AIM Healthcare and social benefits for all

REFORM OF THE PHARMACEUTICAL LEGISLATION

Incentives : regulatory data protection, orphan market exclusivity

What is our feedback ?

- We are against any attempt at prolonging the duration of incentives beyond their duration as per the 2001/83 Directive, as it will have adverse effects on public health.
    - Currently, the European Union's incentives are among the most generous for companies globally[1], while launch prices of medicinal products increase year-on.
    - The longer the protection granted by incentives, the longer the considered product enjoys monopoly status, effectively locking patients out of access from generic and bio-similar medicinal products. In low- and middle-income European countries patients sometimes gain access to these new therapies only once there are generics on the market
    - Actually, past 10 years on average, it is generic competition which increases sales volume (= access to patients) for medicinal products (see Fig. 2 below). Any additional protection beyond those 10 years can amount to unnecessary costs for healthcare systems. The current Commission proposal foresees now up to 12 years of protection, which is already above those 10 years.
    - Some research indicates that for 13.5 years of protection, additional costs to the EU would be to the tunes of €19.5bn. An 18-year prolongation would be to the tunes of almost €100bn. This would put a severe strain on pharmaceutical budgets and would be a severe disruption of solidarity-based healthcare systems.[2]
    - The reduction of the duration of incentives does not mean that the product is not protected as the primary form of protection of medicinal products against competition is the patent. In addition, patents are also prolonged by supplementary protection certificates (SPCs). Currently, for a majority (65%) of medicines the last form of protection is the SPC or the patent.[3] These medicinal products are also the most lucrative medicinal products with average peak annual sales ranging from €300 mn to €360 mn and are going to be left untouched by the current Commission proposal. (See Fig. 1)
    - It should also be noted that incentives do not suffice to explain the degree and level of development of pharmaceutical products. Other factors such as workforce skilling, the existing research infrastructure, etc… explain the decision for companies to locate and develop pharmaceutical products.

[1] European Commission Impact Assessment on the pharmaceutical legislation, pp 37-38 https://health.ec.europa.eu/document/download/027a1084-0540-4bb6-b669-aa6cf3887684_en?filename=swd_2023_192_1_ia_en.pdf

[2] Medicines for Europe, Note for the rapporteurs/shadow rapporteurs of the EU Pharmaceutical legislation: Impact of extending the duration of regulatory data protection in the new EU pharmaceutical legislation. Available here : https://www.medicinesforeurope.com/wp-content/uploads/2024/01/MEMO-_-Impact-of-the-prolonged-exclusivites-.pdf

[3] "We expect this ratio among protection types to remain in the next 15 years, therefore the changes to the RP would concern **around 1/3 (i.e. 35%)** of the new medicines, which have a 23% share among all originator medicine sales in the EU.", European Commission Impact Assessment on the pharmaceutical legislation, p 38

- We are against extending the market exclusivity granted to orphan medicinal products in the proposed Regulation. The mechanisms governing this protection prevent any product from being placed on the market for the same indication if its clinical efficacy is not superior to a product already on the market which benefits from this protection. We may wonder whether it is appropriate to maintain such a mechanism to protect public health at a time when an increasing number of products treating orphan diseases are reaching the market at prices that are simply unaffordable (for example, Zolgensma[4], which was launched on the market for around $2 million in 2019, Libmeldy[5], the most expensive drug in history, which has been launched on the market for €2.5 million, and the forthcoming gene therapies). Market exclusivity effectively prevents drugs that could potentially have a similar level of therapeutic performance but potentially lower costs from being marketed. After this protection period expires and market exclusivity or patents are no longer in place, it is worth noting that biosimilars are rare for orphan drugs and prices stay high.
- We warn against the temptation to develop a bucket list of incentives as the more you add incentives options, the more you increase the chances that the most lucrative products capture additional protection years and manage to extend protections well beyond what they already have today.
- The regulatory data protection period in the Directive should be in *Article 81 Directive*:
    - Four years basic protection.
    - + 30 months, where the marketing authorisation holder supplied all Member States with sufficient quantities.
    - + 18 months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency.
    - + 12 months for an additional indication granted only once.
    - + 2 market protection years *(Article 80 Directive)*.
    - Total: 11 years maximum.
- The regulatory data protection period for orphan medicinal products in the Regulation shall be in the Regulation as follows:
    - 10 years for those orphan medicinal products covering High Unmet Medical Needs *(Article 71 Regulation)*.
    - 5 years for well-established use OMPs (authorised thanks to bibliographic data) *(Article 71 Regulation)*.
    - + 1 year if patient access in all MS *(Article 72 Regulation)*.
    - + 1 year per new indication for only one indication *(Article 72 Regulation)*.
    - Total: 12 years maximum.

[4] Insight: What happens when a $2 million gene therapy is not enough. Reuters, available here: https://www.reuters.com/business/healthcare-pharmaceuticals/what-happens-when-2-million-gene-therapy-is-not-enough-2023-08-12/

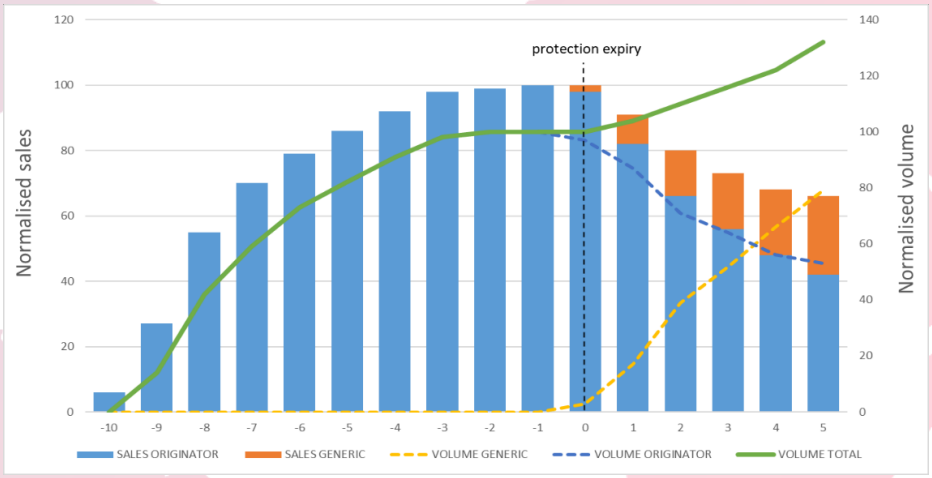
[5] The world's most expensive drug has been approved for use in Ireland, Belgium and the Netherlands. Euronews, 26 January 2024, available here: https://www.euronews.com/health/2024/01/26/the-worlds-most-expensive-drug-has-been-approved-for-use-in-ireland-belgium-and-the-nether

Fig. 1 - Medicines' protection period and revenues by their last layer of protection (for Europe)

Last line of protection	Number of products	Avg. protection duration	Avg peak annual sales[1]
Regulatory protection	69	10.1 years	€ 158.7 m
Market Exclusivity	12	10.7 years	€ 41.7 m
SPC	95	14.3 years	€ 368.3 m
Patent	23	16.7 years	€ 300.5 m
Grand Total	**199**	**12.9 years**	€ 268.2 m

Source: European Commission Impact Assessment on the pharmaceutical legislation, p. 38

Fig. 2 - Normalised sales and volume for products with 8+2 years of RP protection (baseline)



Source: European Commission Impact Assessment on the pharmaceutical legislation, p. 39