Assessing the Impact of EU Pharma Reform on Healthcare Resilience and Medicine Shortages

Recent medicine shortages across Europe have highlighted critical gaps in the resilience and security of our healthcare systems, prompting decisive action from the European Commission. Through an ambitious overhaul of pharmaceutical legislation, the Commission aims to strengthen supply chains, ensure reliable access to essential medicines, and foster sustainable innovation. But will these measures go far enough to secure Europe's health future? How will they impact other aspects of the pharmaceutical sector, from cost and production to job availability? This article explores the key pillars of the proposed Directive and Regulation, examining the far-reaching implications of these changes and addressing pressing questions on the path to a more resilient and responsive healthcare framework for the EU.

On 26 April 2023, the European Commission adopted a proposal for a new Directive and a new Regulation that revise and replace the existing general pharmaceutical legislation, under the following documentation:

- Proposal for a Directive of the European Parliament and the Council of the Union code relating to medicinal products for human use, repealing Directive 2001/83/EC and Directive 2009/35/EC.
- Proposal for a Regulation of The European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use, establishing rules governing the European Medicines Agency, and 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 new proposed Directive is based on four pillars, which include legislative and non-legislative elements:

1. Ensuring access to affordable medicines for patients and addressing unmet medical needs (in areas such as anti-microbial resistance and rare diseases).
2. Supporting competitiveness, innovation, and sustainability of the EU's pharmaceutical industry, and the development of high-quality, safe, effective, and greener medicines.
3. Enhancing crisis preparedness and response mechanisms, securing diversified and resilient supply chains, and addressing medicine shortages.
4. Ensuring a strong EU voice in the world, by promoting a high standard of quality, efficacy, and safety.

In this article, we will focus mainly on the third pillar 'Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, and addressing medicine shortages'; at the same time, we will discuss the common elements across all four pillars and how they relate to each other. For instance, developing high-quality, safe, effective, and greener medicines inevitably impacts the robustness and sustainability of the supply chain, awareness of utilisation, and medicine shortages.

As stipulated in the new proposed Directive, a Marketing Authorisation Holder must ensure the appropriate and continuous supply of a medicinal product throughout its lifecycle, regardless of whether it is covered by a supply incentive.

This is further defined as 'Crisis Preparedness and Response Planning':

1. Better availability of medicines, particularly critical medicines, to EU citizens will need to be guaranteed by setting up earlier warnings from pharmaceutical companies regarding shortages and withdrawals of medicines, including the establishment of prevention plans. Additionally, a list of medicines critical for the EU health systems will need to be drawn up by the Competent Authorities to identify supply chain vulnerabilities and improve the security of such critical supplies. Lastly, there will need to be better monitoring and mitigation of shortages, at both national and EU levels, and a stronger guiding role for the European Medicines Agency and the European Commission on security of supply. The main players mentioned here – pharmaceutical companies, national EU governments, the European Medicines Agency, and the European Commission – will play a crucial role in ensuring access to equitable medicines across the EU and coordinate the efforts across the various stakeholders.
2. To enforce compliance strongly with the new proposed Directive, a marketing Authorisation Holder who fails to comply with the regulations on a stable supply of products may face a fine of up to 5% of the previous year's turnover. Upon repetition, they can be fined daily up to 2.5% of each day's turnover.

There is broad consensus among the various stakeholders on guaranteeing a continuous supply of medicines, as shortages are widely acknowledged as a concerning reality. Especially following the Covid pandemic, which highlighted the need to prevent shortages. The main question remains on whether those measures will be sufficient, assuming seamless implementation, which we know is far from straightforward. Furthermore, what will be the impact of the measures taken on other aspects of the pharmaceutical sector?

In October 2023, the European Federation of Pharmaceutical Industries and Associations (EFPIA) assessed the main provisions of the revision of the pharmaceutical package.[1] The key recommendations on medicines shortage, in summary, were:

1. The creation of a harmonised EU prevention and mitigation system.
2. Increased transparency and understanding of demand, through timely (current and forward-looking) epidemiological data.
3. Use of the European Medicines Verification System (EMVS) for medicine shortage prevention and monitoring of Marketing Authorisation Holder's supplies to wholesalers and pharmacies, i.e. intelligence of the supply chain.
4. Adoption of a risk-based approach focused on critical products/critical shortages, leading to the implementation of targeted Shortage Prevention

Plans (SPPs) for critical products through a collaborative process across the various players. A clear, harmonised definition and list of critical products are needed to ensure a consistent approach at EU level.

It's obvious that harmonisation, as widespread as possible, is an essential yet challenging goal for the EU's general approach. Improved transparency across the supply chain has the potential to increase resilience and prevent shortages, but it's indeed questionable whether this can be achieved at the desired level for all types of treatment. At a minimum, it would certainly be desirable for critical treatments, defined as those with high potential medical impact and a risk of shortage – a classification that should, however, be coordinated at the European level.

However, if we want diversified, secure, and robust supply chains for critical treatments, especially in light of enhanced crisis response capabilities and improved response mechanisms, we must address the elephant in the room and talk about production at local EU level of both Active Pharmaceutical Ingredients (APIs) and Drug Products (DPs) versus production in distant countries with lower labour costs.

So how does a more influenceable and local production of APIs and DPs relate to the total costs associated to crisis response? And how is the European Commission influencing these dynamics? This discussion on the proposed EU pharma legislation reform aspects aimed at strengthening supply chain resilience, poses a few further questions:

- How is the EU parliament prioritising secure patient access, and are cost savings still a major force?
- How might shifting labour costs back to the EU/UK affect job availability, especially given the recent wave of industry layoffs?

The pharmaceutical industry has always recognised the need for dual supply of APIs and DPs and an intention to have a geographical spread. However, with today's global instabilities, the need for crisis preparedness will only strengthen and, in that respect, local production is potentially crucial. Established supply chain models must be re-assessed to avoid shortages of critical medicines.

One element to consider is that a large proportion of critical medicines available today are generics, for which the API and DP manufacturing processes were in many cases developed over twenty years ago. It should be possible to simplify those legacy processes with the help of modern technologies, thereby lowering manufacturing costs, even while downscaling. Why downscaling? To bring added, practical value, for instance with 'make to order' decentralised production, reducing carbon footprint and waste.

Local production could be stimulated by fast-track procedures for assessing variations to achieve this objective. With local production as a potential contributor to solving the puzzle, re-assessing infrastructure capacity is essential. This may, in turn, positively impact job availability, another key issue given recent industry layoffs.

Above all, there is a clear need for innovation: more efficient, more specialised engineering, automation, and robotisation. If ever there was a critical moment in our era for this paradigm shift, it is now. We must focus on this without delay, as innovation takes time, staff training takes time, and development of facilities takes time.

But if we are prepared to look at the bigger picture, we surely can be successful.

What Activities Should be Initiated by Pharmaceutical Companies to Leverage Crisis Preparedness and Response Planning?

Short-term

- Start writing procedures that meet each country's specific requirements on behalf of the Marketing Authorisation Holders to support continuous supply of product throughout its lifetime as per Directive 53.
- Start writing country specific procedures for notifying the competent authority of any plans to cease marketing of a product 12 months before last supply, or proposal to withdraw or temporarily suspend a Marketing Authorisation or any temporary disruption to supply as per Article 116.
- Writing of country specific product shortage prevention plans as per Article 117.
- Writing of country specific product shortage mitigation plans and risk assessments for suspension, cessation, or withdrawal of product from the market as per Article 119.

Long-term

- Development of new ideas and strategies for more cost-effective local production, via simplification, smart downscaling, innovative engineering, or shelf-life extensions.
- In alignment with antimicrobial awareness, development of plans on most efficient offering and usage of medicines.
- Development of plans to avoid over-production and reduce the environmental impact, pollution, etc.

REFERENCES

1. https://www.efpia.eu/media/gy5j1nkt/efpia-recommendations-on-the-revision-of-the-pharmaceutical-package.pdf, downloaded Nov 2024

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