licences, etc.); commercial costs (such as personnel or transport issues); information relating to sales forecasts, market shares, economic analysis and pharmacological costs; "*information which is all covered by professional secrecy; information, as can be seen, whose disclosure could seriously affect the economic and commercial interests of the companies concerned*".

This information, as the Ministry of Health itself points out, benefits from a special confidential regime under article 97.3 of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices.

Secondly, the Directorate General of Pharmacy defends the need to maintain certain levels of confidentiality in relation to the price of medicinal products because this achieves benefits in terms of the protection of public interests, given that confidentiality makes it possible to achieve optimal economic conditions, even better than those obtained by other countries.

In the words of the Ministry of Health itself, "*EU countries use the prices financed in other Member States, when they are made public, to achieve price reductions in their public systems. This creates a situation where Marketing Authorisation Holders for a particular medicine are not willing to make concessions (price reductions) in a given country*

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(e.g., in countries with a less prosperous economic situation) if the prices in that country are made public, as this would force them to apply the same advantages in countries with better economic situations.

As a result, many countries –*includ ing Spain*– *avoid publishing these prices as a measure to protect national interests, since only by maintaining the secrecy of these prices can they ensure that they obtain better conditions. In other words, giving third parties access to the prices at which medicinal products are financed in Spain would mean a loss of credibility for our Administration, and would entail a negotiating disadvantage when it comes to obtaining more competitive prices (which could be achieved taking into account our more disadvantaged economic-financial situation than other neighbouring countries, due to our high public deficit and lower per capita income). Consider that neighbouring countries (UK and France), take great care not to reveal the advantages they obtain in their medicinal products financing negotiations, in the knowledge that this allows them to obtain greater savings compared to countries that do not guarantee the confidentiality of negotiations*".

The Directorate General of Pharmacy concludes by arguing that "*it is contrary to Spain's interests to make available to other Member States information that would help them in their price negotiations in their respective countries, but which would be detrimental to obtaining savings in Spain.*"

All this, but especially this last statement, leads us to ask the following question: can access to information on the price of medicinal products be denied on the grounds that such access may be detrimental to the economic policy of the State?

According to the Directorate General of Pharmacy report, the answer seems obvious and

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can only be in the affirmative. It seems reasonable that the Ministry of Health, when faced with a request for access to information on the price of a medicine, should invoke the application of the limit of article 14.1.i) LTAIBG. This precept indicates that the right of access may be limited when accessing the information would be detrimental to the State's economic and monetary policy. The same argument could be used by any pharmaceutical company when making allegations in response to a request for information on the publicly funded unit prices of its products.

Of the 1,386 refusals issued by the General State Administration as a whole since the entry into force of the LTAIBG, and which can

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be consulted on the transparency portal of the General State Administration[6], in only 9 of them has the limit of article 14.1.i) LTAIBG been invoked as a reason for refusing the requested information. Moreover, in all of them, this limit has been used as an accessory to other limits, without using very elaborate argu ments in this regard. We are, therefore, faced with the limit least invoked by the General State Administration.

With regard to the jurisprudence of the courts on the application of this limit, we are not aware of any judgement in which it has been analysed in depth.

Why do we think we can raise the possibility of invoking this limit? According to data published by the Ministry of Treasury on its website[7], the hospital pharmaceutical expenditure on medicinal products and medical devices, added to expenditure on medicinal products and medical devices dispensed by prescription and dispensing order, reached almost €20 billion in 2020 for all Public Administrations. In view of the magnitude of this figure, and considering the arguments

set out in the Directorate General of Pharmacy report, the application of the limit in Article 14.1.i makes perfect sense.

The LTAIBG establishes that the application of the limits of article 14.1 must be justified and proportionate to its object and purpose of protection, and take into account the circumstances of the specific case, especially the concurrence of an overriding public or private interest that justifies access, and it is notorious that case law has interpreted this precept in a restrictive manner, such that the application of the same must be exceptional.

However, this exceptionality in the application of the limits of Article 14.1 LTAIBG should not prevent them from being applied when the circumstances provided for in the law are met.

In the specific case of advertising the price of medicinal products, and in view of the impact it could have on the State's economic policy, the public interest in providing this information clashes with the public interest in ensuring that the medicinal products financed by the NHS can be acquired under the best possible conditions, which is in line with the objectives of sustainability of the public health system that must prevail in the context of this debate.

3. THE CONFIDENTIALITY OF THE PRICE OF COVID-19 VACCINES AND THE ARGUMENTS USED BY THE EUROPEAN COMMISSION

This is precisely what has happened in the European Union with regard to the purchase price of COVID-19 vaccines, the confidentiality of which has been defended by the European Commission precisely on the grounds that the public interest that should prevail is not indiscriminate transparency, but that the

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purchase of vaccines could be made under the best possible conditions.

As is known, last June 2020, the European Commission issued a Decision[8] approving the agreement with Member States for the joint purchase, on behalf of all Member States, of COVID-19 vaccines. This Decision has its legal basis in Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency assistance in the Union.

Regulation (EU) 2016/369 sets out various methods of emergency assistance by the European Union in the event of natural or man-made disasters, including "*contracting by the Commission, on behalf of Member States, based on an agreement between the Commission and the Member States*".

The joint purchase of COVID-19 vaccines was formulated through Advance Purchase Agreements (APAs) with potential producers of COVID-19 vaccines, whereby the European Commission secured a number of doses which, once authorised and produced, were to be distributed proportionally among the Member States. Subsequently, on the basis of these APAs, the European Commission negotiated with the vaccine producers the Purchase Agreements (PAs) for the vaccines.

Initially, the European Commission decided not to publish neither the APAs nor the PAs. However, following delays in the delivery of the agreed doses of one of the vaccines, the European Commission decided to "*make transparent*" the purchase contract for these specific vaccines. Note that we have put the word *"transparent"* in quotation marks; this is because a relevant part of this contract was censored and its content is no longer accessible. Among the censored information is the price and economic conditions of the contract.

Subsequently, the European Commission has published most of the vaccine sales contracts that have been finalised with other pharmaceutical companies, as well as Advance Purchase agreements. While all of these contracts have their specificities, the published version of all of them have one thing in common: the section on the unit cost of the vaccines and their financing conditions are censored. The European Commission's argumentation[9] for the need to maintain this confidentiality is as follows:

> "*Contracts are protected for confidentiality reasons, which is warranted by the highly competitive nature of this global market. This is in order to protect sensitive negotiations as well as business related information, such as financial information and development and production plans.*
>
> *Disclosing sensitive business information would also undermine the tendering process and have potentially far-reaching consequences for the ability of the Commission to carry out its tasks as set out in the legal instruments that form the basis of the negotiations. All companies require that such sensitive business information remains confidential between the signatories of the contract. The Commission therefore has to respect the contracts it concludes with the companies.*"

This has undoubtedly been a contentious issue that has generated numerous reactions from various sectors of society. Several Members of the European Parliament (MEP) have submitted written questions to the European Commission on the lack of transparency of the European Commission on contracts and their economic conditions.

In recent months, MEPs have submitted more than 14 written questions to the European Commission on the lack of transparency in contracts with pharmaceutical companies[10]. The European Commission has responded on the basis of the same arguments it had

already used on its website: "*the law protects the commercial interests of companies. Non-disclosure clauses are a standard feature of purchasing agreements. They protect the legitimate interests of companies, which have invested heavily in research and production capacity. There are also rules that protect the bidding process. Disclosure of sensitive business information would weaken the EU's position in ongoing negotiations, thereby undermining the beneficial effects of fair competition and the effectiveness of the single procurement process which has led to the best deal for Member States and citizens*".

The CTBG has also ruled on the confidentiality of the APAs in two resolutions[11] that sought to elucidate whether or not the Ministry of Health's refusal to provide a copy of the contracts with the pharmaceutical companies for the acquisition of the COVID-19 vaccines was in accordance with the law.

In both cases, the Ministry of Health had refused to grant the information on the grounds that the APAs are governed by Community legislation on the transparency of the European Commission's activity, which establishes a specific regime for access to information. The LTAIBG establishes, in its first additional provision, that those matters that have a specific legal regime for access to information shall be governed by their specific regulations. On the basis of this first additional provision, the Ministry of Health considered that access to this information should be denied because it should be requested from the European Commission, following the specific procedure established.

The CTBG accepts and shares this argumentation. Specifically, the CTBG takes into account that the APAs were signed by the European Commission and the pharmaceutical companies to include the clauses on the development, production, priority purchase option and supply of the different vaccines with

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the potential to be authorised for immunisation against COVID-19. For this reason, the CTBG considers that the APAs are not a document that is necessarily in the possession of the Spanish Administration, as required by article 13 LTAIBG. Bearing in mind that the European Commission is not a subject included in the scope of application of the LTAIBG, the CTBG dismisses the complaints filed against the Ministry of Health's refusal to provide the requested information.

The arguments used by the European Commission to defend the confidentiality of the price of the COVID-19 vaccines are reasonable and can be perfectly linked to what we have stated regarding the application of the limits of article 14.1 LTAIBG. In short, these are arguments that can be viewed positively from the standpoint of protecting the public interest. If, as in this case, a choice must be made between transparency or access to medicinal products under the best possible conditions, both public interests being worthy of protection, there is no doubt that the latter should prevail.

4. TRANSPARENCY IN PUBLIC PROCUREMENT PROCEDURES FOR MEDICINAL PRODUCTS: ARTICLE 154.7 LCSP AND THE JUDGEMENT OF THE CONSTITUTIONAL COURT

As Alberto Dorrego reasoned in his aforementioned article, the transparency of the award prices of medicinal product supply contracts (i.e. the unit public procurement price) is of great concern to the pharmaceutical industry.

Article 154 of the LCSP sets out the requirements that contract formalisation notices must meet. Among its provisions, the seventh paragraph establishes that "*Certain information relating to the conclusion of the contract may not be published when it is considered, with due justification in the file, that the disclosure of this information may (...) be contrary to the public interest or harm legitimate commercial interests of public or private companies or fair competition between them (...)*" (first paragraph). In its second paragraph, it states that "*prior to the decision not to publish certain data relating to the conclusion of the contract, the contracting bodies shall request the issuance of a report by the Council for Transparency and Good Governance referred to in Law 19/2013, of 9 December, on transparency, access to public information and good governance, which shall assess whether or not the*

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right of access to public information prevails over the assets that are intended to be safeguarded by its non-publication, which shall be issued within a maximum period of ten days" and "*Notwithstanding the above, said report shall not be required by the Council for Transparency and Good Governance in the event that the contracting body has previously consulted on an identical or similar matter, without prejudice to the due justification for its exclusion from the file in the terms established in this section.*" (third paragraph).

Alberto Dorrego raised some interesting questions regarding the practical applicability of the precept. The first referred to the applicability of this precept at the regional level, stating that "*it is not easy to know whether or not the reference to the CTBG extends to the similar transparency bodies of the Autonomous Regions, since here we are dealing with an atypical function of the CTBG, not regulated in the LTAIBG*".

Well, this first question has been partially clarified in Judgement N°. 68/2021, of 18 March, of the Constitutional Court, which resolves the appeal of unconstitutionality filed by the Government of Aragón against various precepts of the LCSP.

As we mentioned in the introduction to this article, the second and third paragraphs of Article 154.7 LCSP were challenged, as the Government of Aragón considered that they violated the constitutional doctrine on the limits that the basic legislation of a matter can regulate.

Article 149.1.18 of the Spanish Constitution grants exclusive powers to the State Government in matters of basic legislation on contracts. The doctrine of the Constitutional Court in relation to this question establishes that basic legislation must allow the Autonomous Regions to develop it through their own legislative options, so that the "*basic*" does not completely exhaust the matter; something which happens when a regulation is excessively detailed or meticulous. In accordance with the doctrine established by the Constitutional Court, those detailed or procedural precepts that could be substituted by other complementary or detailed regulations elaborated by the Devolved Regions with powers to do so cannot be considered as "*basic*".

The Constitutional Court ruled that the report referred to in the second paragraph of Article 154.7 LCSP is articulated as "*an instrument to reinforce the transparency of public activity in matters of contracting, and to guarantee the right of access to information relating to this contractual activity*"; a report of a mandatory nature, prior to the decision adopted by the contracting body and, very importantly, non-binding. From this point of view, according to the Constitutional Court, there would be no objection to describing it as "*basic*". However, the fact that the report is required to be submitted to the CTBG is considered to be a detailed provision, which exhausts any possibility of self-regulation by the Autonomous Regions. This is because the CTBG is configured as an independent body that exercises its powers in relation to the General State Administration, unless by agreement the exercise of its functions is extended to the Autonomous Regions. Consequently, this obligation to refer to the CTBG goes beyond the consideration of "*basic*" legislation.

In accordance with this reasoning, and because they are not of a basic nature, the Constitutional Court declares the second and third paragraphs of Article 154.7 LCSP to be contrary to the constitutional order of competences. However, the Court clarifies that this declaration does not entail their nullity, given that they are applied at the state level without this having been the subject of controversy in the proceedings that gave rise to the Judgement.

So far, the use of the power established in article 154.7 LCSP by contracting bodies has been minimal. At the request of the authors of this article, the CTBG has reported[12] that, during 2018, 2019, 2020 and 2021, it has only issued a single report under article 154.7 LCSP. This report declared the prevalence of the right to public information over the reservation of contractual advertising, expressly admitting that the contracting body may exclude from publication the "*name, address, telephone and fax number and email and internet address of the selected bidder, provided that it is duly assessed and justified that the disclosure of this information could harm the legitimate commercial interest of the company awarded the contract*", an issue that, in view of the information provided by the contracting body, could not be directly assessed by the CTBG.

Many of the Autonomous Regions have their own bodies responsible for overseeing the application of the principle of transparency in their respective communities. These bodies publish on their websites the resolutions and reports they issue under their respective competences. Some of these bodies have issued reports under article 154.7 LCSP, when requested to do so by a contracting body of their Autonomous Regions.

Although we have not been able to have access to a large number of reports issued under Article 154.7 LCSP (we do not know if this is because they have not been issued or because they are not published), we do know that some have been issued.

An interesting question arises here that merits comment.

As we have seen, the LCSP assigns to the CTBG the issuing of the reports related to Article 154.7 LCSP. This provision has been annulled by the Constitutional Court when its application is to be made by a regional contracting body. At this point, we must ask ourselves whether the regional contracting bodies, when they receive a petition requesting the non-publication of certain data relating to the conclusion of a contract, because they consider that the disclosure of this information may harm the commercial interests of the companies, should request some kind of report and from whom they should request it.

To answer this question, we believe that first of all, the regional regulations should be reviewed to see if any of the rules governing the regional bodies responsible for ensuring the transparency of the actions of the regional public administrations include this power. If not, and bearing in mind that the Constitutional Court has annulled the paragraphs that entrusted the report to the CTBG, we understand that it would not be necessary to obtain

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this report in order to decide whether or not to publish any information on public contracts.

In relation to this question, to date, none of the autonomous regional transparency laws expressly includes the possibility of their bodies issuing the report referred to in the second paragraph of Article 154.7 LCSP. Consequently, the issuing of this report would not be legally possible under this legal alternative either.

However, and as the only exception, the most recent version of Law 4/2016, of 15 December, on Transparency and Good Governance of Castilla-La Mancha[13], in its article 63.1.e) includes as a function of the Regional Council for Transparency and Good Governance (CRTBG-CLM) and its Presidency "*to respond to the queries that, on an optional basis, are submitted to it in matters of transparency and good governance*". We understand that the contracting bodies of Castilla-La Mancha, in case of doubt, could consult the CRTBG-CLM on the appropriateness of omitting or publicising certain information in a formalisation notice. In any case, as the law itself indicates, this report would only be an optional opinion.

The Constitutional Court's Judgement also clarifies another of the questions that Dorrego raised in his article: whether or not the reports issued by the CTBG are binding for contracting bodies. In this sense, and despite the fact that it was not the subject of the appeal lodged by the Government of Aragón, the Constitutional Court's Judgement is clear and leaves no room for doubt, adding that *"the report, as is clear from the state regulation, is mandatory and is prior to the decision adopted by the contracting body, but is not binding"*.

We can therefore conclude that the regional contracting bodies are not obliged to request this report. It is necessary to remember that the Government of Aragón did not appeal the first paragraph of Article 154.7 LCSP; that is, the paragraph that states that certain data may not be published when their disclosure could be detrimental to the commercial interests of the companies. As the following two paragraphs have been annulled, we must understand that this decision to make transparent, or not, is left to the discretion of the contracting bodies, without the need to resort to the regional bodies responsible for ensuring the transparency of the actions of the public administrations, as they are not legally empowered to do so.

5. CONCLUSION

The two Judgments discussed in this article, together with the Directorate General of Pharmacy at the Ministry of Health report, as well as the position adopted by the European Commission in relation to the confidentiality of the price of vaccines against Covid-19 show that advertising the price of medicinal products is a complex debate due to the confrontation of interests at stake. On the one hand, greater transparency and control of the actions of the public administration is highly desirable, but on the other hand, it is inevitable that in this area the application of the limits legally provided for in the applicable regulations, whether European or national, serves to protect not only the private interests of companies, but especially the interests of public health systems in terms of obtaining the best possible conditions for the purchase of medicinal products. The case law and the Directorate General of Pharmacy at the Ministry of Health report we have discussed are very clear in this respect: thanks to the reservation of certain information related to the financing conditions of medicinal products, pharmaceutical companies are more willing to make price concessions and public health systems obtain better prices, which benefits patients access to treatment.

Based on the above, given the high economic impact that pharmaceutical provision has

on public accounts, we believe that requests for information related to the unit prices for the supply of medicinal products to Social Security management bodies or the maximum financing prices approved by the Interministerial Commission on Medicinal Product Prices could be denied on the grounds that providing access to this information would negatively affect the State's economic policy (ex. art. 14.1.i LTAIBG).

In the area of public tenders, it would also be appropriate not to make transparent the unit price paid for the supply of medicinal products. The aforementioned Constitutional Court Judgement also allows the bodies of the Autonomous Communities, when they receive a request not to publish certain information on a contract, not to be obliged to request a report from the CTBG. The regulation that included this precept is contrary to the constitutional order and its applicability has been reduced to the General State Administration.

In short, as we have seen, maintaining the confidentiality of the price of medicinal products is fully justified by the benefits it brings for public interests and there are very solid legal arguments for both the Ministry of Health and the European Commission or the contracting bodies and, where appropriate, the CTBG to continue to guarantee this confidentiality.

We believe that requests for information related to the unit prices for the supply of medicinal products to Social Security management bodies or the maximum financing prices approved by the Interministerial Commission on Medicinal Product Prices could be denied on the grounds that providing access to this in-formation would negatively affect the State's economic policy (ex. art. 14.1.i LTAIBG).

[1] Dorrego, Alberto; *"La Transparencia en la Fijación del Precio de los medicamentos y en los Contratos de Suministro Hospitalario"*, Cuadernos de Derecho Farmacéutico Núm. 66, Julio-Septiembre 2018.

[2] Faus, Jordi; Maresma, Mercè y Marquès, Laura; *"La transparencia de los precios de los medicamentos"*, Cuadernos de Derecho Farmacéutico Núm. 68, Enero-Marzo 2019.

[3] García, Pablo y Moren-Tapia, Irene; *"Resolución 92/2019, de 19 de Diciembre de 2019, de la Comisión Vas-*

ca de Acceso a la Información Pública", Cuadernos de Derecho Farmacéutico Núm. 72, Enero-Marzo 2018.

[4] Answer from the Director General of Pharmacy at the Ministry of Health of 26 August 2019 (nº 001-0324250), available in: https://www.mscbs.gob.es/servCiudadanos/transparencia/001-034250-E44GE9WGRT8SER.pdf

[5] Responses from the Director General of Pharmacy at the Ministry of Health of 28 June 2021 (file no. 001-056365) and 11 December 2019 (file no. 001-038323), available in: https://www.mscbs.gob.es/servCiudadanos/transparencia/001056365_JIO4P8RMU8FBTP.pdf

[6] https://transparencia.gob.es/transparencia/transparencia_Home/index/Derecho-de-acceso-a-la-informacion-publica/ResolucionesDenegatorias.html

[7] Available in: https://www.hacienda.gob.es/CDI/Gasto%20Sanitario/SERIE%20Gasto%20Farmac%C3%A9utico%20y%20Sanitario.xlsx

[8] Commission Decision of 18 June 2020 approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

[9] https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_2467

[10] Updated as of 14 October 2021, according to information available on the official website of the European Parliament.

[11] Resolutions of the Council of Transparency and Good Governance 160/2021 and 341/2021, of 2 July and 31 August 2021, respectively.

[12] Response of 13 July 2021 of the Council of Transparency and Good Governance (N/Ref: SI 20-2021 500-005527).

[13] Updated as of 25 June 2021. Last amendment made by Law 4/2021, 25 June, on Urgent Measures to Streamline and Simplify Procedures for the Management and Implementation of European Recovery Funds.

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INTERACTION BETWEEN THE RIGHT OF ACCESS TO PUBLIC INFORMATION AND THE RIGHTS AND INTERESTS OF THIRD PARTIES

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RESUMEN: El presente artículo tiene como objetivo aportar algunas reflexiones sobre la interacción entre el derecho de acceso a la información pública y la protección de los derechos e intereses de terceros que puedan verse afectados cuando se formula una solicitud de acceso a dicha información. Este artículo se muestra crítico con las deficiencias que presenta la Ley 19/2013 en relación con el trámite de audiencia a terceros.

PALABRAS CLAVE: Ley de Transparencia; Acceso a la Información Pública y Buen Gobierno; trámite de alegaciones; audiencia a terceros; acceso a la información; Consejo de Transparencia y Buen Gobierno.

ABSTRACT: The purpose of this article is to provide some insight on the interaction between the right to access public information and the protection of the rights and interests of third parties that may be affected when a request for access to information is made. This article has a critical view of how Law 19/2013 deals with the right of third parties to be heard in these proceedings.

KEYWORDS: Law on Transparency; Access to Public Information and Good Governance; pleading proceeding; hearings; access to information; Council of Transparency and Good Governance.

1. INTRODUCTION

On 9 December 2020, 7 years have passed since the publication in the Official State Gazette of Law 19/2013, on Transparency, Access to Public Information and Good Governance (hereinafter, the "LTAIBG").

The entry into force of the LTAIBG was, as stated in its preamble, an important step forward in terms of transparency, establishing standards comparable to those of other consolidated democracies. However, the passage of time and its effective application have revealed some inadequacies.

As we will see in this article, one of these inadequacies is related to cases in which, in the event of a request for access to public information, there are rights and interests of third parties that may be affected. The LTAIBG incorporates mechanisms for the participation of these third parties, but if the Administration omits the hearing process and prevents them from intervening in the procedure in its initial stages, before deciding whether or not to grant access to the requested information, the process is flawed from the outset, and remedying this infringement of rights ex-post presents certain difficulties.

The purpose of this article is to provide some reflections on the inadequacies we have detected in the application of the LTAIBG in relation to the hearing process for third parties whose legitimate rights and interests may be affected if the Administration agrees to provide information and/or documentation belonging to them without allowing them to intervene before taking this decision.

2. THE PROCEDURE FOR ACCESS TO PUBLIC INFORMATION

2.1. The request for access to the Administration

As established in Article 17.1 LTAIBG, the procedure for exercising the right of access to public information begins with the submission of a request addressed to the head of the administrative body or entity that holds it. It should be recalled that public information is understood to be the contents or documents, whatever their format or media, held by the Administration and which have been produced or acquired in the exercise of its functions. The applicant is in no case obliged to justify his request for access to information; however, the applicant may state the reasons for his request, which may be taken into account when the resolution is issued.

Once the request for information reaches the administrative body that must decide on it, the latter must first analyse whether the grounds for refusal provided for in Article 18.1 LTAIBG apply. The rule states that shall be inadmissible those requests referring to information in the process of preparation or general publication, those referring to auxiliary or support information, those relating to information whose disclosure requires prior redrafting, those addressed to a body that does not hold the information when the competent body is unknown, and those that are manifestly repetitive or abusive in nature not justified by aim of transparency pursued by the LTAIBG.

Having ruled out the application of the aforementioned grounds for inadmissibility, the Administration must analyse the merits of the case. On the basis that public informa-

tion comprises content or documents in the possession of the Administration that have been prepared or acquired in the exercise of its functions, it is quite possible that disclosing such public information may affect the rights or interests of third parties. In conducting this substantive analysis, the Administration is obliged to allow third parties whose interests or rights may be affected by the request to participate in the process. To this end, Article 19.3 LTAIBG establishes that "*if the information requested could affect the rights or interests of third parties, duly identified, they shall be granted a period of fifteen days so that they may make the allegations they deem appropriate (...)*".

Once this interested third party has made its allegations, the Administration must decide whether to grant or deny access by applying the criteria established in articles 14 and 15 LTAIBG. The resolution granting or denying access must be notified to the applicant and to the affected third parties who have previously requested it.

Article 22 LTAIBG establishes the deadlines for the enforcement of the resolution granting access to public information, differentiating between those cases in which there has been opposition from a third party, and those cases in which there has been no such opposition. Where there has been no opposition, access shall be granted at the same time as notification of the resolution or within a period not exceeding ten days. On the other hand, if there has been opposition, access will only be granted when the deadline for lodging a administrative appeal has elapsed without it having been formalised or when it has been resolved confirming the right to receive the information. On this point, the LTAIBG establishes a notoriously protective system, since unlike what happens generally under Article 117 of Law 39/2015, on the Common Administrative Procedure of Public Administrations ("LPAC"), the filing of an administrative appeal against the resolution granting access suspends the execution of said resolution without the need for the appellant to request it as a precautionary measure; and said suspension must be maintained until the appeal has been resolved confirming the applicant's right to receive the information.

(...) the filing of an administrative appeal against the resolution granting access suspends the execution of said resolution without the need for the appellant to request it as a precautionary measure; and said suspension must be maintained until the appeal has been resolved confirming the applicant's right to receive the information.

2.2. The procedure before the Council of Transparency and Good Governance

The applicant and interested third parties who have been served with the request for in-

formation may appeal the resolution granting or refusing to provide the requested information. In the case of a resolution granting access to information, the interested third party who has objected will normally lodge an administrative appeal, which will allow him to withhold the provision of public information to the applicant until such time as a judgment is rendered. On the other hand, in the case of a resolution denying access to public information, the applicant may lodge a administrative appeal or, alternatively, file a complaint with the CTBG[1]. Within the scope of the procedure before the CTBG, Article 24.3 LTAIBG states that when the Administration has justified the denial of access to information in the protection of rights or interests of third parties, the CTBG shall summon the persons who may be affected (understood to be the same holders of the rights or interests considered by the Administration to deny access) so that they may argue to the best of their interests before the CTBG decides on the complaint.

It is at this point that the question arises as to what happens when the Administration has not identified the interested third parties. Should the CTBG carry out an investigation to find out which persons would be affected? Is it possible for the CTBG to uphold a complaint concerning a request for information that affects the rights and interests of third parties who have not been identified or heard at the previous stage before the Administration and grant access?

2.3. A system with inadequacies to be addressed

To these questions, the only answer is that the rules governing the participation of third parties in the proceedings suffer from two inadequacies.

First, they do not specify how third parties whose rights or interests may be affected by the request for access to public information should be identified. This first inadequacy may result in decisions granting access to information being taken without allowing such third parties to make allegations in this regard.

Secondly, in the case of decisions of total or partial refusal of access, without the Administration having summoned the third parties, it can happen (and in fact has happened) that the CTBG decides on the claim formulated by the applicant for information without giving the third parties a hearing.

These inadequacies are compounded by the difficulties that third parties whose rights or interests may be affected have in accessing decisions concerning public information that concerns them.

(...) in the case of decisions of total or partial refusal of access, without the Administration having summoned the third parties, it can happen (and in fact has happened) that the CTBG decides on the claim formulated by the applicant for information without giving the third parties a hearing.

In this regard, it should be noted that the interested party submitting the request for access to public information is not obliged to identify the third parties whose rights or interests may be affected by the request. On the other hand, neither the Administration receiving the request nor the CTBG in the case of a complaint is obliged to publish the receipt of such requests or complaints so that third parties whose rights or interests may be affected can be heard. Moreover, while it is praiseworthy that the General State Administration publishes all its resolutions denying information on its transparency portal2, these decisions are published every three months, by which time the CTBG may have already received the complaint and even ruled on it. As for the CTBG's resolutions, they are published on its website[3] the month after they have been adopted. It would therefore be possible for the CTBG to issue a decision upholding the complaint of a public information requester, ordering the Administration to grant access to the information, and that in compliance with that decision the Administration would provide access before the interested third party, in a review of the CTBG's decisions published on its website, became aware of the existence of the request and the CTBG's upholding of the complaint.

These inadequacies should be solved in the regulatory development of the LTAIBG. In the meantime, and in the field of public information on medicinal products for human use, some court judgements are making it possible to alleviate some of the effects derived from them thanks to the efforts of the companies affected, which have been forced to resort to the administrative jurisdiction to safeguard their legitimate interests. It should also be noted, and we will refer to this later, that some recent resolutions of the CTBG are helping to at least partially alleviate these inadequacies.

3. THE *"KYMRIAH®"* CASE

One of the cases in which the inadequacies noted above were corrected thanks to the in-

It would therefore be possible for the CTBG to issue a decision up-holding the complaint of a public information requester, ordering the Administration to grant access to the information, and that in compliance with that decision the Administration would provide access before the interested third party, in a review of the CTBG's decisions published on its website, became aware of the existence of the request and the CTBG's upholding of the complaint.

tervention of the jurisdiction is the one discussed below.

The origin of this case dates back to January 2019, when a citizen, allegedly in her personal capacity, approached the Ministry of Health requesting access to certain public information relating specifically to the medicinal product Kymriah® owned by Novartis. The applicant wished to know the ex-factory price ("PVL") authorised for that product, as well as the reasons and specific objective criteria under which the economic conditions of the agreement were approved and the main considerations and reflections produced within the Interministerial Commission on the Prices of Medicinal Products and Medical Devices ("CIPM") when deciding on the inclusion of the product in the pharmaceutical provision of the National Health System ("NHS").

The Ministry of Health did not take into account that Novartis could be the holder of rights or interests that could be affected by the request, and without giving it a hearing so that it could make allegations, it decided to partially grant access to the information by informing the applicant of the PVL of Kymriah®. In addition, the Ministry of Health considered that it was responding to the request for information by stating, without further detail, that the criteria that had been taken into account to determine the inclusion of Kymriah® in the public pharmaceutical provision were those indicated in article 92.1 of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices ("LGURMPS").

Not satisfied with the response to the second part of the request, the interested party filed a complaint with the CTBG alleging that the "*simple reference to the criteria for financing medicinal product established in the LGURMPS" is not what she had requested, which is why she requested "a copy of the minutes of the CIPM session or, at least, the full transcript of the agenda item in which, after due deliberation, the PVL of Kymriah, first CART therapy and the documents or technical reports that served as support*" were set.

The procedure before the CTBG took place without Novartis being aware of it or having the opportunity to make allegations in defence of its interests, and concluded with a resolution upholding the complaint filed and

The procedure before the CTBG took place without Novartis being aware of it or having the opportunity to make allegations in defence of its interests, and concluded with a resolution upholding the complaint filed and urging the Ministry of Health to send the association *"the motivation and the specific objective criteria under which this therapy (Kymriah®) is approved, as well as the economic conditions of the agreement and the main considerations and reflections produced within the CIPM".*

urging the Ministry of Health to send the association "*the motivation and the specific objective criteria under which this therapy (Kymriah®) is approved, as well as the economic conditions of the agreement and the main considerations and reflections produced within the CIPM*". The CTBG resolution, on the other hand, did not express any qualification on the scope of the order sent to the Ministry of Health, differing on this point from the position maintained in other previous resolutions[4].

Novartis became aware of the CTBG's resolution during a routine review of the content of the CTBG's website, and filed an administrative appeal requesting, as a precautionary measure, the suspension of the CTBG's resolution until the Court had ruled on the merits of the case. Given that Novartis had become aware of the CTBG's resolution in this way, and that it was unaware of the state of the proceedings, the request for precautionary measures was formulated and granted in very broad terms: an order was issued to both the CTBG and the Ministry of Health to ensure that the Ministry would not provide the information until the Court had ruled on the merits of the case. Furthermore, the order added that if the Ministry had already provided the information, the CTBG and the Ministry should inform the applicant and recipient of the information that it should return it without keeping any copies or, alternatively, keep it under strict confidentiality and refrain from using it for any purpose or disclosing it by any means until the Court had ruled on the merits of the case.

On the merits of the case, some aspects should be highlighted.

Firstly, and with regard to the procedure carried out before the Ministry of Health, there was no doubt that said Ministry, upon receiving the request for information, was perfectly aware of who the local representative of the marketing authorisation holder of Kymriah® was and, therefore, the third party whose rights or interests could be affected was duly identified in accordance with article 19.3 LTAIBG.

On the other hand, with regard to the procedure before the CTBG, a question of particular relevance was the application of article 24.2 LTAIBG, which states that the processing of the complaint shall be in accordance with the provisions on appeals in the LPAC; and to what extent the application of the rules contained in the LPAC would oblige the CTBG to transfer the complaint to Novartis so that it could argue as it deemed appropriate.

In addition, the information requested, relating to the public financing of a medicinal product for human use, was information available to the Ministry of Health under the guarantee of confidentiality established by Article 97 LGURMPS. Under this provision, companies that market medicinal products for human use included in the public pharmaceutical provision must provide the Ministry of Health with all the information on technical, economic and financial aspects, including information that makes it possible to ascertain the allocation to determine the costs affected by the pharmaceutical activity in Spain in the case of companies belonging to a group that carries out other activities or carries them out outside Spain. The information obtained by the General State Administration under this article, according to Article 97.3 LGURMPS, will be confidential.

On 21 April 2020, the Central Administrative Court No. 1 of Madrid issued a Judgment upholding the complaint. In relation to the interpretation of articles 19.3 and 24.3 LTAIBG regarding the hearing of persons whose interests or rights could be affected, the judgment states that in order to apply these articles, three circumstances must be met: (i) that there could be harm to the rights and interests of third parties derived from access to the requested information; (ii) that these

Regarding the due identification of Novartis, the magistrate stated that it was *"notorious"* that the Ministry of Health and the CTBG should have known who was concerned by the information on the medicinal product Kymriah®.

third parties are duly identified and (iii) that the allegations presented by these third parties are taken into account in the resolution of the request for access to information.

Regarding the due identification of Novartis, the magistrate stated that it was "*notorious*" that the Ministry of Health and the CTBG should have known who was concerned by the information on the medicinal product Kymriah®.

Regarding the question of whether the obligation to grant Novartis a hearing in application of article 24.3 LTAIBG, the State attorney had argued that this provision applies only to those cases in which the Administration has denied access to information to protect the rights or interests of third parties. In contrast, the Judgement states that "*the underlying cause of the hearing lies in the possible harm to the economic and commercial interests of the companies affected, harm and consequent defenselessness more appreciable if possible in cases where the claim is upheld than in cases of refusal, so the hearing is due*", to which it adds that "*from an elementary legal logic, the need for the procedure appears more relevant (....) when access is*

[...] *"the underlying cause of the hearing lies in the possible harm to the economic and commercial interests of the companies affected, harm and consequent defenselessness more appreciable if possible in cases where the claim is upheld than in cases of refusal, so the hearing is due"*, to which it adds that *"from an elementary legal logic, the need for the procedure appears more relevant (...) when access is granted than when it is denied, since in the first case the protection of the rights and interests of third parties may be at stake, while in the case of refusal their interests would not in principle be questioned (...)".*

Based on all of the above, the Judgment orders to reverse the proceedings so that the Ministry of Health, in compliance with the provisions of article 19.3 LTAIBG, may grant Novartis a hearing so that it can make the allegations it deems appropriate.

granted than when it is denied, since in the first case the protection of the rights and *interests of third parties may be at stake, while in the case of refusal their interests would not in principle be questioned (...)*".

The Judgment concludes by affirming the relevance of the hearing, given that its omission prevented "*the possibility of making allegations to the person who holds the status of local representative of the holder of the marketing authorisation for the medicinal product Kymriah® and to whom all the information on technical, economic and financial aspects for setting the price of the medicinal product was requested and provided, and which could contain information on operational aspects of the company*".

Based on all of the above, the Judgment orders to reverse the proceedings so that the Ministry of Health, in compliance with the provisions of article 19.3 LTAIBG, may grant Novartis a hearing so that it can make the allegations it deems appropriate.

It should be noted that the Judgement has not been appealed and is therefore final, and the inadequacies we referred to in the sense of forcing the Ministry of Health to be proactive in identifying interested third parties who should be given the opportunity to make allegations in compliance with article 19.3 LTAIBG, before the matter reaches the CTBG, if applicable, were corrected.

4. THE "TRUVADA®" CASE

The position of the CTBG in cases where the Administration has acted without summoning potentially interested third parties, and the application of Article 24.3 to these cases, is also at the heart of this case, which is pending before the Supreme Court[5].

[...] the Judgement has not been appealed and is therefore final, and the inadequacies we referred to in the sense of forcing the Ministry of Health to be proactive in identifying interested third parties who should be given the opportunity to make allegations in compliance with article 19.3 LTAIBG, before the matter reaches the CTBG, if applicable, were corrected.

The position of the CTBG in cases where the Administration has acted without summoning potentially interested third parties, and the application of Article 24.3 to these cases, is also at the heart of this case, which is pending before the Supreme Court.

The case originates from a request for access to information regarding the evolution of the number of containers and cost of treatment with the medicinal product Truvada®, owned by Gilead, from 2000 to 2018. The Ministry of Health denied access to the information on the grounds of section h) of Article 14.1 LTAIBG, which provides that the right of access may be limited when access to information would be detrimental to economic and commercial interests. Despite invoking this ground for denying access, and despite the fact that the request referred to a specific medicinal product, for which the Ministry was obviously aware of its holder as its supplier to the NHS, the Ministry denied access without summoning Gilead so that it could make the allegations it deemed appropriate.

In response to this refusal, the applicant lodged a complaint with the CTBG, once again referring to the fact that his request for access related to a specific medicinal product. In its decision, the CTBG expressed a certain surprise that the Ministry refused access to the information under Article 14.1 (h) of the LTAIBG when it turns out that it did not forward the request to the third party holders of those economic and commercial interests. At the same time, the CTBG points out that the company that markets the medicinal product must be the entity that could be affected by the publication of the information; but adds that if the Ministry did not comply with the provisions of article 19.3 LTAIBG and did not summon the company to present allegations, "*the alleged harm to economic and commercial interests alleged by the Ministry lacks the necessary evidence or documentary evidence that would make it directly applicable*".

Based on this reasoning, the CTBG upheld the complaint in its resolution 231/2017 of 18 August and ordered the Ministry of Health to provide the information to the person who had requested it. In this resolution, the CTBG does not assess whether it should, in application of Article 24.3 LTAIBG, grant a hearing to the company that could be affected, especially considering that the CTBG itself has no doubts as to the identity of this company or how to identify it. Ultimately, the CTBG takes the position that if the Ministry of Health has not notified any third party, article 24.3 LTAIBG does not impose on it the obligation to do so. Nor does the CTBG assess whether the fact that the complaint must be processed in accordance with the provisions of the LPAC implies the obligation to forward it to the other interested parties in application of article 118.2 LPAC; and this despite the fact that the CTBG should not have had any doubts about the existence of these other interested parties.

Ultimately, the CTBG takes the position that if the Ministry of Health has not notified any third party, article 24.3 LTAIBG does not impose on it the obligation to do so.

The CTBG's resolution was the subject of an administrative appeal filed by the Ministry of Health. In the first instance, the Central Administrative Court No. 5 dismissed the appeal, but the National High Court overturned the Judgement and on 6 March 2019 ruled that the CTBG had infringed Article 24.3 LTAIBG by having upheld the complaint without summoning Gilead to make allegations. The Chamber understood that, since the request for information referred to a specific medicinal product, the interested parties were duly identified and should have been heard.

In view of this situation, the CTBG has lodged an appeal in cassation before the Supreme Court, whose Order 2110/2020, of 6 March, declares that the issue raised is of objective interest for the formation of jurisprudence. This order allows us to foresee the CTBG's position on the matter. According to the order, the CTBG, in its appeal, points out that interpreting article 24.3 LTAIBG in the sense that the CTBG should give the interested parties a hearing even when the Administration has not done so *ex* Article 19.3 LTAIBG could be an obstacle to the exercise of the right of access to information because it could lead to the collapse of the functioning of the CTBG, also highlighting that while article 19.3 allows for the suspension of the resolution period during the period in which third parties can make allegations, article 24.3 does not contemplate such a suspension. The CTBG, on the other hand, is critical of the National High Court's Judgement, which accuses it of infringing article 24.3 LTAIBG, pointing out that in its opinion it should have agreed to take the proceedings back to the time when the Ministry of Health should have identified those potentially affected and given them the corresponding hearing.

The National High Court over-turned the Judgement and on 6 March 2019 ruled that the CTBG had infringed Article 24.3 LTAIBG by having upheld the complaint without summoning Gilead to make allegations.

The rules governing the participation of third parties in the process suffer from two inadequacies: they do not specify how third parties whose rights or interests may be affected by the request for access to public information should be identified; and they do not make it clear, at least in the opinion of some, what the CTBG should do when a com-plaint is submitted in relation to which there may be clearly identified rights of third parties (or at least identifiable) but which have not been summoned by the Administration so that they can make the allegations they deem appropriate.

In short, in a few months' time we will have at least one judgement from the Supreme Court whose main objective will be to interpret Articles 19.3 and 24.3 LTAIBG in order to clarify and delimit their areas of application, as well as the relationship between these two Articles in those cases in which, during the procedure for processing a request for information, the provisions of Article 19.3 LTAIBG have been omitted.

5. SOME CONCLUDING THOUGHTS

As noted above, our opinion is that the rules governing the participation of third parties in the process suffer from two inadequacies: they do not specify how third parties whose rights or interests may be affected by the request for access to public information should be identified; and they do not make it clear, at least in the opinion of some, what the CTBG should do when a complaint is submitted in relation to which there may be clearly identified rights of third parties (or at least identifiable) but which have not been summoned by the Administration so that they can make the allegations they deem appropriate.

Until these inadequacies are resolved by other means, case law can and should contribute to defining guidelines for action that allow the objectives pursued by the LTAIBG to be met, not in relation to access to public information (which is not questioned) but to the protection of the interests of third parties that may be affected by the disclosure of certain public information. It is reasonable for the CTBG to be concerned to ensure that the objective of protecting the interests of third parties does not lead to a collapse of the system, but neither should we forget that the LTAIBG is a law that is careful and protective of the rights of third parties. We therefore believe that it is reasonable for the Supreme Court, as appears from the Order of 6 March 2020, to give special consideration to the consequences of each possible solution without

It is reasonable for the CTBG to be concerned to ensure that the objective of protecting the interests of third par-ties does not lead to a collapse of the system, but neither should we forget that the LTAIBG is a law that is careful and protective of the rights of third parties.

losing sight of the need to comply with the requirement to hear interested third parties.

At the same time, the CTBG can also contribute to the same sense, and in fact it is doing so, by urging the acting Administration to reverse the proceedings in such a way as to give a hearing to the interested parties that could be affected and that the CTBG itself identifies. This has been done on some occasions by the CTBG[6] and has now been confirmed by the National High Court in a recent Judgement[7], which upholds the CTBG's decision to order the proceedings to be reversed to when the Administration had to give a hearing to the interested third party.

Finally, we believe that the regulatory development of the LTAIBG could impose on those submitting a request for access to public information the obligation to identify third parties whose rights or interests may

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be affected by their request. The regulation of the LTAIBG could also contemplate the obligation to register requests for information on the transparency portal of the entities obliged to provide such information, as well as to publicise the complaints received through the CTBG website, so that third parties whose rights or interests may be affected may be able to appear in person.

It is clear that the issue is complex and that the interests involved are diverse and all deserving of a certain level of protection. When assessing the different options, it should not be forgotten that the LTAIBG establishes a system that guarantees the interests of third parties and that it is reasonable that the burden of identifying these third parties should fall on the Administration receiving the access requests.

[1] It is not possible to file a complaint before the CTBG when the decision denying access has been issued by His Majesty the King's Household, the Congress of Deputies, the Senate, the Constitutional Court, the General Council of the Judiciary, the Bank of Spain, the Council of State, the Ombudsman, the Court of Auditors, the Economic and Social Council and similar autonomous institutions. In these cases, only administrative appeals may be lodged.

[2] *Vid.,* https://transparencia.gob.es/transparencia/transparencia_Home/index/Derecho-de-acceso-a-la-informacion-publica/ResolucionesDenegatorias.html.

[3] *Vid.,* https://www.consejodetransparencia.es/ct_Home/Actividad/Resoluciones.html .

[4] At CTBG Resolution 239/2018 of 13 July 2018, the Ministry was urged to provide copies of the "*Approved minutes of the meetings of the Interministerial Commission on Medicinal Product Prices with all the agreements adopted from 2007 to 2017*" expressly stating that "*From these minutes, those classified matters or others whose dissemination is legally prohibited must be kept hidden, at the considered and loyal discretion of the Administration*".

[5] *Vid.* Auto 2110/2020, of 6 March, of the Sala de lo Contencioso Administrativo del Tribunal Supremo, at http://www.poderjudicial.es/search/AN/openCDocument/47c54a4d73e1a1968bdd7e58756e8e498d1289701b272b91.

[6] See in particular the recent Resolution 470/2020 of the CTBG, of 5 November, regarding a request for access to the technical and administrative files for the pricing of medicinal products whose active ingredients are Natalizumab and Fingolimod. The CTBG, citing the aforementioned Judgement in the "*Kymriah®*" case, ordered the Ministry of Health to reopen the proceedings so that the companies owning the medicinal products whose active ingredients are Natalizumab and Fingolimod could be heard.

[7] Judgment of the Audiencia Nacional, of 4 November 2020.

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THE PRICE OF MEDICINES: TRANSPARENCY *VERSUS* CONFIDENTIALITY

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RESUMEN: El dilema entre el principio de transparencia y el derecho a la confidencialidad, está dando lugar a distintos planteamientos de abordaje, en función del concepto al que se le otorgue un valor superior a proteger. Este dilema está teniendo especial relevancia en relación al precio de los medicamentos.
El cambio de criterio del Consejo de Transparencia y Buen Gobierno, puesto de manifiesto en su Resolución 478/2019, de 26 de septiembre y las conclusiones contenidas en la Resolución 92/2019, de 19 de diciembre, de la Comisión autonómica del País Vasco, suponen un evidente punto de inflexión en el criterio mantenido desde los órganos institucionales de transparencia.
El análisis de este punto de inflexión y el contenido de los argumentos que en ambas resoluciones se plantean, hacen oportuna una reflexión sobre la consistencia de los mismos y su encuadre en el marco jurídico tanto comunitario como nacional que le son de aplicación.

PALABRAS CLAVE: Acceso a la información; asimetría de la información; buen gobierno; confidencialidad; precio medicamento; secretos comerciales; transparencia.

ABSTRACT: The dilemma between the principle of transparency and the right to confidentiality, is giving rise to different ways of dealing, depending on the concept that is given a higher value to protect. This dilemma is having special relevance in relation to the price of medicines.
The change in criteria of the Transparency and Good Governance Council, showed in its Resolution 478/2019, of September 26 and the conclusions contained in Resolution 92/2019, of December 19, of the Basque Country's Autonomous Commission, are assuming an obvious turning point in the criteria maintained by the institutional transparency organs.
The analysis of this turning point and the content of the arguments that these resolutions raise make an opportune reflection on its consistency and its setting within the legal framework, both community and national, that are applicable to it.

KEYWORDS: Access to public information; information asymmetry; good governance; confidentiality; drug price; commercial secret; transparency.

1. STATEMENT OF THE DILEMMA

The medicine market has been an intervened market, perhaps one of the most intervented ones. This Intervention is determined by different singularities that configure its own reality.

Medicines are a unique product because of their direct impact on such an essential good as health. This uniqueness justifies a monitoring and control in all its phases:

PHASES
• Preclinical
• Clinic
• Approval & Registration
• Prescription
• Dispensation
• Administration
• Monitoring & Reporting

This intervention aims to guarantee citizens and healthcare professionals the quality, safety, efficacy and correct information of medicines.

In addition to said intervention in the aforementioned areas (where there is a clear impact on a clinical area), prices are generally intervened by state Governments. This intervention is based on the principle of equity in access tomedicines.

From the observation of healthcare markets, it can be extracted a common characteristic regarding said markets, a characteristic that is specified in the existence of a triangular relationship between users (patients), healthcare providers and the entities that finance this care. In healthcare systems. It is very uncommon for users to be directly responsible for; it will be the State that, through taxes or social contributions, provides it self with the necessary resources to finance or compensate the providers of health services (the model is also replicated in cases of privateinsurance, through the payment of premiums and compensation by theinsurance company to the healthcare service provider. This singularity has an impact on the functioning of themarket, since even though the economic rule is that the demand for services varies depending on whether the prices are more or less high, in the presented healthcare market model, as users do not directly pay for the medical care costs (service is perceived as *"free of charge"),* prices lack that ability to balance supply and demand.

For all these reasons, with regard to public health services, it must be the financing State that balances the market through price intervention, guaranteeing equity in access and the sustainability of healthcare systems.

The intervention of prices by the regulator leads towards the dilemma which is this article's object: if it is advisable or not to make public the regulated price (as well as the specific criteria for doing so), or to prioritize the right to commercial secrecy otherwise.

Both aspects, transparency and trade secrecy, are legal assets that the legal system recognizes as entitled to their protection:

- Law 19/2013, of 9 December, on transparency, access to public information and good governance.

- Law 1/2019, of 20 February, on Trade Secrets.

On the one hand, transparency and secrecy are opposite concepts that have an impact on legitimate interests subject to protection subject to protection. Moreover, since those concepts coexist within the framework of the same legal reality, they must undergo an appropriate modulation.

Transparency and secrecy are opposing concepts that have an impact on legitimate interests subject to protection and that, coexisting within the framework of the same legal reality, must be subject to adequate modulation.

2. THE THORNY ISSUE OF MEDICINE PRICES

The Health at a Glance 2019[1] report, presented by the Organisation for Economic Co-operation and Development (OECD), compares different countries according to different health indicators. Regarding pharmacy spending[2] it points out that it represents almost a 20% of total health expenditure. On the other hand, total health spending in 2018 stood at 8.8% of GDP (ifwe look at any of the countries, the US is the one that allocated the highest percentage with 16.9% of GDP, followed by Switzerland with 12.2%; Spain stands at 8.9% and at the bottom are countries such as Mexico, below 6%). Pharmaceutical expenditure represents a market of almost 1.8% of total GDP within the OECD, which shows the economic magnitude of the market.

As we have shown, the medicines market is one of the most regulated markets internationally and price is one of the factors subject to intervention.

In our country, we can currently observe an apparent duality, given the existence of prices for the public sphere (intervened price) and prices for areas other than those financed by public services (prices that in a general way we can indicate are free prices). Through separate decisions, the National Commission on Markets and Competition[3] has stated that such duality does not exit, it recognises a singleprice freely set by the laboratory, a price that is not legally imposed in areas in which the competent administration has administratively determined a different price.

In any case, in our country we can find, in the medicine market, thefollowing prices:

- The publicly financed **industrial price**, for those medications included in the pharmaceutical benefit and are financed by the state.
- **Notified price**, in the following cases:
  - Prescription medicines excluded from pharmaceutical services and dispensed in Spain (Article 93 of Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on Guarantees and Rational Use of Medicines -TRLGURM-).
  - Prescription drugs, not financed (article 94.5 TRLGURM).

- Over-the-counter medicines (article 94.3 TRLGURM).

- **Free price**, without administrative intervention, for exports.

- In addition, the same medicine can be subject to three prices:

  - The **intervened price** for prescriptions for medicinesfinanced by the National Health System.

  - The **notified price** for user-funded prescriptions or private insurance.

  - The **free price** without administrative intervention for exports.

In general, the notified price, as it is outside the Funding by the public health system has been operating as a price freely set by the laboratory. Even so, article 94.4 of the TRLGURM provides that in any case, the obligation of marketing authorisation holders to communicate the price of medicines under the notified price regime is understood in such a way that the Ministry of Health may object to it for reasons of public interest. This power has recently been exercised by the administration.[4]

In addition to this checkerboard of intervened prices, regarding the medicines market it must be added to the resulting price the award price coming from public tenders carried out mainly in the hospital field.[5]

Likewise, public tenders derived from procurement processes covered by Law 9/2017, of 8November, on Public Sector Contracts, have also their own legal framework, including aspects related to transparency and confidentiality that will be further analyzed.

3. THE DIFFERENT POSITIONS IN RELATION TO THE DILEMMA

In our field of analysis, the different positions found are based on a disparate approach.

Public tenders derived from procurement processes covered by Law 9/2017, of 8 November, on Public Sector Contracts, have also their own legal framework, including aspects related to transparency and confidentiality that will be further analyzed.

Francisco Mezones, in his book *"Transparency in Public Managements*[6] collects the experiences and reflections of a group of experts on the subject of transparency in public management. It recognises transparency as acontextual value. This means that the way in which it is conceived, measured and implemented depends on the context in which it is discussed. Forexample, if the context is only business-based, the concerns about what transparency is and how it can be promoted are different from whether the context is political and specifically refers to the guarantees of an electoral process for the change of public authorities[7].

This different perspective leads us to different positions depending on the context in which we allocate ourselves.

Developing the public authority willingness to determine the price of medicines is the perspective which gives transparency the meaning of subjecting that decision to public scrutiny and therefore to social control. From this point of view, more transparency leads to greater democracy and greater efficiency. As Bobbio[8] points out, in the first instance, transparent democracy is opposed to the exercise of *invisible power*.

On the other hand, from a business context, trade secrets (which could protect the opacity of the price) and its protection is a tool to stimulate innovation, guarantee competitiveness based on know-how and avoid unfair practices. The protection of trade secrets confers on its holder a genuine subjective right of a patrimonial nature.

It is clear that both positions are entirely plausible, but in scenarios -such as the one that is the subject of this study-, in which these different and opposite perspectives (derived from the intervention by the public authorities in the drug market with the fixing of its price) leads to a situation of conflic of intereset.

From a business point of view (as recognized in the preamble to the Trade Secrets law), companies value their trade secrets as much as industrial and intellectual property rights. They use confidentiality as a tool for managing business competitiveness, public-private knowledge transfer and innovation in research. with the aim of protecting information thatencompasses not only technical or scientific knowledge, but also business data relating to customers and suppliers, business plans, and market studies or strategies. The standard recognises the need to ensure that competitiveness, which is underpinned by know-how and undisclosed business information, is adequately protected, aswell as to improve the conditions and framework for development and the exploitation of innovation andknowledge transfer in the market.

Companies value their trade secrets as much as industrial and intellectual property rights and use confidentiality as a tool for managing business competitiveness, public-private knowledge transfer and research innovation, with the aim of protecting information that covers not only technical or scientific knowledge, but also business data relating to customers and suppliers. business plans and market studies or strategies.

Even Law 19/2013, of 9 December, on transparency, access to public information and good governance, recognises limits to the general principle of transparency that it re-

gulates. Article 14 of the law expresses note that the right of access to the information may be limited, including as expressed in the other cases, when accessing detrimental to economic and commercial interests.

Likewise the Public Sector Contracts Law recognizes in its Article 133 that "not with standing anything to the contrary established in the current legislation regarding public information access and the provisions included in this Act, which relate to the publicity of the award and the compulsory information that must be provided to candidates and tenderers, contracting authorities will not disclosure any information labeled as confidential by the entrepreneurs when submitting their commercial offer.

Among other aspects, this confidential nature affects the technical or commercial secrets, the confidential aspects of the offers and any given information which can be used to misrepresent competition. The latter including that or subsequent tendering procedures. The recognition and respect of confidentiality is reiterated in different precepts of the law.[9]

From a public management perspective, as stated in the Preamble of the Transparency Law, public information access and fair government rules must be the the fundamental axes of all political action. Furthermore, the beginning of a process where public authorities start to answer to a critical and demanding society that claims for more implication from the aforementioned public authorities will be determined only when said public authorities activities are scrutinized, when citizens know how the decisions that affect them are taken, when public budget management is disclosure and operational criteria for public entities are well known.

Countries with higher levels of transparency and good governance standards have stronger institutions, which are conducive to economic growth and social development. In these countries, citizens can judge better and more judiciously the capacity of their public officials and decide accordingly. Allowing for better oversight of public activity contributes to the necessary democratic regeneration promotes the efficiency and effectiveness of the State, and favors economic growth.

As can be seen, we are faced with two different dimensions of the same reality. Depending on the contextual position in which we find ourselves, each one of them has its own legitimate interests, interests which, as has been indicated, have been the object of doctrinal treatment and normative development.

Allowing for better oversight of public activity contributes to the necessary democratic regeneration, promoting efficiency and effectiveness of the State.

4. EVOLUTION OF REGULATIONS AND INFORMATION CRITERIA OF THE RIGHT TO ACCESS TO INFORMATION

The right of access to public information is a key right for transparency in public management and accountability.

At the European level, Article 41.2 of the Charter of Fundamental Rights of the European Union[10] recognises the right of every person to have access to the file concerning them, in compliance with the legitimate interests of confidentiality and professional and commercial secrecy.

Article 105 b) of our Constitution establishes that the law shall regulate citizens' access to administrative archives and records. In compliance with this constitutional mandate, our rules of administrative procedure have been regulating this right to information. Currently, Article 13 d) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations refers to Law 19/2013 of 9 December 2013 on transparency, access to public information and good governance.

Law 19/2013 of December 9, 2013 is made by the legislator for providing the definite endorsement to access to public information, configuring the norm as the cornerstone in the development of the provisions of article 105.b) of the Constitution. In this norm, levels of transparency are distinguished and developed. Active Advertising and Passive Advertising.

On the other hand, Law 9/2017, of November 8, 2017, on Public Sector Contracts, states in its preamble that the first objective that inspires it is to achieve greater transparency in public procurement. In its first article, the law aims to regulate public sector procurement, in order to ensure that it meets with the principles of freedom of access to tenders, publicity and transparency of procedures, non-discrimination and equal treatment of tenderers.

The Council for Transparency and Good Governance has issued several interpretative criteria in this area. Of particular interest is the specific interpretative criterion adopted jointly by the Council and the Spanish Agency for the Protection of Intellectual Property. (AEPD) - specifically No. CI/002/2015 of 24 June 2015 on the application of limits to the right of access to information[11] .

Interpretative Criterion 1/2019, of 24 September 2019, of the Council for Transparency and Good Governance, on the application of Article 14, number 1, section h) of Law 19/2013, of 9 December: damage to economic and commercial interests[12], is also relevant. Article 14.1.h) of the Transparency Law refers to the restriction of access to information when it is damages the economic and commercial interests. In this interpretative criterion, it focuses on the analysis of both concepts, economic interest and commercial interest.

The Council considers that the copulative conjunction *"and"* to link of the concepts of *"economic interests"* and *"commercial interests"* indicates that the drafters of the law had a separate understanding of both, according to which the two concepts are independent and denote different realities. Conceptually, commercial interests are a sector of economic interests, are highlighted at the same level due to their relevance.

In any case, *"economic interests"* are understood as *"the convenience, advantageous position or importance of an individual or collective subject in the field of production, distribution and consumption of goods and services"*.

"Commercial interests" means *"favours, positions of advantage or positions of importance in matters relating the volume of the exchange of goods or services in a market area*".

The Council concludes that, in the field of the exercise of the right, the following rules should be taken into account for the application of the limit:

- The limitation on harm to the economic and commercial interests of an organisation, undertaking or person, like the other limitations in Article 14, is not automatic and does not by itself imply a direct exclusion of the right of access to information or of the obligations relating to active promotion.

- On the other hand, as stated in Article 14 itself, the application of the limitations will be optional, justified and proportionate to the object and purpose of the protection and taking into account the circumstances of the specific case (Article 14.2).

- Each case must be the subject of an individual study, the application of the test of damage, and the weighing of its circumstances as set out in the Preamble of the Law.

- It is not sufficient to argue that the existence of an uncertain possibility is likely to cause damage to economic and commercial interests in order to apply the limit generally. The damage must be defined, undoubted and concrete.

- That damage must be substantial, real and manifest. It must be directly related to the disclosure of the information.

- In order to determine the extent of the damage found and its consequences, it is necessary to weigh up the existence of an overriding interest, which will ultimately determine the weight of such damage in economic and commercial interests against the legitimate interest existing in knowing the specific information to be disclosed. In the light of the injury found and its impact, it should be proceeded to the weighing of the existence of a prevailing interest that will ultimately mark the weight of such damage in economic and commercial interests against the legitimate interest existing in knowing the specific information to be disclosed.

In several resolutions since 239/2018, of 13 July 2018 (13), this body has focused on the Council's criteria related to financing and pricing agreements for medicines, considering requests for access without any restrictions.

This criterion has been revised since resolution 478/2019, of September 27, 2019[14] The content of this resolution has been extensively studied by Beatriz Cocina Arrieta in this publication,[15] so we will limit ourselves to a few aspects of interest.

The Ministry of Health, Consumption and Social Welfare, when processing the file, invoked art. 14.1, h), j) and k) of Law 19/2013, of 9 December, relating to the protection of economic and commercial interests, professional secrecy and the guarantee of confidentiality in decision-making. The Ministry stated that:

> *" ... a decontextualised disclosure of the information concerning the content of Hyrimoz's pricing decision in Spain could have a serious impact on the pricing of the same medicine in other Member States of the European Union, whose pricing systems are based on neighbouring countries, with the effect on the pricing policy of the same company in other countries, and, once again to the detriment, of the economic and*

commercial interests of the undertaking which owns it, protected by Article 14 of the Transparency Law".

In its resolution, the Council refers to its interpretative criterion CI/002/2015 of 24 June 2015 on the balancing of the interests of the individuals concerned and the possible interest justifying publicity or access (public interest test). It also considers the applicability of Law 1/2019, of 20 February, on Trade Secrets. Finally, it concludes that:

"The pharmaceutical industry justifies price confidentiality on the basis of the possibility it offers to 'maximise patient access to innovative medicines'. In this regard, they state that this confidentiality allows "each country to obtain the best possible price according to its circumstances (public coverage, co-payments, economic capacity...)", always in "balance with the necessary economic return for pharmaceutical companies". "If there were no confidentiality at the European level, prices would tend to converge towards in a single value which could be relatively low for the richest countries, but too high for those with less economic capacity," and which they say, -"could make access more difficult for those with fewer resources".

The case analysed by the State Commission concerns the fixing of the price of medicines, within the framework provided for in the revised text of the Law on Guarantees and Rational Use of Medicines. For its part, the Basque Commission for Access to Public Information ruled on a case within the scope of the Law on Public Contracts. The factual situation corresponded to an action by the Basque Government, which in 2019 published on its public procurement platform the award resolution for the purchase of Kymriah, with a break down od the total budget excluding VAT, without specifying the cost of each individualised treatment or th number of therapies that wouold be covered by this award. Faced with a complaint against this action, the Autonomous Commission, by the Resolution 92/2019, of 19 December[16], decided in favour of the Basque Government, with the following arguments:

"In view of the above, in the opinion of this Basque Commission for Access to Public Information, access to the content of the unit price per complete treatment, as well as to the number of treatments provided for in the tender, may cause reasonable and not merely hypothetical damage to the economic and commercial interests of the parties concerned, so that access must not be granted. The Ministry of Health argues that "the knowledge by third parties of the agreed price of a medicinal product, as well as its financing conditions, involves the disclosure of data of an economic nature relating to the business object of a commercial entity, which could be used by its competitors to its detriment. At the same time, and with regard to the necessary confidentiality and secrecy of administrative decisions when they are likely to affect the particular interests of third parties, it must be borne in mind that disclosure, out of context, of the information relating to the content of the decision on the unit price of Kymriah could have serious repercussions on the determination of the price of the same medicinal product in other Autonomous Communities and even in the other Member States of Kymriah. the European Union, whose pricing systems take as a reference those of the countries around it, with the following effect on the pricing policy of this same company in countries and, to the detriment, again, of the economic and commercial interests of the entity that

owns it, protected by Article 14 of the Transparency Law".

5. SOME REFLECTIONS ON THE STATE OF THE ART IN RELATION TO THE TRANSPARENCY OF DRUG PRICES

It is clear that the pharmaceutical market is far from being considered a perfect market in the terms defined by Adam Smith in the eighteenth century. In a perfect market, it would be the interaction between suppliers (firms) and demanders (customers) that would determine its price. Obviously, this is a theoretical concept that we hardly find in reality.

The perfect market is based on the symmetry of information, in such a way that the information about the conditions of what is being negotiated is the same for all bidders and demanders (there is no information exclusive or privileged) and price and volume information is also available to all. In the reality that concerns us, there is an undeniable asymmetry in the information derived from the secrecy of the pharmaceutical industry in relation to its costs of putting a new molecule on the market. In addition, the need to guarantee the right to protect citizens through efficient and sustainable health systems justifies intervention in the prices of medicines. Both circumstances, secrecy and intervention, are the source of multiple distortions that create tensions in the combination of two undoubtedly legitimate interests that are recognized and defended in the legal systems, the right to transparency and the right to confidentiality.

The pharmaceutical industry justifies the defence of confidentiality under the argument that, if there were no confidentiality at European level, prices would tend to equalise in a single value that could converge to an average price, perhaps relatively low for the richest countries, but too high for those with less economic capacity. According to the industry's argument, it could complicate access in countries with fewer resources1. Likewise, and also taking into account the arguments of the pharmaceutical industry, the Autonomous Commission of the Basque Country, through Resolution 92/2019, of 19 December already expressed, comes to consider that a decontextualised disclosure of the information relating to the content of the resolution of the unit price could have a serious impact on the determination of the price of that same medicine in other Autonomous Communities and even in the other Member States of the European Union. This last argument is surprising to say the least in the light of Article 13 of the Treaty on European Union (EU), which enacts that EU institutions and states must maintain between them, loyal cooperation, as well as the general principles of inter-administrative relations set out in Article 140 of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector, which provides that the different Public Administrations act and relate to other Administrations and entities in accordance with, among others, the *principles of institutional loyalty, collaboration and cooperation.*

Within the framework of another line of argument, it is stated by those responsible for the pharmaceutical industry that providing greater transparency to the financing process of public medicines would only increase their price[18]. Contrary to this claim, a study by the European Commission[19] estimates that the confidentiality of drug prices makes them more expensive, concluding that if EU Member States shared this information, the cost of funded drugs could fall on average by up to 41.2 percent.

Transparency must not be an end in itself and consequently we cannot allow ourselves to be led into an *"information pornography"*[20], transparency must be the means to good gover-

nance. As previously indicated in Law 19/2013, of 9 December, transparency access to public information and the rules of good governance must be the cornerstones of all political action. In the area that concerns us, that of medicines, the relevance and the need for knowledge on the part of society of the decisions that are taken is evident, precisely because they have a decisive influence on the health of the population, also having a very significant impact on the application of public resources and on the sustainability of our health system.

It is true that the principle of transparency may have limitations when it coincides with other legitimate interests, such as the economic and commercial interests of the pharmaceutical industry, but it must be based on the premise that transparency is a higher value, that it cannot be relegated in a general way and that it should only be ignored in a very limited way.

In accordance with the foregoing and in the area covered by this article, both decisions to intervene the prices of medicinal products and those corresponding to public procurement of medicines must be based on a general principle of transparency, a principle that should only be limited when, in specific cases. Only when there are reasons that justify their subordination to interests that represent a higher value.

From my point of view, criteria such as those expressed in the aforementioned Resolution of the Autonomous Commission on Transparency of the Basque Country, the reasons already stated at the time (which would obviate prevailing principles in relations between public institutions), do not seem acceptable to put economic and commercial interests before transparency of public activity.

Nor do the arguments that attempt to justify opacity, in hypothetical favourable repercussions of equity (such as has been held by the Council for Transparency and Good Governance), or in better economic conditions (we refer again to the *"Study on enhanced cross-country coordination in the area of pharmaceutical product pricing"* of the European Commission, which states the opposite).

Both decisions to intervene the prices of medicinal products and those corresponding to public procurement of medicines must be based on a general principle of transparency, a principle that should only be limited when, in specific cases. Only when there are reasons that justify their subordination to interests that represent a higher value.

Faced with these latter arguments to the detriment of transparency, perhaps we should ask ourselves whether the problem does not stem from transparency, but from the absence of a common European policy on the pharmaceutical market, a policy in which, in applica-

tion of the *"sincere cooperation"* established by the treaties, information is shared. making it possible to make joint decisions on prices, decisions that, while taking into account the singularities of each country (mainly with regard to its economic capacity and standard of living), will derive from an orderly, global and common European vision.

Europe is taking steps, still shy, along these lines with initiatives such as the Online Database for the Regulation and Control of the Price of Medicinal Products (EURIPID), a Commission initiative which, through collaborative action between States, aims to make information on the pharmaceutical products available to national authorities, making it easier to control your costs.

Finally, I do not want to overlook the high social sensitivity that the transparency of prices in medicines is beginning to have, referring to the initiative, which certain organisations have launched, to collect the necessary 500,000 signatures, to promote a popular initiative in the Congress of Deputies, in order to promote greater transparency around the price of medicines and eliminate possible conflicts of interest[21] .

6. RECAP

Advanced societies require mechanisms that make it. To this end, citizens should not be prevented from accessing the information that has underpinned the decisions of the public authorities.

As stated in the preamble of the Transparency Law, "*Countries with higher levels of transparency and good governance standards have stronger institutions, which promote economic growth and social development. In these countries, citizens be able to judge better and more judiciously the capacity of their public officials and decide accordingly. Allowing a better control of public activity contributes to the necessary democratic regeneration, promotes the efficiency and effectiveness of the State and favors economic growth.*"

Clearly, transparency is not an end in itself, but a means to strengthen that democracy. For this reason, transparency cannot be predicated at the expense of everything, it will be necessary, in some cases, to weigh the con-

Transparency is not an end in itself, but a means to strengthen that democracy. For this reason, transparency cannot be predicated at the expense of everything, it will be necessary, in some cases, to weigh the conflict or harm against other legitimate interests at stake (harm test/public interest test).

flict or harm against other legitimate interests at stake (harm test/public interest test).

With regard to the price of medicines, we find relevant interests that may affect research, equity, the sustainability of health systems, or the viability of the drug industry, among others. In the resolution of these conflicts, it does not seem possible to establish a criterion of general application and the only plausible approach seems to be the one already highlighted by the Supreme Court in a Judgment of October 16, 2017, of the Contentious-Administrative Chamber, which considers that the legal regulation of the right of access to the information requires a strict, if not restrictive, interpretation of both the limitations on the right of access to information (which are contemplated in article 14.1 of Law 19/2013, of 9 December), and the causes of inadmissibility of requests for information (which are listed in article 18.1), without accepting limitations that entail an unjustified and disproportionate impairment of the right of access to information.

[1] https://www.oecd-ilibrary.org/sites/4dd50c09-en/index.html?itemId=/content/publication/4dd50c09-en

[2] The report refers to data from 2017.

[3] Decisions of 19 January 2017 and 30 August 2018.

[4] Denying Johnson & Johnson's request to increase the price of *"DCI loperamide."*

[5] As an exception, we can point to the case of the Andalusian auctions, which have their scope in the market of dispensing in pharmacies.

[6] Francisco Mezones (editor), *Transparency in Public Management: Ideas and Experiences for its Viability.* Guatemala 2006.

[7] Telma Almeida de Oliveira.

[8] Bobbio, Norberto. *El futuro de la Democracia* (2001).

[9] Articles 52.1; 56.5; 138.2 a); 169.7; 171; 321.1; 328.5; DA 16; among others.

[10] Published in the Official State Gazette of 31 July 2008, through Organic Law 1/2008, of 30 July, authorising the ratification by Spain of the Treaty of Lisbon, amending the Treaty on European Union and the Treaty Establishing the European Community, signed in the Portuguese capital on 13 December 2007.

[11] https://www.consejodetransparencia.es/ct_Home/Actividad/criterios.htmll

[12] https://www.consejodetransparencia.es/ct_Home/Actividad/criterios/1-2019.html

[13] https://www.consejodetransparencia.es/ct_Home/dam/jcr:26773310-91a3-439e-9864-1c049d127aea/R-0239-2018.pdf

[14] https://www.consejodetransparencia.es%2Fct_Home%2Fdam%2Fjcr%3A84cec08c-1e72-4b1f-acc3-96d1573d-149d%2FR-0478-2019.pdf

[15] Cocina Arrieta, Beatriz. *Cuadernos de derecho farmacéutico* nº 71 (October-December 2019).

[16] https://www.gardena.euskadi.eus/documentacion-relevancia-juridica/resolucion-922019/webgar00-contgen/es/

[17] This reasoning is made explicit in Resolution 478/2019, of September 27, 2019, of the Council for Transparency and Good Governance, to which reference has already been made.

[18] Martín Sellés. President of Farmaindustria (XVI Seminar on the Pharmaceutical Industry & Media) of Communication).

[19] *"Study on enhanced cross-country coordination in the area of pharmaceutical product pricing"* (https://op.europa.eu/en/publication-detail/-/publication/b1565784-9a9c-11e6-9bca-01aa75ed71a1)

[20] Concepto acuñado por Byung-Chul Han. La sociedad de la transparencia (traduc. Raúl Gabas). Herder, 2013.

[21] https://civio.es/novedades/2019/11/26/comienza-la-recogida-de-firmas-para-llevar-al-congreso-el-debate-sobre-el-precio-de-los-medicamentos-y-su-transparencia/

Francisco Valero Bonilla

RESOLUTION 478/2019 OF THE COUNCIL OF TRANSPARENCY AND GOOD GOVERNANCE OF 26 SEPTEMBER 2019 INFORMATION ON THE PRICE AND INCLUSION OF A MEDICINE IN THE NATIONAL HEALTH SYSTEM

Beatriz Cocina Arrieta

Counsel Uría Méndez

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RESUMEN: Esta reseña se hace eco de una importante y pionera Resolución del Consejo de Transparencia y Buen Gobierno, de 26 de septiembre de 2019, relativa a la aplicación de los principios de transparencia a la información sobre el precio e inclusión de un medicamento en el Sistema Nacional de Salud. El CTBG, acogiendo los argumentos del Ministerio de Sanidad, entiende que resultan de aplicación los límites legales al acceso a la información basados en la protección de los legítimos intereses económicos y comerciales, y aprecia que existe un interés público en mantener la confidencialidad de los precios, puesto que lo contrario complicaría el acceso a los medicamentos en los países de menos recurso.

PALABRAS CLAVE: Transparencia; confidencialidad de precios de los medicamentos; intereses económicos y comerciales; precio y financiación de medicamentos.

ABSTRACT: This review echoes an important and pioneering Resolution of the Spanish Council for Transparency and Good Governance, dated 26 September 2019, regarding the application of the principles of transparency to the information on the price and reimbursement of a medicine in the National Health System. The CTBG, accepting the arguments of the Ministry of Health, understands that the legal limits to access to information based on the protection of legitimate economic and commercial interests are applicable, and appreciates that there is a public interest in maintaining the confidentiality of prices, since otherwise it would complicate access to medicines in countries with fewer resources.

KEYWORDS: Transparency; confidentiality of medicine prices; economic and commercial interests; price and reimbursement of medicines.

1. INTRODUCTION

Recently, the Council of Transparency and Good Governance ("CTBG") has issued the very interesting Resolution 478/2019, of September 26, 2019, regarding the application of the principles of transparency to information on the price and inclusion of a medicine in the National Health System.

This resolution, which is reproduced in full below, is of particular importance because it marks a distinct shift from the CTBG's previous doctrine and the adoption of a criterion [ ]. and adopts the criterion already expressed by other European bodies in the field of transparency (see "*Resolution of the Irish Information Commissioner of 13 April 2018 on the application of transparency rules to the prices of medicines",* by Beatriz Cocina Arrieta, in *Cuadernos de derecho farmacéutico* nº 69, April-June 2019, CEFI). In particular, the CTBG understands that the legal limits on access to information based on the protection of legitimate economic and commercial interests (ex article 14.1 h) of Law 19/2013, of 9 December, on transparency, access to public information and good governance) are applicable.

The CTBG accepts the arguments of the Ministry of Health, Consumer Affairs and Social Welfare, subsequently reiterated by the pharmaceutical company concerned, and considers that those arguments are consistent with the justified and restrictive application of the limits on access to information. In particular, the CTBG considers that the confidentiality of information on the price of medicines is justified because of the possibility it offers to *"maximise patients' access to innovative medicines"* and to allow *"each country to obtain the best possible price according to its circumstances (public covers, co-payments, economic capacity, etc.). (...) in balance with the necessary economic return for pharmaceutical companies."* Thus, the Council adds, *"if there were no confidence at the European level, prices would tend to equalize in a single value that could be relatively low for the richest countries, but too high for those with less economic capacity", which "could complicate access in those with fewer resources".*

Like the *Information Commissioner,* it can be seen that not only private business interests, but also, and especially, public health and budgetary interests, justify the confidentiality of such information.

2. RESOLUTION 478/2019/2019

***Date**: September 26, 2019*

***Administration/Agency:** Ministry of Health, Consumer Affairs and Social Welfare **Information requested:** Price and inclusion of medicines in the National Health System **Meaning of the resolution:** Discouragement.*

2.1. Background

1. According to the documents in the file. On April 22, 2019, the claimant requested the following information from the Ministry of Health, pursuant to Law 19/2013 of December 9, 2013, on Transparency, Access to Public Information, and Good Governance (LTAIBG).

> *The date, content and URL or electronic copy of the resolution (or any other document or procedure in this regard, to prevent the issue from being ignored due to terminology , in the same way as Request 001-032710) of the Directorate-General for the Basic Portfolio of Services of the SNS and Pharmacy, in which it was decided to prescribe and include drug X in the NHS.*
>
> *Since the resolutions regarding the first medicines are public because they are published, it does not make sense for the copies to be less public.*There is no response from the Administration.

2. On 8 July 2019, the applicant submitted, pursuant to the provisions of Article 242 of the LTAIBG, a complaint to the Transparency and Good Governance Council with the following content:

1. Application 001-034250 was submitted on 2019-04-22, I received notification of the start of the procedure by the relevant department day later.

2. The deadline for resolving requests for access to information is 1 month as provided for in article 20.1 of Law 19/2013, of 9 December, which in this case ended on 23/05/2019, without having received a response.

3. In accordance with the provisions of Article 20.4 of the Law, if the maximum period for a decision has elapsed without an express decision having been issued and notified, it shall be understood that the application has been rejected.

4. In accordance with the Interpretative Criterion CI/001/2016 on Article 20.2, the reiterated jurisprudence of the Constitutional Court set out therein, Articles 122.1 and 124.1 of Law 39/2015 and the Basic Guide for the Processing of Access Requests shall not be subject to a deadline.

For all these reasons, I file this claim in which it is REQUESTED.

That the competent body resolves favorably and as soon as possible the request for access to information that motivates this letter.

3. On 10 July 2019, the Council for Transparency and Good Governance forwarded the file to the Ministry of Health, Consumer Affairs and Social Welfare, through its Transparency Information Unit, so that it could make the allegations it deemed appropriate. This requirement was reiterated by this Council on August 21, 2019, in the absence of a response from the Ministry.

Finally, through a letter dated August 30, 2019, the Department made the following allegations:

In relation to this request, the criterion of this steering centre is the partial denial of access to information on the grounds provided for in article 14.1 (h), (j) and k) of Law 19/2013 of 9 December 2013 on Transparency, Access to Public Information and Good Governance (hereinafter, LTAIBG), namely: the limitation of the right of access to information when this may affect economic and commercial interests, professional secrecy and the guarantee of confidentiality in decision-making processes. Knowledge by third parties of the price agreed for a medicinal product, as well as its financing terms, entails revealing data of an economic nature affecting the business of the commercial entity which could be used by its competitors to its detriment. At the same time, and with regard to the necessary confidentiality and secrecy of administrative decisions when they may affect the particular interests of third parties, it must be borne in mind that a decontextualized disclosure of the information relating to the content of the resolution of X's price in Spain could have a serious impact on the determination of the price of the same medicinal products in other Member States of the European Union, whose pricing systems are based on those of neighbouring countries, with the consequent effect on the pricing policy of the same company in other countries and, to the detriment, once again, of the economic and commercial interests of the entity that owns it, protected by Article 14 of the Transparency Law.

That is why in the reply to the interested party, only the retail price notified by the owner of the medicinal product is provided, which

is the price that appears in the Official Catalogue of Drug Prices (Nomenclator).

II. In line with the above arguments, it is meant that any decision granting access to the requested information must pass, as a prior and any decision granting access to the requested information mus involve, as a prior and unavoidable step, the submission of the request to the entity that owns the medicinal product concerned. Since this submission has not been made in the context of the proceedings before this board – because it is considered unnecessary, in view of the reasoning set out above against the dissemination of the requested information – this procedure should be carried out at the current stage of the proceedings, as imperatively established in article 24.3 of the LTAIBG, according to which "when the denial of access to information is based on the protection of the rights or interests of third parties, prior to the resolution of the complaint, a hearing shall be granted to the persons who may be affected so that they may allege what is appropriate to their right".

4. In view of the allegations made and the provisions of article 24.3 of the LTAIBG– *when the denial of access to information is based on the protection of the rights or interests of third parties, prior to the resolution of the claim, the persons who may be affected shall be granted an opportunity to allege what is appropriate* to their to allege what is approriate to their right, on September 3, 2019, a hearing was opened in order for the company identified by the Ministry as potentially harmed by the disclosure XX FARMACEÚTICA, S.A., could make the allegations it considered appropriate in defence of its rights and interests. By letter of 17 September 2019, XX FARMACEÚTICA, S.A. stated the following:

In accordance with the provisions of article 14.1 h), j) and k) of Law 19/2013, of 9 December, on Transparency, Access to Public Information and Good Governance, the right of access to information may be limited when this may affect economic and commercial interests, professional secrecy and the guarantee of confidentiality in decision-making processes.

As stated by the Ministry of Health, Consumer Affairs and Social Welfare (MSCBS) in its response to the request for information relating to our medicinal product X, the knowledge by third parties of the agreed price of a medicinal product, as well as the conditions of its financing, means revealing data of an economic nature that would seriously affect our business as it could be used by a competitor. In addition, as stated by the MSCBS, it should be borne in mind that a decontextualized disclosure of the information relating to the content of X's price resolution in Spain could have a serious impact on the determination of the price of the same medicinal product in other Member States of the European Union, whose pricing systems take as a reference those of the countries around them. with the consequent impact on our company's pricing policy and, to the detriment, once again, of our economic and commercial interests, which are protected by the aforementioned Transparency Law.

2.2. Legal bases

1. In accordance with the provisions of Article 24 of the LTAIBG, in conjunction with Article 8 of Royal Decree 919/2014 of 31 October 2014 approving the Statute of the Council for Transparency and Good Governance[3], the Presidency of this Organisation is competent to resolve complaints that, prior to a possible and optional Contentious-Administrative Appeal, are presented within the framework of an access to information procedure.

2. Article 124 of the LTAIBG regulates the right of all persons to access public information, under-

stood, a ccording to article 13 of the same regulation, as "*the contents of the or documents, whatever their format or medium, which are in the possession of any of the subjects included in the which have been prepared or acquired in the exercise of their functions*".

Therefore, the Act defines the subject matter of a request for access to information as information that already exists, either because it is in the possession of the agency receiving the request, or because it has prepared it itself or because it has obtained it in the exercise of the functions and powers entrusted to it.

3. In the present case, it is necessary to begin by making a series of formal considerations concerning the time limit within which a request for access to information must be answered, the petitioner points out in his complaint.

> *In accordance with Art. 20 of the LTAIBG: The decision granting or refusing access shall be notified to the applicant and to affected third parties who have requested it within a maximum period of one month from the receipt of the request by the body competent to decide. This period may be extended for a further month if the volume or complexity of the information requested makes it necessary and upon notification to the applicant.*
>
> *Paragraph 4 of the same provision provides that if the maximum period for a decision has elapsed without an express decision having been issued and notified, the application shall be deemed to have been rejected.*

In the case at hand, as stated in the dossier, the request for information was submitted on April 22, 2019, and reached the competent body to resolve on the 23rd, according to the statements of the Ministry itself, and the notification to the interested party, so the term to resolve and notified expired on May 23. Notwithstanding the above, the Ministry has not issued a decision within deadline, finally making allegations once it has received the complaint, and after having been requested twice.

In this regard, it should be recalled that the Preamble to the Law, in order to facilitate the exercise of the right of access to public information, refers to the establishment of an agile procedure, with a short response time, and the creation of information units within the Central Administration. in order to make it easier for the citizen to know the body to which the application must be submitted as well as the competent body which will deal with it.

This Transparency Council has already ruled in previous cases (for example, in the case R/0100/20165 or the more recent R/0234/20186 and R/0543/20187) on this delay in the processing of the application by the Administration, concluding that this lapse of time, not attributable to the applicant but to the Administration, damages the interests of the former, which is in contradiction with the principle of administrative efficiency in Article 103.1 of the Spanish Constitution, according to which *"The Public Administration serves the general interests objectively and acts in accordance with the principles of efficiency, hierarchy, decentralization, decentralization and co-ordination with full submission to the law and the law"*. The Constitution's categorization of the duty to be effective as a principle implies that the Administration must not only respect the principle of legality the principle of legality in its actions, but must also provide all the material and human means to carry out the purpose assigned to it by the Constitution itself: the achievement of the general interest.

4. As regards the merits of the case, it should be noted that, as is apparent from the allegations made by the Ministerial Department, the reply to the request for information indicates that only the retail price notified by the

holder of the medicinal product is provided, which is the price set out in the Official Nomenclator of Prices for Medicinal Products.

However, the requested information (the date, content and URL or electronic copy of the decision on the price and inclusion in the NHS of drug X) is denied, because it is considered that the limits laid down in Article 14.1 (h), (j) and (k) apply, which provide that [ ] When considering the limits laid down in Article 14.1 (h) to apply, (j) and (k) which provides that the right of access may be limited where access to information would be detrimental to: (h) economic and commercial interests; (j) Professional secrecy and intellectual property; k) The guarantee of confidentiality or the secrecy required in decision-making processes.

The Administration, as does the interested third party, argues that the knowledge by third parties of the agreed price for a medicinal product, as well as its financing terms, entails revealing data of an economic nature affecting the business object of a commercial entity that could be used by its competitors to its detriment, and that the necessary confidentiality and secrecy, it must be borne in mind that a disclosure of the information relating to the content of the resolution of the price of X in Spain could have a serious impact on the determination of the price of the same medicinal products in other Member States of the European Union, whose pricing systems are based on those of neighbouring countries.

In the first place, it should be recalled again that the application of the limits contemplated in the LTAIBG must be in accordance with the Interpretative Criterion CI/002/2015, of 24 June, of this Transparency Council[8], drawn up according to the powers granted by its article 38.2 a), a criterion in which it is indicated that:

> *"The limits referred to in Article 14 of the LTAIBG, unlike those relating to the protection of personal data, do not apply directly, but in accordance with the wording of the text of the text of paragraph 1, "may" be applied.*
>
> *In this way, the limits do not operate either automatically in favour of refusal or absolutely in relation to the contents.*
>
> *The invocation of grounds of public interest to limit access to information must be linked to the specific protection of a rational and legitimate interest.*
>
> *In this sense, these limits will in no case be automatic: on the contrary, it will be necessary to analyse whether the acceptance of the request for information entails a specific, defined and assessable damage (damage test). This, moreover, cannot affect or be relevant to a certain material area, because otherwise a complete block of information would be excluded.*
>
> *Similarly, a justified and proportionate application is necessary in the light of the circumstances of the specific case and provided that there is no interest justifying publicity or access (public interest test)."*

It is also necessary to take into account the rulings adopted by the Courts regarding the application of those limits:

- Judgment No 60/2016 of 18 May 2016 of the Central Administrative Court No 6 of Madrid, delivered in OP 57/2015: "*(...) " The law recognizes the primacy of the subjective right to obtain information and, correspondingly, the duty to provide it, unless there are justified reasons that limit this right, as referred to in art. 14. Such reasons constitute indeterminate legal concepts whose relevance and significance must be specified in each case,* balancing the conflicting interests, as the rule indicates, in such a way that in the face of typically discretionary acts, (...).

- In the Judgment of November 7, 2016, issued in the Appeal filed against the Judgment of the lower court indicated above, the National Court expressly stated that *"And if any of the limits of Article 14 must be accredited".*

- Judgment no. 85/2016 of 14 June 2016 of the Central Administrative Court No. 5 of Madrid, handed down in ordinary proceedings 43/2015: *"Well, when interpreting that provision – 14.1 h–, we must bear in mind that the aforementioned Law, in its Preamble, expressly states that it broadly configures the right of access to public information and that this right will only be limited in those cases in which it is necessary due to the very nature of the information or because of its conflict with other protected interests". "Thus, the purpose, the principle and the philosophy that pervades the Act is broad access to public information;* ***and the limits to such access must be justified, interpreted and applied in a reasoned, restrictive manner and assessed according to the so-called damage test;*** *in the light of the determination of the prejudice that access to certain information may cause to the interest that the limitation is intended to safeguard."*

- Finally, the judgment of the Supreme Court of 16 October 2017 in Cassation Appeal No 75/2017 states the following: (...) *"This broad formulation in the recognition and legal regulation of the right of access to information* ***requires a strict, if not restrictive, interpretation of both the limitations to that right referred to article 14.1*** *of Law 19/2013 as the grounds for inadmissibility of requests for information listed in Article 18.1". (...) without accepting limitations that entail an unjustified and disproportionate reduction of the right of access to information (...)*

Likewise, the possibility of limiting the right of access to information does not constitute a discretionary power of the Administration or entity from which information is requested, since this is a broadly recognized right that can only be limited in the cases and under the terms provided for in the Law."

Taking into account all of the foreging and in view of the circumstances replicate in the background, it must be concluded that the application of the limits in the response to a request for information that is provided only when the interested party has filed a complaint before the Council for Transparency and Good Governance for negative silence rejecting it, is not in accordance with the interpretation made by both the Transparency Council and the Courts of Justice.

5. With regard to secret commercial information and possible damage to economic and commercial interests (art. 14.1 h), it is a consolidated criterion of this Transparency Council that the concept can be derived from the disclosure of what is ruled as a trade secret by Law 1/2019, of February 20, 2019, on Trade Secrets9, the transposition of Directive 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

Prior to this rule, the Commission Notice on the rules on access to the Commission's file in cases pursuant to Articles 81 and 82 of the EC Treaty, Articles 53, 54 and 57 of the EEA Agreement, and Council Regulation (EC) No 139/2004 (2005/C 325/07) stated:

3.2.1. Trade secrets

18. In so far as disclosure of information about an undertaking's business activ-

ity could result in a serious harm to the same undertaking, such information constitutes business secrets (...). Examples of information that may qualify as business secrets include: technical and/or financial information relating to an undertaking's know-how, methods of assessing costs, production secrets and processes, supply sources, quantities produced and sold, market shares, customer and distributor lists, marketing plans, cost and price structure and the sales strategy.

For its part, the directive reads as follows:

Businesses and non-commercial research institutions invest in acquiring, developing and applying know-how and information which is the currency of the knowledge economy and provides a competitive advantage. This investment in generating and applying intellectual capital is a determining factor as regards their competitiveness and innovation-related performance in the market and therefore their returns on investment, which is the underlying motivation for business research and development. (...) Recital 1.

(...) By protecting such a wide range of know-how and business information, whether as a complement or as an alternative to intellectual property rights, trade secrets allow creators and innovators to derive profit from their creation or innovation and, therefore, are particularly important for business competitiveness as well as for research and development, and innovation-. Recital 2.

(...) The unlawful acquisition, use or disclosure of a trade secret compromises legitimate trade secret holders' ability to obtain first-mover returns from their innovation-related efforts. Recital 4.

The unlawful acquisition, use or disclosure of a trade secret by a third party could have devastating effects on the legitimate trade secret holder, as once publicly disclosed, it would be impossible for that holder to revert to the situation prior to the loss of the trade secret. As a result, it is essential to provide for fast, effective and accessible provisional measures for the immediate termination of the unlawful acquisition, use or disclosure of a trade secret, including where it is used for the provision of services. (...) Recital 26.

Article 2 also defines trade as:

(...) information that meets all of the following requirements:

a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

b) it has commercial value because it is secret;

c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret;

Finally, the aforementioned Law 1/2019 defines as a trade secret *any information or knowledge, including technological, scientific, industrial, commercial, organisational or financial knowledge, that meets the following conditions:*

a) It is secret, in the sense that, as a whole or in the precise configuration and assembly of its components, it is not generally known to or readily accessible to persons belonging to the circles in which the type of information or knowledge in question is normally used;

b) It has a business value, whether actual or potential, precisely because it is secret, and

c) it has have been the subject of reasonable measures by its holder to keep it secret.

6. In view of the foregoing, in the opinion of this Council for Transparency and Good Governance, there may be a reasonable and not a merely hypothetical damage to economic interests and commercial with access to the content of the resolution (though not to its date) in which the price and inclusion in the SNS of drug X was decided, since the price of medicines is set by the Interministerial Commission on Drug Prices, to which the company that owns the medicine submits a request for price and reimbursement, together with a dossier used for the preparation of a report and an analysis of the application.

Among the criteria taken into account (Law 29/2006, of 26 July, on Guarantees and Rational Use of Medicines and Medical Devices10) and incorporated into the report (resolution) are the severity, duration and sequelae of the different pathologies for which the medicines are indicated; the specific needs of certain groups; **the therapeutic and social value of the medicinal product and its incremental clinical benefit taking into account its cost-effectiveness; the availability of medicinal products or other therapeutic alternatives for the same conditions at a lower price or lower cost of treatment, as well as the level of innovation of the medicinal product.**

The pharmaceutical industry justifies price confidentiality by the possibility it offers to *"maximize patient access to innovative medicines"*. In this regard, they state that this confidentiality allows *"each country to obtain the best possible price according to its circumstances (public coverage, co-payments, economic capacity...)", always in "balance with the necessary economic return for pharmaceutical companies". "If there were no confidentiality at the European level, prices would tend to equalize at a single value that could be relatively low for richer countries, but too high for those with less economic capacity,"* and that, they say, *"could complicate access in those with fewer resources."*

The arguments alleged, as stated in the factual background, in the opinion of this Transparency Council, are consistent with the justified and restrictive application of the limits on access to information and, specifically, the one set out in Article 14.1 h) of the LTAIBG.

Therefore, on the basis of the arguments set out in the preceding paragraphs of this resolution, and without prejudice to the deficient processing of the request for information that we have indicated, the complaint must be rejected.

2.3. Resolution

In view of the Background and Legal Grounds described, the complaint filed by XX, with entry on July 8, 2019, against the Ministry of Health, Consumer Affairs and Social Welfare, must be DISMISSED.

In accordance with Article 23, number 111, of Law 19/2013, of 9 December, on Transparency, Access to Public Information and Good Governance, the Claim provided for in Article 24 thereof is considered a substitute for administrative appeals, in accordance with the provisions of Article 112.2 of Law 39/2015, of 1 October12, on the Common Administrative Procedure of Public Administrations.

Against this Resolution, which puts an end to the administrative procedure, an Administrative Appeal may be filed, within a period of two months, before the Central Adminis-

trative Courts of Madrid, in accordance with the provisions of Article 9.1 c) of Law 29/1998, of July 13, 1998, Regulating the Contentious-Administrative Jurisdiction"[13].

The President of thel CTBG
P.V. (Art. 10 of R.D. 919/2014)

The Deputy Director General for
Transparency and Good Governance

[1] https://www.boe.es/buscar/act.php?id=BOE-A-2013-12887

[2] https://www.boe.es/buscar/act.php?id=-BOE-A-2013-12887#:~:text=Art%C3%ADculo%24.&text=art%C3%ADculo%2024.%20reclamaci%C3%B3n%20ante%20el%20consejo%20de%20transparencia%20y%20buen%20gobierno.

[3] https://www.boe.es/buscar/doc.php?id=-BOE-A-2014-11410#:~:text=Art%C3%ADculo%8.&text=art%-C3%ADculo%208

[4] https://www.boe.es/buscar/act.php?id=-BOE-A-2013-12887#:~:text=Art%C3%ADculo%2012.&text=Art%C3%ADculo%12.

[5] https://www.google.es/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiP_Kr_wva-GAxUS_QIHHTEGDFgQFnoECBIQAQ&url=https%3A%2F%2Fwww.consejodetransparencia.es%2Fdam%2Fjcr%3A3d826179-8e4e-4360-8789-edf3cce1a04d%2FR-0100-2016.pdf&usg=AOvVaw2R77lF0C-1CwdTEoh4qgZfb&opi=89978449

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[7] https://www.google.es/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjvjb6lxPaGAxVF_gIHHeUIDg0QFnoECBMQAQ&url=https%3A%2F%2Fwww.consejodetransparencia.es%2Fct_Home%2Fdam%-2Fjcr%3A5093e8b6-efcd-48cc-a995-3f69e4d75c88%-2FR-0543-2018.pdf&usg=AOvVaw2LC2aYbDy9f4Fg_QT-M21rK&opi=89978449

[8] https://www.google.es/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwi13KnCxPaGAxVkMD-QIHc_DAlMQFnoECBoQAQ&url=https%3A%2F%2Fwww.consejodetransparencia.es%2Fdam%2Fjcr%3A77d11404-2f9a-45e6-be70-d6c96409acd5%2FC2_2015_limites_derecho_de_informacion_Censurado.pdf&usg=AOvVaw04F-VlDC4mq0MvVehuIvq9z&opi=89978449

[9] https://www.boe.es/buscar/doc.php?id=-BOE-A-2019-2364

[10] https://www.boe.es/buscar/act.php?id=BOE-A-2006-13554

[11] https://www.boe.es/buscar/act.php?id=-BOE-A-2013-12887#:~:text=Art%C3%ADculo%2023.&text=Art%C3%ADculo%23

[12] https://www.boe.es/buscar/act.php?id=-BOE-A-2015-10565#:~:text=Art%C3%ADculo%112.&text=art%C3%ADculo%20112

[13] https://www.boe.es/buscar/act.php?id=-BOE-A-1998-16718#:~:text=Art%C3%ADculo%209

Beatriz Cocina Arrieta

TRANSPARENCY AND COMPETITION IN THE PHARMACEUTICAL SECTOR: A COMPLEX BALANCE

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RESUMEN: La transparencia, como mecanismo de control del poder público, está adquiriendo una relevancia notoria en los últimos tiempos, manifestándose una tendencia al reconocimiento del derecho de acceso a la información pública con un amplísimo alcance. Los límites a este derecho, previstos en la propia Ley de Transparencia, son de rara aplicación y el mercado farmacéutico no es una excepción. Proponemos que, en el análisis de ponderación de los intereses públicos y privados en juego, se incorpore el impacto que el conocimiento de cierta información puede tener en el proceso competitivo del mercado de que se trate, muy especialmente en el mercado farmacéutico. Ello estaría en línea con la preocupación manifestada históricamente por las autoridades de competencia en relación con conductas de empresas que han contribuido a un incremento de la transparencia en los mercados.

PALABRAS CLAVE: Transparencia; acceso a información pública; incertidumbre; medicamentos; Comisión Nacional de los Mercados y la Competencia.

ABSTRACT: Transparency is becoming increasingly relevant as a mechanism to control public authorities, confirming a widespread trend recognizing the right to access public information. The limitations to this right established in the Transparency Act are rarely applied, and the pharmaceutical market is not an exception. We propose that the impact of having access to certain information on the competitive process should be included when assessing the public and private interests at stake, especially in the pharmaceutical market. This would be consistent with the concerns repeatedly expressed by competition authorities in relation to corporate behaviors that have contributed to a higher degree of market transparency.

KEYWORDS: Transparency; access to public information; uncertainty; pharmaceutical products; Spanish Commission of the Markets and Competition.

1. INTRODUCTION

For some time now, transparency, as a mechanism for controlling public authorities, has been gaining significant importance. Since the entry into force, in December 2014, of Law 19/2013, on transparency, access to public information and good governance[2] ("Law 19/2013"), any person has the right – without the need to give reasons for their request – to access public information, understood as *"the contents or documents, whatever their format or method, that are in the possession of any of the subjects included in the scope of application of this title and that have been prepared or acquired in the exercise of their functions."* We are talking about public administration in a broad sense, at any level (national, regional and local), including public agencies and autonomous bodies, entities and corporations under public law, as well as state and regional institutions. We are also talking about any field of activity.

That regulation created the Council for Transparency and Good Governance ("CTBG"), whose purpose is to *"promote the transparency of public activity, ensure compliance with publicity obligations, safeguard the exercise of the right of access to public information and guarantee compliance with the provisions of good governance."* Specifically, the CTBG is competent to deal with complaints against the express or tacit resolutions of the administration regarding access. This Council periodically publishes its resolutions (www.consejodetransparencia.es), which are dozens per month; and settle claim claims of a very diverse nature.

The right of access established in Law 19/2013 is not absolute. Article 14 includes certain cases that limit it. Among them, and for the purposes that interest us (the pharmaceutical sector), there is the protection of economic and commercial interests (not specifically defined by the law), and intellectual property.

Article 14 itself already states that the application of the limits *"shall be justified and proportionate to their object and purpose of protection and shall take into account the circumstances of the specific case, especially the concurrence of an overriding public or private interest that justifies access"*, a provision that makes it clear that the starting principle is the right to access and, Limits to this right may be envisaged only exceptionally, provided that justified specific circumstances are revealed; limits that will also be applied in proportion to the specific interests that are intended to be protected[3]. Therefore, the limits of the article will be interpreted, as such exceptions, in a restrictive manner. The analysis of the CTBG's resolutions confirms this approach to the widest possible recognition of the principle of transparency and a very restrictive application of exceptions.

At European Union level, this issue has been ruled since 2001 by Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 on public access to European Parliament, Council and Commission documents[4]. These rules have been the subject of numerous judgments by the Courts of the European Union, which have confirmed that the purpose of the regulation is *"to assure the widest possible right of access to the documents of the institutions"* and that the exceptions, since they *"invalidate the principle of the the widest possible public access to documents, must be interpreted and applied strictly"* (see, for example, the judgment of the Court of Justice of the European Union of 17 October 2013, in Case C-280/11P5). This numerous jurisprudence could undoubtedly serve as an inspiration in our country.

The principle of transparency, and the rights that derive from it, must be welcomed as they represent the recognition of a power-

ful and effective mechanism for controlling the arbitrariness or negligence of the public authorities, directly related to the concept of democracy. However, it must be recognised that the possibility of exception recognised by Law 19/2013 itself cannot be taken to the extreme that, in practice, it means emptying that possibility of content. In the particular case of information relating to medicinal products, we believe that there are circumstances to conclude that the interests whose protection is intended to be protected by not disclosing the requested information - prima facie private - match with the public interest that it serves, as will be explained below.

In this article, we intend to (i) critically present some recent pronouncements of the CTBG; (ii) analyze the approach expressed by competition authorities in relation to conduct that results in greater transparency in the markets; (iii) understand what would be the concrete impact of greater (and forced) transparency in a market as sui generis as the pharmaceutical market; and (iv) to make some brief reflections by way of conclusions[6].

2. PRECEDENTS OF THE CTBG

In this section, we refer to some CTBG Resolutions on requests for access to documentation relating either to the financing of certain medicines or to their conditions of acquisition by the administration[7].

A first Resolution, regarding file R/0254/2015, dealt with the complete dossier for the approval of a certain medicine, a request that the Ministry of Health, Social Services and Equality rejected on the grounds that such dossier contained a technical report based on *"the economic data provided by the marketing authorisation holder or the new medicinal product under scrutiny, as well as its therapeutic alternatives."* According to the administration, that information was protected by Law 19/2013 and, in particular, by one of the interests listed in Article 14 thereof.

The CTBG, while criticizing the Ministry's response, which denied access to the entire file, considered it reasonable not to give access to information relating to *"the price-setting? procedure and it is understood that this information relates to the technical, economic and financial aspects that pharmaceutical companies bring to the attention of the Administration. (...) it also affects everything that allows us to know the expenses allocated to the pharmaceutical activity in Spain."* The CTBG (only) explains that this information is considered confidential by Royal Legislative Decree 1/2015, but it seems clear from the reasonableness criterion referred to in that Resolution that it prioritises an exhaustive assessment of the balance between the request for access and the commercial nature of the information requested. Thus, the CTBG urges the Ministry the information to provide the file *"eliminating the information that, under the rigorous assessment of the Ministry of Health, Social Services and Equality, relates to the matter declared confidential."*

The Resolution regarding file R/0239/2018 recognises a similar solution, leaving out from the applicant's right of access to the minutes of the meetings of the Interministerial Commission from 2007 to 2017 *"those classified matters or others whose dissemination is legally prohibited, at the balanced and fair discretion of the Administration."* The CTBG indicates, however, that only these matters deserve the protection of confidentiality since, it can be deduced, this is expressly indicated in the applicable regulations. The Resolution's express reference to the concept of trade secrets[8] suggests that they are excluded from access.

More recent resolutions of the CTBG follow a different line of reasoning, enshrining the right of access in a very broad way, combining it with a very restrictive interpretation of legal exceptions. We are referring to cases of requests for access to extremely sensitive information about medicines, such as

the cost per day and per capita of a certain medicine and, failing that, the corresponding ATC[9] code; the total number of products purchased, in volume and value, during 2015 and 2016, by a hospital in Castilla La Mancha Region[10]; the authorized Ex-factory Price of medicines approved in 2017 by the Interministerial Prices Interministerial Commission of Medicines[11] or the same information for a specific medicine[12]; or the detailed breakdown of public hospitals pharmaceutical expenditure in 2018, including information on the active ingredient, brand name, number of units, acquisition price and marketing company[13].

Leaving aside considerations relating to procedural issues (such as deadlines) or formal issues (such as the concept of reworking), we are particularly interested in how the real possibility of opposing a request for access is approached due to the existence of higher interests worthy of protection and the analysis carried out by the body, or lack there is a point at the end that must be deleted, in light of Article 14 of Law 19/2013.

We note in the above-mentioned resolutions that there is little reasoning for the non-application of Article 14, which could lead in practice to its devoid of content. In particular, in its Resolution regarding file R/0262/2019[14], the CTBG rejects the allegations of the requested administration, simply stating - with all due respect - that it has not explained why the invoked limit applies and that the information *"in view of its nature"*[15] does not harm the interests of individuals or legal entities. But it doesn't motivate him in turn either.

We had no objection if, first, we were not talking about information that fully affects - or directly is - what can be considered the most strategic and secret of the companies concerned (prices and commercial policy in general, investments, costs); secondly, because those undertakings have not always been called to the proceedings and have therefore not had the opportunity to defend their interests; and, finally, because the conclusions of the CTBG are based, in almost all cases, solely on the insufficiency of the arguments of the requested administration, which is precisely not the holder of the interests whose protection is invoked through Article 14 of Law 19/2013.

It is true that, in many of the cases referred to, the allegations of the administration required to deny access were, at the very least, unlikely; however, in the mentioned cases, the CTBG does not seem to feel the need or the temptation to go further in the analysis and effectively consider all the interests (public and private) in conflict, which we believe is what is required by article 14.2 of Law 19/2013. In this regard, while it must be required that the requested administration invoking a limit on access must justify it in a concrete manner to the satisfaction of the CTBG or the courts, nothing in the law 19/2013 obliges the CTBG to limit itself to what is invoked by the requested administration or the interested parties who may be called to the proceedings[16].

In this sense, and focusing on the purpose of this article, the aforementioned Resolutions have not taken into account the consequences that may arise from the general knowledge (by citizens, but also by other administrations and by other market operators) of information on prices, costs, investments, etc. relating to certain products and specific companies. We are referring here to the impact of that knowledge on the very process of price formation of such products and, therefore, on the competitive process, an impact that cannot be disregarded since the competition authorities have in many cases expressed their concern about a high degree of transparency in the markets.

In this regard, Article 14 of Law 19/2013 refers to the possibility of restricting access *("may be limited")* when access to the information would be detrimental to certain interests, but in no way prevents the CTBG or the requested administration from carrying out

To date, the CTBG has not taken into account the consequences that may arise from the general knowledge (by citizens, but also by other administrations and other market operators) of information on prices, costs, investments, etc. relating to certain products and specific companies.

an overall analysis, even taking into account, motu proprio, all the interests at stake. These including the protection of competition; This is all the more so when Article 14 expressly refers to the protection of economic and commercial interests (without identifying the subjects of such interests, which includes, for example, the State itself) and the protection of economic policy. For this reason, what we are proposing would not be contrary to the restrictive interpretation of the exceptions as indicated by the courts[17] to the extent that, depending on the case, those interests actually exist and must be protected[18].

Consistently and in view of what will be explained, we believe that it is imperative that the aspect we are analysing be incorporated into the weighted analysis of interests at stake in the application of Law 19/2013. This should in no way exclude an entire sector from the scope of that law; It is a question of taking into account, to a proportionate extent, i.e. in the light of the nature of the information requested and the specific circumstances of the market concerned, the impact (both negative and, where appropriate, positive) of greater transparency[19].

3. POSITION OF COMPETITION AUTHORITIES WITH RESPECT TO TRANSPARENCY IN THE MARKET

There are many cases in which, both at European Union and national level, exchanges of strategic information between competitors have been sanctioned because they increased the degree of transparency of the market and thereby weakened or eliminated the degree of uncertainty about the functioning in the market.

As early as a 1992 decision (*UK Agricultural Tractor Registration Exchange* case),[20] the European Commission stated as follows: *"In the absence of the Agreement, companies would have to compete in the market with a certain degree of uncertainty as to the precise location, extent and means of possible offensives by their rivals. Such uncertainty constitutes a normal risk of a competitive situation which, in turn, fosters greater competition, since price reactions and reductions cannot be limited to the level strictly neces-*

sary to defend the position acquired. Uncertainty would lead companies to compete more intensely than if they knew exactly the magnitude of the reaction needed to cope with competition. They would have to go beyond a minimal reaction, for example by offering more favourable discounts to facilitate the movement of their stocks or by offering discounts on a larger number of products or areas. The Agreement decreases uncertainty by disclosing the actions and reactions of all its members (...). In this way, the Agreement necessarily leads to the prevention of invisible competition." The information exchanged in this case concerned the retail sales volume and market shares of eight manufacturers and importers of agricultural tractors on the United Kingdom market.

Years later, in 2011, the European Commission updated its Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements[21] and included a chapter dedicated to exchanges of information. This assessment, which is currently the reference legislation (although they are not binding as guidelines), confirms the 1992 approach (paragraph 61): *"(...) The exchange of information may constitute a concerted practice if it reduces strategic uncertainty in the market thereby facilitating collusion, i.e. that is, whether the data exchanged is strategic. Thus, the exchange of strategic data between competitors amounts to concerted action, because it reduces the independence of competitors' conduct on the market and diminishes their incentives to compete."*

The Guidelines define what is to be understood by strategic information (paragraph 86): *"prices (i.e. actual prices, discounts, increases, reductions or rebates), customer lists, production costs, quantities, turnover, sales, capacities, qualities, marketing plans, risks, investments, technologies and R&D programmes and the results thereof. Generally, price and quantity information is the most strategic, followed by cost and demand information."* However, they add that exchanges of aggregated strategic information are much less likely to have restrictive effects on competition because they make it sufficiently difficult to identify the development of each company (paragraph 89), although that may not be the case in the case of restricted oligopolies, that is to say, where supply is seriously reduced.

It is also relevant whether or not the information is current or recent: the less old the information, the greater the possibility of intuiting the future behavior of the companies to which it refers.

This theoretical approach has also been applied by The Spanish National Markets and Competition Commission (CNMC) – the previous competition authorities– in many cases; Examples include the decisions handed down in the cases of Beer Statistics[22], STANPA[23], Professional Hairdressing[24], Automobile Manufacturers[25] and, more recently, Tobacco[26]. In all these cases (except the first[27]), the CNMC imposed severe sanctions.

The Guidelines also recognise, however, that exchanges of information can generate efficiencies, both for companies because they can organise themselves better by knowing the evolution of the market as a whole, and for consumers, who reduce their search costs (paragraph 57). But these efficiencies can only be generated, in principle, when the information does not allow companies to infer the evolution or intentions of specific competitors (therefore, the information is aggregated, or not strategic, or historical). This confirms that the assessment of exchanges of information, in terms of impact on the market, depends on the circumstances in which they occur, unless they are mere instruments for monitoring a cartel, in which case they will always constitute an infringement.

And, always depending on the circumstances of each case, there is consensus on what has been said so far: exchanges of strategic information can have restrictive effects on competition because they can reduce the incentivesof companies to compete.

It is true that the mentioned cases led to sanctions because the greater transparency derived from agreements for the exchange of information between competitors, even though the existence of an "agreement" is one of the key elements of the type of sanction listed in the Law on the Defense of Competition and in the Treaty on the Functioning of the European Union[28]. However, the fact remains that the specific concern of the competition authorities lies in the knowledge of strategic information on the part of competitors, from which their use in determining their own business strategy necessarily derives and, hence, the reduction of the intensity of competition.

The existence of an agreement is relevant only for the purposes of determining the competence of the CNMC to assess the existence of an antitrust offence and to sanction it. But whether the information comes from another company or from the administration itself, the legal right protected remains the same: the maintenance of an acceptable degree of uncertainty in the market as a mechanism to protect the competitive process.

4. SPECIFIC REFLECTIONS ON THE PHARMACEUTICAL SECTOR

We have already said that transparency must be assessed in the light of the characteristics of the market in question, that is to say, the conditions of competition which exist in that market. In this respect, as we have also said, the pharmaceutical sector is not a typical market.

To begin with, the reference markets are defined based on the therapeutic applications of the products, sometimes even taking into account the presentation or method of application of the products, and the distribution channel (hospitals, pharmacies). Therefore, markets are often small, not necessarily by volume or value, but by number of operators. In addition, the importance of intellectual property rights (especially patents) means that, on many times, there are situations of monopoly or oligopoly. The barriers to entry, for example due to the relevance of R&D and the high sunk costs, are significant, when competition is also determined more by investments in R&D than by prices, because these are largely limited by the administration. Indeed, at least in Spain, a large number of operators share the Social Security system as a relevant customer, which also means that purchasing through public bidding procedures is more than common. In addition, the sector is highly regulated and there is already a significant degree of transparency; but the health systems remains beeing an exclusive competence of the sovereign Member States, and different financing systems co exist in the European Union.

In those circumstances, when it comes to making information transparent regarding the unit cost of acquisition of certain products, or costs incurred by Companies in R&D (relevant for negotiations on the financing of medicines), i.e. data that affect key factors for competition such as prices, particular economic conditions and costs, it cannot be denied that competition in the market is being disrupted or, at the very least, there is a more than theoretical risk that it will be disrupted. Knowledge by competitors of this information, which is requested in most cases with an extreme breakdown and detail, would mean, according to the precedents we have mentioned, a dramatic reduction in uncertainty that could lead to undesirable alignments.

On the other hand, consideration should be given to the impact that advertising of commercial conditions granted by a company to a particular customer (public system) could have. It is precisely the confidentiality of the agreed prices, in particular the particular economic conditions, by virtue of the negotiation held with that customer, which allows them to be granted as long as the company can profitably discriminate prices between customers. Otherwise, (i.e., if all customers are aware of the conditions applied to each of them), it is likely that the provider will prefer not to grant particular conditions to a client facing the risk of having to generalize them among all of them (and generalize the lower profitability as well). Far from leading to a reduction in prices for all customers, transparency would possibly imply an increase in prices in this case[29].

In the light of what we have said, it would be desirable - even imperative, as we have already indicated - for the above considerations to be taken into account when deciding whether certain information should be made public. Otherwise, there would not be a genuine balanced analysis of all the interests at stake, as we understand Article 14.2 of Law 19/2003 to requires.

5. CONCLUSIONS

Transparency is, without doubt, an obvious tool for controlling the exercise of public power. It is necessary – possibly essential – in democratic systems, such as ours. The current trend both in Spain and at the European Union level is aimed at expanding the proactive publicity, by the administration, of its activity, expenses and planning; and the right of access by citizens or interest groups, who do not even need to invoke a legitimate interest or give reasons for their request.

Our 2013 Transparency Law is marked a milestone in this area and requests for access - of a very diverse nature - are multiplying every month on the Transparency Council's website. There have also been requests regarding the detail of public pharmaceutical expenditure, which is not surprising given the relevance it has in the Spanish public sector as a whole.

The Council's resolutions in this area provide a somewhat limited analysis of all the public and private interests at stake, in the light of the type of information and detail requested, as well as the characteristics of the pharmaceutical market.

It is in no way intended to argue that this sector should be excluded from the Transparency Law; rather, it seems appropriate to take a holistic approach, in order to find a balance between the right of citizens to know public spending, the commercial interests of the companies concerned (expressly recognized in the Law) and the impact of all this on the conditions of competition in the market. It is a complex balance, but it is undoubtedly necessary to avoid greater evils[30]

[1] Counselor at Cuatrecasas. Opinions are personal. The author would like to thank Carlos Alberto Ruiz and Pablo García Vázquez for their contribution to this article.

[2] Official State Gazette number 295, 10/12/2013.

[3] The Explanatory Memorandum states in the following terms: *"the limits provided for shall be applied on the basis of a test of harm (of the interest to be safeguarded by the limit) and of the public interest in disclosure (meaning that in the specific case the public interest in the disclosure of the information does not prevail) and in a manner proportionate and limited by its subject matter and purpose."*

[4] Official Journal of the European Union (OJEU) L145, 31.5.2001, p. 43.

[5] ECLI:EU:C:2013:671.

[6] In the following articles published in previous issues of Cuadernos de Derecho Farmacéutico, the debate we are proposing is masterfully exposed, although in broader terms than those covered here: *"Transparency in the setting of drug prices and hospital supply contracts",* by Alberto Dorrego de Carlos (CDF nº 66, page 33) and *"The transparency of drug prices",* by Jordi Faus Santasusana, Mercè Maresma Casella and Laura Marquès Mas (CDF nº 68, page 18).

[7] Although some of these decisions have been appealed before the courts and annulled the reasons for these annulments derive from procedural errors and not from substantive issues.

[8] Directive (EU) 2016/943 of the European Parliament and Council Directive of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJEU L 157 of 15 June 2016, p. 1). The Resolution also refers to the definition of trade secret in the European Commission's Communication on the rules for access to the Commission's file in cases of application of Articles 101 and 102 of the Treaty on the Functioning of the European Union (OJEU C325 of 22 December 2005, p. 7).

[9] File R/0231/2017: (i) The evolution of the number of containers, DHD (daily inhabitant dose) and CTD (daily treatment cost) in containers and evolution of the amount, DHD (daily inhabitant dose) and CTD (daily treatment cost) in amount of the Truvada drug per year from the year 2000 to the present. (ii) If it is not possible to extract this information from the drug Truvada, I ask to provide with the same information for the active ingredient code J05AF30.

[10] File R/0475/2017: list of all pharmaceutical products purchased, during the years 2015 and 2016, from public budgets and through procurement procedures and other forms of procurement, by the General University Hospital of Ciudad Real, indicating the number of units purchased per referral/medicinal product as well as the unit amount paid from the public budget.

[11] File R/0257/2018.

[12] File R/0266/2018 (Sovaldi 400mg).

[13] File R/0262/2019: (i)) The breakdown of the medicines that make up hospital pharmaceutical expenditure for the year 2018, including information on the active ingredient, trademark, number of units, acquisition price and laboratory marketed, by each of the Autonomous Communities and other public administrations in an editable format (excel or scv). (ii) According to statements by the Director General of Pharmacy, Patricia Lacruz, 25.4% of hospital pharmaceutical expenditure corresponds to oncological drugs, so I request to know the complete information regarding this expenditure with the breakdown indicated above.

[14] See footnote above. The requested administration had refused to provide the requested detail because it undermined the guarantee of confidentiality or the secrecy required in the decision-making processes (article 14.1.k of Law 19/2013).

[15] Recall that this is hospital pharmaceutical expenditure corresponding to the year 2018, including information on the active ingredient, commercial brand, number of units, acquisition price and laboratory marketed.

[16] In fact, in one case, as far as we know R/0239/2018), the CTBG considers it necessary to refer to the possible implications in terms of personal data protection, *"even if they have not been expressly alleged by the Administration", to indicate that they the people who appear in the minutes "by reason of their position, in a governing body of an entity subject to the LTAIBG"* but of natural persons *"who are not public officials with decision-making capacity".*

[17] Judgment of the Supreme Court of 16 October 2017, in appeal 75/2017 (ECLI: ES:TS:2017:3530): *"(...) we have pointed out that the limitations contemplated in Article 14 of Law 19/2013 (...) must be interpreted strictly and based on the premise that the right of access to information appears configured in our legal system with a broad formulation, so that only limitations that are justified and proportionate are acceptable."*

[18] Precisely, in the judgment cited in the footnote above, in a market other than the pharmaceutical market, the Supreme Court reached this conclusion in the opposite direction by understanding that the interest in question did not exist: *"It is not questioned here that the RTVE Corporation is an operator that competes in a competitive market such as the audiovisual market; but, accepting that fact, it has not been justified that providing information on the expenses incurred to participate in the Eurovision Song Contest 2015 could lead to damage to economic and commercial interests, taking into account that no sensitive information is requested on the internal functioning of the Corporation, nor on its programme production system or cost structure; And the request does not even refer to a self-*

production program. In short, it is not possible to understand, nor has the appellant attempted to justify, how the provision of that information is likely to harm RTVE's commercial interests or favour its competitors on the audiovisual market. "

[19] Notwithstanding the above, it might be appropriate to consider general presumptions of confidentiality with respect to information of a certain nature, in a manner similar to what has been done at the level of the European Union (see, for example, the judgment of the Court of Justice of European Union of 16 July 2015, in Case C-612/13P, ECLI:EU:C:2015:486). Envelope discussion of the application of a possible general presumption of confidentiality in the pharmaceutical field, see Opinion of Advocate General Gerard Hogan of 11 September 2011, in Cases C-175/18P (ECLI:EU:C:2019:709) and C-178/18P (ECLI:EU:C:2019:710). The appeals are still at the stage of being decided by the Court of Justice of the European Union.

[20] Commission Decision 92/157/EEC of 17 February 1992 relating to a proceeding under Article 85 of the EEC Treaty (IV/31.370 and 31.446 - UK Agricultural Tractor Registration Exchange) (OJEU L 68 of 13 March 1992, p. 19), confirmed by the Court of Justice of the European Union..

[21] OJEU C11 of 14 January 2011, pág. 1.

[22] Resolution of 31 March 2004, file A/329/02 (exchange of production and sales information, broken down by geographical area, type of beer and distribution channel).

[23] Resolution of February 7, 2011, file S/0155/09 (exchange of rates and sales in various working committees).

[24] Resolution of 2 March 2011, file S/0086/08 (exchange of sales and forecasts of price increases).

[25] Resolution of 23 July 2015, file S/0482/13 (exchange of information on commercial distribution strategies, brand results, remuneration and commercial margins of dealer networks, after-sales services and activities, marketing activities, end-customer campaigns, loyalty programmes).

[26] Resolution of 10 April 2019, file S/DC/0607/17 (exchange of daily information on sales to tobacconists of all the brands of all the manufacturers to which Logista distributes, broken down by province).

[27] The Resolution in the Beer Statistics file occurred at a time when, in our country, restrictive agreements on competition had to be authorized by the competition authority; That authorisation was refused on the basis of the characteristics of the notified agreement. Currently, the reporting system has been replaced by a self-assessment system.

[28] EIn the absence of an "agreement" in the sense of a concurrence of wills, Article 1 of the Law on the Protection of Competition or Article 101 of the Treaty on the Functioning of the European Union (judgment of the Court of Justice of the European Union of 6 January 2004 in Joined Cases C-2/01P and C-3/01P, ECLI:EU:C:2004:2).

[29] This line of reasoning has recently been reflected by the Italian Consiglio di Stato (equivalent to the Spanish Supreme Court), in its judgment of March 17, 2017, in case 10086/2016, Agenzia Italiana del Farmaco - AIFA, Abbvie and Gilead Sciences. In that judgment, it is stated that the considerations relating to the impact on the level of discount are linked to the public interest in keeping public expenditure under control.

[30] At the time this article went to press, we were aware of a Resolution of the CTBG that would have rejected a request for access to information on the prices of a drug based on considerations similar to those set out in this article. We welcome what seems to be a change in trend, which we hope will be consolidated in future CTBG Resolutions as well as in the judicial reviews of them.

Irene Moreno-Tapia

DECISION OF THE IRISH *INFORMATION COMMISSIONER* DATED 13 APRIL 2018, ON THE APPLICATION OF TRANSPARENCY STANDARDS TO THE PRICES OF PUBLICLY FUNDED MEDICINES

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RESUMEN: El artículo reseña una resolución del *Information Commissioner* irlandés (Resolución de 13 de abril de 2018, caso 170395), que analiza una cuestión que era entonces, y continúa siendo, de la máxima actualidad: el conflicto entre los (legítimos) intereses de transparencia en relación con los precios de los medicamentos financiados con cargo a fondos públicos, y la necesidad de mantener confidenciales las condiciones de precios ofrecidas por las empresas a los Estados. El interés de esta Resolución radica en que reconoce que la información obrante en los expedientes de solicitud de financiación de medicamentos debe ser mantenida confidencial por el Estado, puesto que existe un interés público relevante en asegurar que el Estado esté en la mejor posición posible para negociar mejores condiciones con las compañías farmacéuticas. Este interés ha de prevalecer frente al interés público en asegurar que los organismos gubernamentales sean transparentes y se responsabilicen del uso eficiente de los recursos.

PALABRAS CLAVE: Transparencia; confidencialidad de precios de los medicamentos; intereses económicos y comerciales; precio y financiación de medicamentos.

ABSTRACT: The article reviews a decision of the Irish Information Commissioner (Decision of 13 April 2018, case 170395), which discusses an issue that was then, and remains, highly topical: the conflict between the (legitimate) interests of transparency in relation to the prices of publicly funded medicines, and the need to keep the pricing conditions offered by companies to States confidential. The interest of this Resolution lies in the fact that it recognises that the information contained in the application dossiers for the financing of medicines must be kept confidential by the State, since there is a relevant public interest in ensuring that the State is in the best possible position to negotiate better conditions with pharmaceutical companies. This interest must prevail over the public interest in ensuring that government agencies are transparent and accountable for the efficient use of resources.

KEYWORDS: Transparency; confidentiality of medicine prices; economic and commercial interests; price and reimbursement of medicines.

We present an interesting decision by the Irish Information Commissioner (Decision of 13 April 2018, case number 170395), regarding the application of transparency rules to decisions on medicines prices.

The *Information Commissioner* is the body responsible for reviewing appeals against the decisions of Irish public authorities and bodies regarding transparency under the Freedom of Information (FOI) Act of 2014. Although exact parallels with Spain cannot be drawn, the Information Commissioner performs functions similar to those attributed to the Transparency and Good Governance Council *(Consejo de Transparencia y Buen Gobierno)* in Spain under Law 19/2013, of 9 December, on Transparency, Access to Public Information, and Good Governance (the *"Transparency Law"*), and its statute (Royal Decree 919/2014, of 31 October).

This decision analyses an issue that is currently of the utmost importance in Spain: the conflict between (legitimate) transparency interests regarding the prices of medications developed with public funds and the need to keep the pricing conditions offered by companies to States confidential.

The decision is of enormous significance, as we will see, because it is not private business interests that conflict with the interest in making that information public. Instead, the Information Commissioner observes that there is significant public interest in preserving the confidentiality of those pricing conditions: if those conditions were to be disclosed everywhere, no company would likely offer them, depriving public coffers of the opportunity for significant savings.

Thus, it is concluded that granting access to confidential information about the conditions offered by pharmaceutical companies would *"seriously prejudice the financial interests of the State,"* justifying the refusal to provide the requester with that information under article 40(1)(a) of the Irish FOI Act.

The Spanish legal framework contemplates similar precautions. Specifically, article 14 of the Transparency Law provides that the right of access to public information may be limited when accessing it would cause harm to, among others, "economic and commercial interests" (subsection h) of article 14 of said Law). Similarly, Law 9/2017 of November 8 on Public Sector Contracts (LPSC), regulates various exceptions to the principles of publicity and transparency and the right of access to public procurement files, including, for the purposes of interest here, when the disclosure of that information may be contrary to the public interest or to the legitimate commercial interests of public (or private) companies (thus, among others, articles 155.3 and 154.7 LPSC).

Leaving aside possible considerations regarding (legitimate) private commercial interests, we believe that the reflections of the Information Commissioner on the possible impact on the State's public interests of publishing specific offers or agreements are fully applicable to Spain and should therefore also be considered by the bodies and authorities responsible for defining the currently unclear transparency policies regarding medicines prices in our country.

1. BACKGROUND

On 17 April 2017, the applicant made an FOI request to the HSE for:

- Copies of all internal and external correspondence between/from the office of the DG, the HSE primary care division, the HSE corporate pharmaceutical unit and the PCRS that referenced or concerned Orkambi/Vertex and/or new drug approvals since October 2016 to date.

- Copies of any communication between any of the above and the Department of Health as well as the Office of the Minister for Health that referenced or concerned Orkambi/Vertex and/or new drug approvals since October 2016 to date.

Decision of the Irish Information Commissioner dated 13 April 2018 (case number 170395), on whether the health service executive was justified in completely denying a request for access to records related to decisions on funding new medicines since october 2016.

- Copies of any communication from the HSE drugs committee to the HSE leadership team and/or HSE directorate that referenced or concerned Orkambi/Vertex and/or new drug approvals, as well as any related papers for consideration since October 2016.

- Directorate minutes (since October 2016 to date) relating to any new drug approvals.

- Any correspondence related to Orkambi within the HSE primary care division since October 2016.

The HSE did not issue a decision on the request within the statutory timeframe, effectively refusing it. The applicant sought an internal review of this effective decision on 22 June 2017. On 19 July 2017, the HSE issued its internal review decision, in which it granted full and partial access to some of the 70 records to which it had given individual consideration (the 70 records). It refused access to the rest of the 70 records under sections 15(1)(d) (information in the public domain), 30 (negotiations of an FOI body), 35 (confidential information), 36 (commercially sensitive information) and 37 (personal information). It refused access to other records relevant to parts of the request under section 15(1)(c) (voluminous records). It also referred to other records (the other records) that it said it was refusing under sections 31(1)(a) (legal professional privilege), 35 and 36. On 4 August 2017, the applicant sought a review by this Office of the HSE's decision.

I am now concluding the review by way of binding decision. In carrying out my review, I have had regard to the above correspondence; to details of contacts between this Office, the HSE, and the applicant; to the content of the 70 records, copies of which were provided to this Office for the purposes of this review; and to the provisions of the FOI Act. In the course of the review, members of my staff met with the HSE in order to get a better understanding of the process the subject of the records in this case. Material issues arising from the review in this case were put to the applicant for comment in this Office's email to her of 24 January 2018. I note that she did not reply to this email.

2. SCOPE OF THE REVIEW

This review is confined to whether or not the HSE has justified its refusal to fully grant the applicant's request.

2.1. The Reimbursement Approval Process

To give this decision some context, it is useful to set out the following background information provided by the HSE:

While there is a private market for medicines in Ireland, most pharmaceutical companies also want a HSE approved maximum reim-

bursement price for their medicine so that the medicine can be made available to patients who benefit from full or partial cover for their medicines' costs under various State schemes such as the General Medical Card Scheme and the High Tech Medicines Scheme. A maximum reimbursement price is the maximum price the State is willing to pay for a medicine that is so covered.

Section 21(2) of the Health (Pricing and Supply of Medical Goods) Act 2013 sets out seven factors that the HSE must take into account when considering the price submitted by a pharmaceutical company. One such factor is the agreement between the HSE and the Departments of Health and Public Expenditure and Reform, and the pharmaceutical industry (which is represented by the Irish Pharmaceutical Healthcare Association (IPHA)), regarding the setting of prices for medicines (the IPHA Agreement).

In essence, a pharmaceutical company submits an application form for a maximum reimbursement price to the HSE. The applicant specifies a maximum reimbursement price, which is calculated in accordance with the requirements of the IPHA Agreement (i.e. an average of the maximum reimbursement price for the same medicine in a number of specified EU member states).

If the cost is expensive (in the thousands of euro per patient), the HSE can send the medicine for health technology assessment (HTA). HTA is carried out by the National Centre for Pharmacoeconomics (NCPE), which is part of the Department of Health and based in St James' Hospital. It assesses the cost-benefit of the medicine based on clinical and cost-benefit data supplied by the pharmaceutical company. The NCPE sends the HTA results and its recommendation to the HSE. The HSE may still consider the medicine for reimbursement even if the HTA assessment is negative on cost grounds versus the patient benefit, but must follow the criteria set out in section 21(2) and Schedule 3, Part 3 of the Health (Pricing and Supply of Medical Goods) Act 2013. Schedule 3, Part 3 requires the HSE to consider nine criteria in deciding on the application, including the health needs of the public, the potential or actual budget impact of the medicine, the clinical need for it, and the resources available to the HSE.

The HSE's Director General has delegated his authority for deciding on reimbursement applications to a member of the HSE Directorate team. The HSE has also established a *"Drugs Group"* consisting of medical experts, who assess reimbursement applications for expensive medicines based on the documents and submissions made by the applicant companies, any summaries of information prepared by the HSE Corporate Pharmaceutical Unit, and the HTA results and recommendations. The Drugs Group makes a recommendation to the Directorate, which, including the Director General, is given full copies of the documents that were before the Drugs Group. The HSE Primary Care Reimbursement Service (PCRS) administers the reimbursement applications, the decisions and the prices.

Generally, where the main issue with an application is the proposed maximum reimbursement price (as opposed to any efficacy concerns), and before the final decision is made by the Directorate, there can be negotiations between the applicant company and the HSE, with the intention of reducing the price originally applied for. As noted above, that price is not freely determined by the applicant but is based on an average of the maximum reimbursement price for the same medicine in a number of specified EU member states. The HSE says that the pharmaceutical companies will not engage in price negotiations unless their pricing proposals and related information, and the general content of the negotiations, are kept confidential.

The HSE did not grant reimbursement approval to Vertex for its medicines (including

Orkambi) upon the first application. Discussions took place between the HSE and Vertex in 2016 and 2017, on the basis that the negotiations and information disclosed in them would be treated as confidential, to see if better terms could be arrived at. Further to the agreement reached, Orkambi (and another Vertex drug, Kalydeco) was added to the HSE's High Tech List on 1 June 2017.

3. FINDINGS

Section 15(1)(c) - retrieval of records/unreasonable interference with work due to volume and nature of records.

While that part of the HSE's internal review decision dealing with section 15(1)(c) says that the applicant had used the term *"and/or new drug approvals since October 2016"* throughout her request, it seems to rely on section 15(1)(c) only in so far as part 3 of the request included the term. However, the HSE's submission to this Office says it relied on section 15(1)(c) in so far as parts 1 to 3 contained the phrase *"and/or new drug approvals since October 2016"*. This Office informed the applicant of this in its email to her of 24 January 2018.

Section 15(1)(c) of the FOI Act provides that a request may be refused where *"in the opinion of the head, granting the request would, by reason of the number or nature of the records concerned or the nature of the information concerned, require the retrieval and examination of such number of records or an examination of such kind of the records concerned as to cause a substantial and unreasonable interference with or disruption of work (including disruption of work in a particular functional area) of the FOI body concerned"*.

Section 15(4) provides that section 15(1)(c) shall not be applied unless the FOI body has assisted, or offered to assist, the requester to amend the request for re-submission such that it no longer falls within the provision.

The HSE's email to the applicant of 30 June 2017 says it needed *"clarification … on an aspect of [the] request, specifically "and/or new drug approvals since October 2016"" and asked her to explain what she meant by the term. The applicant's reply of 7 July 2017 says "[j]ust novel drugs."*

The HSE's submission argues that searches for records covered by parts 1 to 3 of the applicant's request, even relating only to novel drugs, are such that section 15(1)(c) applies. It says it gets 30-50 reimbursement applications per year, and holds both hard copy and electronic records. While it is difficult to estimate how many records would be involved, it says that a preliminary search of electronic records in relation to four reimbursement applications resulted in more than 400 emails, with attachments containing 304MB of data, being located.

It supplied this Office with the details of the novel drugs that had been added to the HSE Reimbursement List of Items (which I understand to be reimbursed under the General Medical Card Scheme) and the High Tech List between October 2016 and 17 April 2017 (the Lists) i.e. 24 entries referring to different dosages of 10 drugs or tablets. I understand that the HSE also provided these details to the applicant with its internal review decision.

The HSE says that the Corporate Pharmaceutical Unit (with a staff of seven which, as the applicant knows, is responsible for the negotiation process itself), the Drugs Group, the Directorate, and the PCRS would hold records. It estimates that up two staff in each section would be involved in searching for records, for at least one or two days each, and that the examination process would require two or three staff (most likely from the PCRS) to be diverted to the task. Finally, it says that additional searches would be needed to look

for records held by staff who do not work in these areas/divisions.

Section 15(1)(c) is an administrative provision that recognises the burden that certain FOI requests can place on FOI bodies, and provides that such requests can be refused. Noting that the preliminary search for records relating to four applications resulted in 304MB of attachments, it is reasonable to assume that even if only 10 applications had been made in relation to the drugs added to the Lists from October 2016 and 17 April 2017, over 700MB of electronic records would be in scope of the applicant's request. I accept that this would be a considerable volume of records and does not include whatever other paper records may exist. It also seems to me that the diversion of staff within the Corporate Pharmaceutical Unit for the search and examination process described above could have a considerable impact on the usual work of that unit in particular. Thus, I accept that it would be unreasonable to direct the HSE to retrieve and examine the records it holds concerning the novel drugs added to the Lists between October 2016 and 17 April 2017.

However, before I can affirm the HSE's application of section 15(1)(c) to parts 1 to 3 of the request in so far as they concern *"new [i.e. "just novel"]* drug approvals since October 2016", I must consider if it has complied with section 15(4). The HSE considers the email to the applicant of 30 June 2017 to be sufficient and argues that section 15(4) does not require it to refer to or describe section 15(1)(c).

It is not reasonable to refuse a request under section 15(1)(c) when the requester does not know that the provision is likely to be relied on in the first instance and where they have not at least been offered some assistance to amend their request. I consider the HSE's email of 30 June 2017 to be simply an attempt to clarify what the applicant is seeking, and I find that it does not meet the requirements of section 15(4).

I cannot affirm the HSE's application of section 15(1)(c) in these circumstances, but neither do I consider it appropriate to direct it to search for and examine the records concerned. Accordingly, I annul the HSE's decision to rely on section 15(1)(c) in relation to parts 1 to 3 of the request in so far as they contained the phrase *"and/or new [i.e. "just novel"] drug approvals since October 2016*. Subject to the applicant's confirmation to the HSE that she wishes it to do so, I direct it to make a fresh decision on these parts of the request. Should the HSE wish to rely on section 15(1)(c), which it is entitled to do, it must properly comply with section 15(4) and, if relevant, consider any attempt that the applicant may make to amend the scope of these parts of her request before relying on section 15(1)(c). Any decision by the HSE to rely on section 15(1)(c), or any other FOI Act provision, is subject to the statutory rights of internal and external review.

Section 15(1)(d) - information already in the public domain

Section 15(1)(d) may be relied on to refuse records where the information is already in the public domain. The HSE's internal review decision gave the applicant details of where records covered by part 4, and some records that seem to me to be relevant to part 1, are available online. I accept that the records concerned are in the public domain. I find that section 15(1)(d) applies to them.

Section 37 - personal information

The HSE has refused access to three of the 70 records on the basis that they contain personal information and are exempt under section 37(1). Records 23, 49 and 52 (in part) concern contacts with the HSE by advocacy groups regarding the funding of Orkambi with reference to particular individuals. I accept that granting access to the relevant details would identify the individuals concerned. I find that the details concerned contain personal infor-

mation and are exempt under section 37(1) of the FOI Act, which requires personal information to be protected. I do not consider the exceptions to section 37(1) (including the public interest test at section 37(5), having regard to the weight of the public interest in protecting Constitutional rights to privacy) to apply.

Section 40(1)(a) - information having a serious, adverse effect on the financial interests of the State

The HSE has relied on a number of provisions of the FOI Act in relation to the remainder of the 70 records i.e. sections 30(1)(c) (positions or procedures for negotiations of the Government or an FOI body), 35(1)(b) (information subject to a duty of confidence), 36(1)(b) (information resulting in a material financial loss or gain to, or prejudice to the competitive position of, the person to whom it relates), and 36(1)(c) (information prejudicial to negotiations of the person to whom it relates). I do not necessarily disagree with the HSE's decision to rely on these provisions. However, based on its arguments set out below, in my view section 40(1)(a) is the more appropriate exemption to consider in the circumstances of this case.

Section 40(1)(a) provides that a request may be refused if the head of the body is of the opinion that *"access to the record could reasonably be expected to have a serious, adverse effect … on the financial interests of the State"*. For section 40(1)(a) to apply, the potential harm that might arise from disclosure must be identified - a serious, adverse effect on the financial interests of the State - and the expectation that the harm will occur must be reasonable.

The HSE says that:

> It has a limited budget to spend on novel drugs. Pharmaceutical companies have a monopoly on new and unique drugs, and they make 30-50 reimbursement applications each year.

It is possible for the HSE to be transparent if it agrees to pay the initial price quoted by the companies in their applications. While the companies will enter into negotiations with the HSE about its first price/offer, which result in better overall deals from a public expenditure perspective, these are contingent on confidentiality. Confidentiality is a feature of all deals the HSE has made with pharmaceutical companies, as it is of Patient Access Schemes made by health authorities in other countries. It has achieved savings of, conservatively, over €500m over the next decade as a result of such deals.

Various oversight mechanisms are in place, such as the Comptroller and Auditor General, who would have access to relevant records but would also be required to observe the confidentiality requirements imposed by the companies on the HSE.

If the HSE disclosed the details of any confidential negotiations and their outcome to the world at large (which is understood to be the equivalent of a grant of access to a record under FOI), other pharmaceutical companies would refuse to negotiate with it. The increased expenditure on the drugs that these companies supply would either impact on budgets for other parts of the health service or result in fewer drugs receiving reimbursement approval.

4. ANALYSIS

I accept the HSE's position that the manufacturers of novel drugs have a monopoly. It seems to me that the circumstances are completely different to those of the typical case of an FOI body tendering for the supply of goods or services in a competitive market.

I also accept the HSE's position that, in the circumstances, it has no scope to negotiate better deals with pharmaceutical companies other than in complete confidence. In addi-

tion, I accept its position that disclosure of records covered by this request could reasonably be expected to result in pharmaceutical companies refusing to enter into negotiations with the HSE in future. The content of the records, which I have examined, supports the position outlined. There is no doubt that difficult and protracted negotiations take place and that the conflicting demands pose a dilemma for all involved, not least the patients who will benefit from access to the novel drugs.

As the applicant knows, I understand that the published Lists comprise the price that the HSE would have to pay for the relevant drugs if no deal was done. In the case of Orkambi, for instance, I note that one packet has a list price of €12,144 (a 28 day supply).

Based on 700 patients needing 13 packets a year, this drug alone would cost €110,510,400 based on its list price. While Orkambi may be a particularly expensive drug, I have no reason to dispute the amount the HSE says it has saved as a result of deals it has struck with drug manufacturers. It follows that I accept that the annual cost of treatment using novel drugs, in the absence of such deals, would be at considerable additional cost to the Exchequer.

In the circumstances, it seems to me to be reasonable to expect that granting access to the records *"could have a serious, adverse effect … on the financial interests of the State"*. I find that section 40(1)(a) applies in the particular circumstances of this case. This is subject to the consideration of the public interest test at section 40(3), however.

Section 40(3) must be considered regarding a record to which section 40(1)(a) applies. It provides that section 40(1) does not apply in a case where the public interest would, on balance, be better served by granting than by refusing to grant the FOI request concerned.

On the matter of where the public interest lies, I have had regard to the comments of the Supreme Court in *The Governors and Guardians of the Hospital for the Relief of Poor Lying-In Women v. the Information Commissioner*[2011] IESC 26 (the Rotunda case). In particular, the Supreme Court indicated that a public interest is *"a true public interest recognised by means of a well known and established policy, adopted by the Oireachtas, or by law"*. Although these comments were made in relation to another provision of the FOI Act, I consider them to be relevant to consideration of public interest tests generally.

The FOI Act itself recognises a public interest in ensuring that FOI bodies are open about, and can be held accountable for, how they carry out their functions. However, the Act also recognises a public interest in protecting information that is exempt under its provisions. Specifically in this case, there is a public interest in not granting access to information that could have a serious, adverse effect on the financial interests of the State.

The applicant says that there is much concern about the medicines approval process at present, which she describes as opaque and lacking in transparency.

The HSE argues that the procedures for seeking reimbursement approval (including the details of the IPHA agreement), as set out in the Health (Pricing and Supply of Medical Goods) Act 2013, are transparent. It also says that summaries of the HTA recommendations, along with list prices and the minutes of the HSE Directorate board meetings recording outline decisions taken on reimbursement applications, are published on the NCPE and HSE websites, respectively.

The HSE also refers to sections 7(1) and 7(5) of the Health Act 2004. Section 7(1) provides that the object of the HSE is *"to use the resources available to it in the most beneficial,*

effective and efficient manner to improve, promote and protect the health and welfare of the public." Section 7(5) obliges the HSE to have regard to the resources, wherever originating, that are available to it for the purpose of performing its functions, and the need to secure the most beneficial, effective and efficient use of those resources. The HSE argues that there is, accordingly, a clear statutory public interest in it using resources efficiently and achieving value for money.

It seems to me that the information already in the public domain serves the public interest in openness and accountability in this case to some extent. I accept that granting access to the records would further serve that public interest in that it would reveal the ultimate cost to the State of funding the various drugs, disclose the positions taken by the HSE in the negotiations, and promote accountability for the HSE's overall decision making process on reimbursement approvals. This public interest is entitled to significant weight, particularly when one considers the amount of public monies that are spent on novel drugs.

It must be recognised, however, that such details, by their nature, also disclose information about the negotiation tactics of the pharmaceutical companies and the deals they ultimately did with the State, which is information they require the State to keep confidential in order to do those deals. I also accept that there is a significant public interest in ensuring that the State, through the HSE, can continue to negotiate better terms with pharmaceutical companies, which reduce the overall costs of funding novel drugs and thus make funds available for other novel drugs or other health services.

I am conscious of the fact that the current system of arriving at a reimbursement process for medicines in order for the State to secure the best possible terms may not be ideal in terms of transparency and determining the value for money resulting from the particular deals struck. However, I can only consider the situation as it exists at present where there cannot be alternative suppliers.

Having considered the matter, I consider that the public interest in granting access to the records does not outweigh the public interest in refusing access to them. I also accept that sections 7(1) and (5) of the Health Act 2004 represent *"a true public interest recognised by means of a well known and established policy, adopted by the Oireachtas, or by law"* that weighs in favour of not granting access to the records.

Finally, section 18(1) provides, that *"if it is practicable to do so*", access to an otherwise exempt record shall be granted by preparing a copy, in such form as the head of the public body concerned considers appropriate, of the record with the exempt information removed. Section 18(1) does not apply, however, if the copy provided for thereby would be misleading (section 18(2) refers). Generally speaking, I take the view that neither the definition of a record nor the provisions of section 18 envisage or require the extracting of particular sentences or occasional paragraphs from the remaining withheld details for the purpose of granting access to those particular sentences or paragraphs.

I do not consider it practicable to attempt to extract any details in the records that might not qualify under section 40(1)(a) while at the same time ensuring that the redacted copies are not misleading under section 18 of the Act.

Other Records - withheld because of their general nature.

The HSE withheld more than 1,000 other records that it did not list in the schedule to its internal review decision, on the basis that they are exempt under sections 31(1)(a) (legal professional privilege), 35 and 36. It has said

that, given their general nature, the internal reviewer did not consider it necessary to conduct a detailed examination of the contents of each record.

It is not appropriate for this Office to decide on access to records in such circumstances. The most appropriate decision for me to make on these records is to annul the HSE's refusal of them and to require the HSE to undertake a fresh decision making process on them, subject to the applicant confirming to the HSE that she wishes it to do so. While not pre-empting any decision that the HSE may make, it is open to it to rely on section 15(1)(c) in relation to the records (subject to compliance with section 15(4)) in the first instance. Any decision to this effect, or under any other FOI Act exemption provision, is subject to the statutory rights of internal and external review.

5. DECISION

Having carried out a review under section 22(2) of the FOI Act, I hereby vary the HSE's decision.

I affirm its refusal of the records it refused under sections 15(1)(d) and 37. I affirm its refusal to grant full access to the remainder of the 70 records, albeit under section 40(1)(a) rather than the provisions explicitly relied on.

I annul its application of section 15(1)(c) to those parts of the request seeking records of *"new [i.e. "just novel"] drug approvals since October 2016"*, and its refusal of access to the 1000+ records that it withheld having regard to their general nature. I direct the HSE to undertake a fresh decision making process on these parts of the request/records, subject to the applicant confirming to the HSE that she wishes it to do so, and to inform the applicant of the outcome in accordance with section 13 of the FOI Act.

I specify that, subject to sections 24 and 26 of the FOI Act, effect shall be given by the HSE to my decision within five working days of the expiration of the 4 week period for the bringing of an appeal to the High Court from this decision as provided for at section 24(4) of the FOI Act.

Right of Appeal

Section 24 of the FOI Act sets out detailed provisions for an appeal to the High Court by a party to a review, or any other person affected by the decision. In summary, such an appeal, normally on a point of law, must be initiated not later than four weeks after notice of the decision was given to the person bringing the appeal.

Beatriz Cocina Arrieta

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