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Law Alert

EU Pharmaceutical Legislation Reform

EU Commission Proposal

EU pharmaceutical legislation (Directive 2001/83 and Regulation 726/2004) has enabled the authorisation of safe, effective and high-quality medicinal products. After four years of deliberation, the EU Commission submitted its proposals for new legislation on 26th April 2023. The proposed revision of the abovementioned EU pharmaceutical legislation is the first momentous review of the pharmaceutical legislation since 2004. The aim of the reform is to enhance innovation and ensure timely and equitable access to medicines. Another objective of the reform is to enhance security of supply and address shortages through specific measures. To support the pharmaceutical sector's global competitiveness and innovative power, the right balance needs to be struck between giving incentives for innovation, placing more focus on addressing unmet medical needs, and taking measures towards more equitable access and affordability.

The proposed revision of the pharmaceutical legislation will consist of two legislative proposals: a new Directive, repealing and replacing Directive 2001/83/EC and Directive 2009/35/EC of the European Parliament and of the Council and incorporating relevant parts of the Paediatric Regulation (Regulation (EC) No 1901/2006) and a new Regulation, repealing and replacing Regulation (EC) No 726/2004, repealing and replacing the EU Regulation No. 141/2000 on "orphan" medicinal products and repealing and incorporating relevant parts of the Paediatric Regulation (Regulation (EC) No 1901/2006).

What is the scope of the reform?

- **The creation of a modulated system of incentives that rewards companies that fulfil important public health objectives:**
  Incentives will be given to companies which launch medicines in all Member States, develop medicines that address unmet medical needs, conduct comparative clinical trials or develop medicines that can treat other diseases as well (second indications of repurposing).
- **Faster availability of generics and biosimilars:**
  The reduction of the standard regulatory protection period as indicated in Article 14 par. 11 of Regulation 726/2014 by 2 years (6 years' data protection compared to 8 years today) results in early market access of more affordable options to patients and health systems. Moreover, the 'Bolar exemption'[1] will be broadened in scope and its harmonized application in all Member States ensured.
- **Transparency of public funding:**
  Given the practical difficulty to identify how indirect public funding instruments (e.g., tax advantages) have supported a particular product, marketing authorization holders will be required to publish a report listing all direct financial support received from any public authority or publicly funded body for the research and development of the medicinal product (clinical trials), whether successful or not.
- **Safeguarding the adequacy of medicines:**
  The European Commission's evaluation identified that shortages of medicinal products are an increasing problem in the EU. According to the preamble of the proposal for the new Regulation, all marketing authorization holders should have shortage prevention plans in place, to prevent shortages. The European Medicines Agency (EMA) should provide guidance to marketing authorization holders on approaches to streamline the implementation of those plans. The national competent authorities should be empowered to monitor shortages of medicinal products that are authorized through both national and centralized procedures, based on notifications of marketing authorization holders.
- **Regulatory framework amendments:**
  The reduction of the overall period for marketing authorization procedure from 210 days to 180 days is foreseen. The proposal also aims at optimising the regulatory support (e.g., scientific advice) to SMEs (small-medium enterprises) and non-commercial organisations, resulting in additional reductions of administrative costs for these parties. According to the proposed Regulation, scientific advice from EMA is also provided for any legal or natural person developing a medicinal product intended for paediatric use.
- **Environmental Awareness:**
  According to the Preamble of the proposal for the new Directive, the Marketing authorization applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment (ERA) or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorization should be refused.
- **Tackling antimicrobial resistance (AMR)[2]:**
  The scope of the abovementioned ERA is extended to cover new protection goals such as the risks of antimicrobial resistance. The reform introduces the AMR "vouchers" system. It will provide 'transferable data exclusivity vouchers' to developers of 'game changing' novel antimicrobials, which they can either use themselves or sell. The voucher will offer to the developer an additional year of data protection from competition for the medicine that the voucher applies to.

[1] Under which studies can be carried out for subsequent regulatory approval of generics and biosimilars during the patent or supplementary protection certificate protection of the reference medicinal product, according to art. 10 of Directive 2004/27 amending Directive 2001/83/EC.

[2] Antimicrobial resistance (AMR) is the ability of micro-organisms to survive or to grow despite the presence of an antimicrobial agent that normally inhibits or kills that micro-organism. AMR causes more than 35,000 deaths every year in the EU/EEA

What is the plan for the promotion of innovation?

To enable innovation and promote the competitiveness of the EU pharmaceutical industry, a system of incentives is proposed. Special incentives are offered for medicines delivering high unmet medical needs in the case of rare diseases. Marketing authorization holders will benefit from additional periods of data protection (beyond the standard six years) if they launch the medicinal products in all Member States covered by the marketing authorisation, +2 years, if they address unmet medical needs, +6 months, if they conduct comparative clinical trials, +6 months, or for an additional therapeutic indication, +1 year. According to the European Commission, the additional regulatory protection of 2 years if medicines are launched in all Member States is expected to increase access by 15%.
This means that 67 million more people in the EU could potentially benefit from a new medicine. In addition, the act provides an incentive for repurposing off-patent, added value medicinal products.

Are there any concerns?

According to the Proposal's Impact Assessment Report, SMEs may find it more difficult to adjust to a modulation of incentives linked to market launch as they often lack capacity to serve all Member States in a timely manner. Some stakeholders[3] have also expressed their concerns about the Commission's proposal to modulate and reduce the Regulatory Data Protection (RDP) period from eight (8) to six (6) years, since the eight-year protection has been crucial for steering the development of innovative therapies.

Meanwhile, stakeholders from the pharmaceutical industry warn that weakening market exclusivity protections could discourage companies from researching and launching treatments in Europe. The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Hellenic Association of Pharmaceutical Companies (SFEE) have also risen concerns about the impact of the policies set out across these proposals, on European competitiveness against mainly the USA and China, patient access and innovation. Other stakeholders have a negative view for the introduction of vouchers to encourage the development of new antimicrobials, as they believe that this could prolong pharmaceutical monopolies, undermine generic competition and severely slow down people's access to new, affordable medicines.[4]

What's next?

The Commission's Proposal will be discussed by the EU Parliament and the Council. In light of the emerging controversy between Member States and the impact this legislation will have on important stakeholders, it remains to be seen whether, when and how soon its adoption will be achieved.

[3] EUCOPE's statement on the Commission's proposal for the EU Pharmaceutical Package.

[4] European Commission Finally Releases Pharma Law Reforms, Proposing Cuts to Market Exclusivity for New Drugs at https://healthpolicy-watch.news/european-commission-finally-releases-pharma-law-reforms-proposing-cuts-to-market-exclusivity-for-new-drugs/

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