New Proposed European Commission Pharmaceutical Regulation – Potential Changes and Impact on Biosimilars

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OBJECTIVES

- To review the implications of the proposed changes in the European Union (EU) Commission pharmaceutical legislation
- To explore the impact of the new proposed European Commission pharmaceutical regulation on manufacturers of biosimilar medicines

METHODS

We reviewed the EU pharmaceutical legislation, compare the new legislation's implications, and considered how these changes could affect biosimilar medicines.

PROPOSED NEW LEGISLATION[1,2]

The proposed legislation consists of two proposals:

- A regulation of the European parliament and council (which would consist of a merger of the Orphan (EC 141/2000) and Paediatric Regulations (EC 1901/2006))
- A directive of the European parliament and council (which would consist of a merger of the Directive 2001/83/EC, Directive 2009/35/EC, Paediatric Regulation (Regulation (EC) No 1901/2006));

The objectives of the proposed legislation are to:

- Ensure the quality, safety, and effectiveness of medicinal products for patients in the EU, so that a high level of public health is guaranteed
- Provide an environment that is conducive to research, development and production of medicines, while fostering innovation and competitiveness
- Ensure that patients in any location within the EU have timely access to necessary medicines, without any disruption in the supply
- Improve the environmental sustainability of medicinal products

CHANGES TO THE LEGISLATION FOR BIOSIMILAR PRODUCTS

Bolar exemption

The 'Bolar exemption' enables manufacturers of generic medicines to be exempt from patent law under specific circumstances. In the new legislation the Bolar exemption will be clarified and broadened in scope.

Patent rights shall not be regarded as infringed when a reference medicinal product is used for the purposes of:

"(a) studies, trials and other activities conducted to generate data for an application, for:

(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;

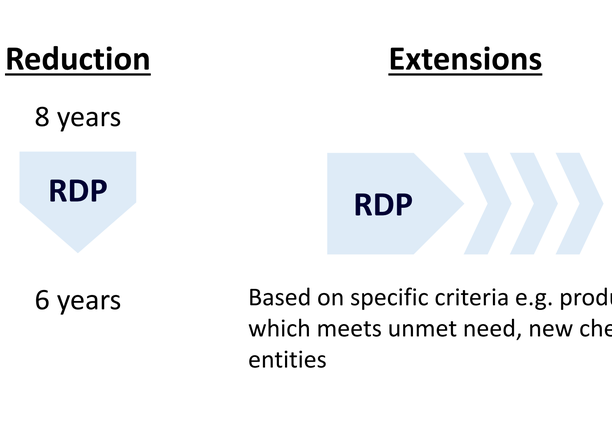
(ii) health technology assessment as defined in Regulation (EU) 2021/2282;

(iii) pricing and reimbursement.

(b) the activities conducted exclusively for the purposes set out in point (a), may cover the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers."[2]

Exclusivity period

The Regulation Data Protection (RDP) period for pharmaceutical products in the EU is proposed to be reduced. Additional RDP extensions may apply based on certain criteria.



Bioequivalence

Based on Member States (MS) experience with approved biosimilar medicinal products over the past 15 years, the evidence submission for bioequivalence will not be a requirement if equivalence of the generic medicinal product with the reference medicinal product is demonstrated.

Risk management plan

The risk management plan is no longer necessary if there are no additional risk mitigation measures available for the reference product.

IMPLICATIONS

Member States: Health Systems

- Increased clarity: The Bolar exemption covers all studies/trials for marketing authorization (MA), health technology assessment (HTA) and pricing and reimbursement (P&R)
- Increased consistency across MS
- Early market entry of generic and biosimilar medicinal products, contributing to patient access and affordability

Manufacturer:

- Improved clarity for manufacturers wanting to bring biosimilar products to market
- The exclusivity period will increase manufacturer interest in biosimilars and reduce the time to market. Conversely, manufacturers for non-biosimilar products may be discouraged from investing due to the possibility of reduced returns on investment
- Removing the requirement for the risk management plan and bioequivalence studies will result in reduced costs pre-/post-MA for biosimilars

Key: Negative Impact; Neutral or Mixed Impact; Positive Impact

CONCLUSIONS

Under the new EU legislation proposed, biosimilars may be able to enter the market faster due to shorter Regulatory Data Protection exclusivity on originator products and potentially less cost burden post marketing authorization. Launching biosimilars relates to many challenges including high development costs, high purchasing costs of the relevant reference comparator biologic products or high regulatory requirements. Shortened data protection for originators may incentivize biosimilar development leading to increased competition between drugs. That will improve equitable access to biosimilars for patients but may also cause unprofitable price drops for manufacturers amidst high development and purchasing costs.

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