Revision of the EU General Pharmaceuticals Legislation

Policy Brief

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Summary: *The European Commission is proposing a major reform of the EU's pharmaceutical legislation to improve access, affordability, and innovation in medicines. The reform aims to address challenges such as slow patient access, unequal availability, high prices, and environmental impact. It also includes measures to combat antimicrobial resistance (AMR) and promote a One Health approach.*

Key Words: ***Reform, Medicines, Access, Innovation, Antimicrobial resistance (AMR).***

Introduction

In November 2020, the Commission introduced a Pharmaceutical Strategy for Europe with the goal of establishing a resilient and patient-centered pharmaceutical environment. This strategy is crucial for building a strong European Health Union and aligns with other initiatives like reinforcing health security frameworks, establishing the Health Emergency Preparedness and Response Authority (HERA), implementing the Beating Cancer Plan, and creating the European Health Data Space. It serves as the catalyst for a comprehensive revision of existing pharmaceutical legislation to address the current challenges in the EU pharmaceutical sector.

The Proposals

There are two proposals within this legislative package:

1. Proposal for a **Directive on the Union code relating to medicinal products for human use**, and repealing Directive 2001/83/EC and Directive 2009/35/EC

The main elements of this Directive include all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at EU and national level:

- ✓ Concerns regarding patient access to medicinal products and supply security are growing in the EU.
- ✓ Shortages of medicinal products in several EU/EEA countries are leading to decreased treatment quality and burden on healthcare systems.
- ✓ The pharmaceutical legislation offers regulatory incentives for innovation but does not ensure consistent patient access.
- ✓ There are market failures in developing priority antimicrobials and underutilization of scientific and technological advancements.
- ✓ The proposed EU pharmaceutical strategy aims to address these challenges through legislative and non-legislative actions.
- ✓ The reform focuses on ensuring timely and equitable access to medicines, enhancing supply security, supporting innovation, and reducing environmental impact.
- ✓ Simplifying the regulatory framework, adapting to scientific advancements, and reducing administrative costs are key objectives.
- ✓ The reforms aim to streamline procedures, enhance coordination, facilitate digitization, and provide regulatory support to SMEs and non-commercial entities.
- ✓ Cost reductions for businesses and administrations are expected, benefiting the pharmaceutical industry and promoting the 'one in one out' approach.

2. Proposal **for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency**, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

The proposed Regulation seeks to improve patient access, supply security, innovation, and environmental sustainability while simplifying the regulatory framework and reducing administrative burdens and costs:

- ✓ EU pharmaceutical legislation has allowed the authorization of safe and high-quality medicinal products, but concerns about patient access and supply security are growing.
- ✓ Shortages of medicinal products in the EU/EEA countries lead to decreased treatment quality and burden on healthcare systems.
- ✓ The legislation provides regulatory incentives for innovation, but not all patients have equal access to innovative therapies.
- ✓ There are market failures, particularly in the development of antimicrobials to address antimicrobial resistance.

- ✓ The proposed EU pharmaceutical strategy aims to ensure timely and equitable access to medicines, enhance supply security, support innovation, and reduce environmental impact.
- ✓ The strategy involves reviewing the pharmaceutical legislation and addressing factors beyond legislation that impact innovation, access, and affordability.
- ✓ The objectives of the proposal include guaranteeing public health, harmonizing the internal market, ensuring patient access, enhancing supply security, promoting innovation, and improving environmental sustainability.
- ✓ The proposed revisions aim to simplify the regulatory framework, reduce administrative costs for businesses and competent authorities, streamline procedures, enhance coordination, and facilitate digitization.

- ✓ The reforms are expected to benefit SMEs and non-commercial entities and yield cost savings for the pharmaceutical industry.

The reform also includes a **Council Recommendation** on antimicrobial resistance (AMR).

What does this mean for the pharma industry:

The pharmaceutical reform aims to enhance security of supply of medicines for EU patients and health systems, through preventative and reactive measures. It does so by proposing concrete measures, including the earlier notification of shortages and withdrawals, a company requirement to maintain shortage prevention plans for all medicines and the adoption of an EU list of critical medicines. The intention is to ensure the security of supply of those critical medicines, through recommendations on measures to be taken by supply chain stakeholders, and in certain cases by reinforcing those recommendations by imposing stronger obligations through Commission implementing acts.

Security of manufacturing and supply is a crucial element to ensure continued availability of medicines. **Strategic autonomy and reshoring are not directly addressed** in the proposal. However, there is sufficient flexibility to target specific vulnerabilities, including problematic dependencies, through those provisions described.[i]

Link to more information: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en

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[i] https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_1844