Bristows

Through inquisitive minds

Propuestas de cambio en la legislación farmacéutica comunitaria

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Agenda

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- Changes to regulatory exclusivities
  - Regulatory Data Protection
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Introduction

Parliament adopts its position on EU pharmaceutical reform

Press Releases PLENARY SESSION ENVI 10-04-2024 - 18:28

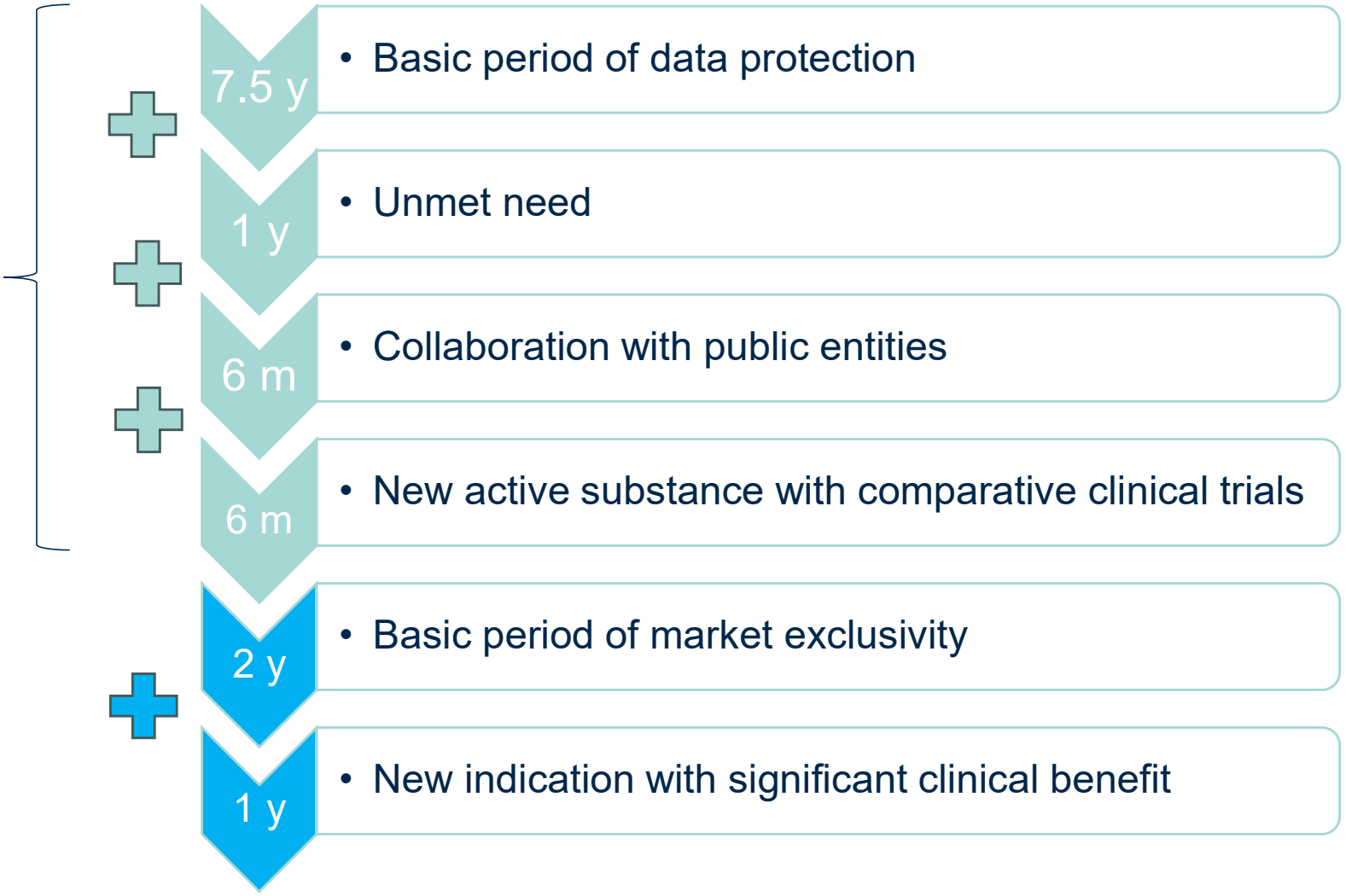
- Ensuring safe, efficient and quality medicinal products
- Fostering innovation and development of medicines to address unmet medical needs
- Boosting research in novel antimicrobials to fight antimicrobial resistance (AMR)

A recap: what preceded the European Parliament's Plenary Vote?

- European Commission (EC) issued a proposal to reform the EU pharmaceutical law in April 2023
  - The proposal was subject to heavy criticism from all trade associations, European Parliament (EP) and some Member States
  - Proposed RDP system particularly problematic, especially around the EC's proposal to improve timely and equitable access to medicines in all Member States (+2 years of data protection for launching in all Member States within 2/3 years of MA grant)
- ENVI at EP made substantial amendments to the proposals and adopted the proposals on 19 March 2024
- Proposal adopted by the European Parliament on 10 April 2024

Regulatory Data Protection: Goodbye to “8+2(+1)”

Total RDP period **capped** at 8.5 years



Unmet medical need (+ 1 year)

EP proposes to extend the incentive from 6 months to 1 year

- A medicinal product is considered to address an unmet medical need if at least one of its indications relates to a **life threatening or severely debilitating disease** and:
  - No medicinal product is authorised in the EU or a high morbidity or mortality remains even if there is a medicine approved; and
  - Use of the medicinal product results in a meaningful **reduction** in disease morbidity or mortality for the relevant patient population
- Orphan medicines are considered to address an unmet medical need
- For conditional MAs, extension only available if conditional MA has been converted into a full MA within four years of being granted

Collaboration with public entities (+ 6 months)

New incentive proposed by the EP

- MAH must demonstrate that a significant share of R&D related to the product was:
  - carried out in the EU; and
  - at least in part in collaboration with *public entities*
- Public entities include university hospital institutes, centres of excellence or bioclusters within the EU
- The EC to adopt further legislation setting out the procedural aspects and criteria related to this incentive

Comparative trials (+ 6 months)

EC and EP proposals coincide

- Clinical trials supporting the initial MA for a new active substance that use a **relevant and evidence-based comparator**
- The EMA to publish guidelines

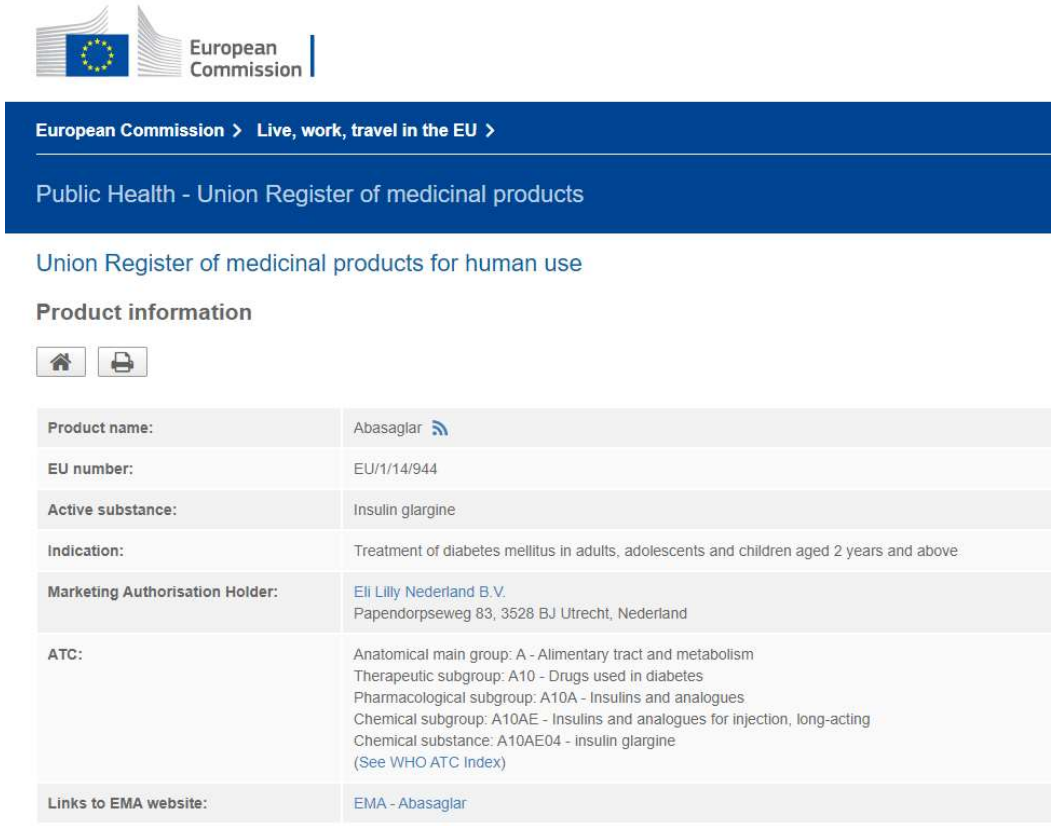
New indication with significant clinical benefit (+ 1 year)

Important divergence in terms of the type of incentive proposed by the EC and the EP

- Criteria for granting the additional protection is the same as the “+1” in the current regime
  - Significant clinical benefit over existing therapies
  - New indication to be granted during the data protection period
- There is no change to this reward and the “+1” extends the period of **market exclusivity**
- Extension can only be granted once

When will one know what the total duration of RDP for a particular product?

- EP proposes applicable periods of regulatory protection to be published and updated by the EC in the Union Register of medicinal products:



European Commission

European Commission > Live, work, travel in the EU >

Public Health - Union Register of medicinal products

Union Register of medicinal products for human use

Product information

Product name:	Abasaglar
EU number:	EU/1/14/944
Active substance:	Insulin glargine
Indication:	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above
Marketing Authorisation Holder:	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland
ATC:	Anatomical main group: A - Alimentary tract and metabolism Therapeutic subgroup: A10 - Drugs used in diabetes Pharmacological subgroup: A10A - Insulins and analogues Chemical subgroup: A10AE - Insulins and analogues for injection, long-acting Chemical substance: A10AE04 - insulin glargine (See WHO ATC Index)
Links to EMA website:	EMA - Abasaglar

Orphan medicines: back to basics

- Orphan Regulation (EC) 141/2000 to be repealed and incorporated into new draft Regulation for centralised procedure
- Criteria for orphan designation broadly the same, with deletion of “return on investment”
- Orphan medicinal products currently benefit from a period of market exclusivity of 10 years (+2 if paediatric reward is granted)
- During this period no MAA can succeed for the same therapeutic indication as the orphan medicine in respect of a similar medicinal product
  - Derogations apply: consent, lack of supply or clinical superiority

Orphan medicines: "*high unmet medical need*"

Medicine is considered to address a **high unmet medical need** (HUMN) if:

- There is no approved medicinal product in the EU for the condition, **or**
- Where there are medicinal products authorised for the condition, in addition to having a **significant benefit**, the applicant demonstrates that the orphan medicinal product will bring **exceptional therapeutic advancement** and the use of the orphan medicinal product results in a **meaningful reduction in disease morbidity or mortality** for the relevant patient population.

Orphan medicinal products: market exclusivity

EP proposes to extend the incentive for HUMN by 1 year, but to reduce it by 1 year for applications based on bibliographic data

Market exclusivity periods proposed by the EP

- 9 years for [regular/standard] orphan medicinal products
- 11 years for orphan medicinal products addressing a HUMN
- 4 years for orphan medicinal products where authorisation is based on bibliographic data
- **Transitional** provisions are still **uncertain** in relation to products granted under the **old** framework

Extensions

- + 1 year if the MAH obtains a MA for new indication for a different orphan condition at least 2 years before the end of the exclusivity period
  - It can be granted twice, each time for different conditions
  - This extension is in alternative to the data protection extension for new indications demonstrating significant clinical benefit

Paediatric reward

EC and EP proposals coincide

- Regulation (EC) 1901/2006 to be repealed and incorporated into new draft Regulation for centralised procedure
- Paediatric obligations remain the same
- 6-month extension to SPC remains
- +2 years of orphan market exclusivity disappears
- EMA to draw up guidelines on waivers

Priority antimicrobials

- “Priority antimicrobial”: antimicrobial with clinical data that underpin a **significant clinical benefit** with respect to antimicrobial resistance and:
  - New class of antimicrobial;
  - Mechanism of action is distinctly different from any other authorised antimicrobials; and
  - Contains a new active substance that addresses a multi-drug resistant organism and serious or life-threatening infection.

- EP proposed rewards:
  - Milestone payment reward scheme to be awarded by the EC
  - Subscription model for joint procurement of antimicrobials
  - Transferable data exclusivity voucher

Priority antimicrobial reward: transferrable voucher

EP dilutes the incentive and introduces stricter conditions

Transferrable data exclusivity voucher as proposed by EP: max + 1 year RDP

- Voucher: right to maximum of +1 year of data protection for one CAP within the first four years of data protection
  - RDP award depends on WHO priority of relevant pathogen:
    - 1 year for *critical*
    - 9 months for *high*
    - 6 months for *medium*
- Voucher can be transferred to another product but it cannot be used for a product which already benefitted from the maximum RDP period (8.5 years)
- Voucher can be sold once, but the EC to receive the monetary value which it then distributes in yearly instalments to the antimicrobial MAH

Proposal, progress, next steps and timing

- Proposal adopted by the European Parliament on 10 April 2024
- The proposal will be followed up by the new EP after the 6-9 June European elections
- The prospects of Ursula von der Leyen presiding the EC for a second term are high
- European Council's position is still unclear, despite some Member States having been vocal about some EC proposals
- Given the divergence between the positions of the EP and EC, the trilogues between them and the European Council will be key to agreeing the final language
- Transitional provisions: 18 months
- Best guess: main changes to be applicable from **2027**

Reactions

> **EFPIA responds to the European Parliament plenary vote: Despite improvements, the Pharmaceutical Legislation has a long way to go to restore Europe's competitive edge**

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Thank you

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