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Contact: Ifeoma Asiegbu,
Director, Country Lead Regulatory Affairs
T: +46 72 142 01 32
E: ifeoma.asiegbu@msd.com

msd.com

To: s.remissvar@regeringskansliet.se
Copy to: s.sl@regeringskansliet.se

Merck Sharp & Dohme (Sweden) AB
Gävlegatan 22
113 30 Stockholm
Sweden

Introduction

The Swedish life science sector is home to one of the world's most innovative ecosystems. Pro-innovation policies, multi-stakeholder partnerships and strong R&D investment have all contributed to making Sweden a global leader in oncology, neuroscience, genomics, and diagnostics.

The pharmaceutical industry constitutes a significant part of this ecosystem and of the Swedish economy. With approximately 15,000 employees of which 3,000 are working within R&D, the Swedish pharmaceutical industry annually contributes 56bn SEK to GDP and has made pharmaceuticals the 3rd largest export item. Even more importantly, this has allowed for Swedish patients to gain fast access to innovative treatments, medicines, and vaccines.

The Critical Medicines Act aims to strengthen security of supply and availability of critical medicines in the EU as well as improve the availability and accessibility of other medicines where the market does not sufficiently ensure their availability and accessibility.

The key provisions in the legislation include;

- Promote investment to support the manufacturing capacity of critical medicinal products in the EU.
- Reduce the risk of shortages by incentizing the diversification and resilience of supply chains and considering EU stockpiling.
- Establish public joint procurement processes for critical medicinal products and/or medicines of common interest to address inequities in the availability of medicines in the different Member States.

The initiative to improve access to critical medicines within the EU is positive and welcome. However, some of the current proposals are cause for concern and risk having a contrary impact to access and innovation. Therefore, MSD as a company and as part of the wider industry have compiled a number of proposed changes that we believe would ensure that the legislation achieves its ultimate goals without unwarranted consequences.

General Input

MSD welcomes the Commission's proposal for the "Critical Medicines Act" and its goal of improving access to critical medicines in the EU. We are present in all EU countries and as a company, we always strive to ensure patients have access to our medicines. We urge the Commission to consider our views

and proposals to ensure that the regulation is effective and sustainable, without creating barriers to innovation and access to medicines.

Specific Input

Extended Scope of Joint Procurement:

- We believe that extending the scope of joint procurement to include non-critical medicines of common interest, covered by the EU's HTAR (all new products from 2030), could be distorting the purpose of the legislation, which is to ensure availability to critical medicines.
- Based on experiences from Joint procurement for COVID-19 vaccines, Member States may view joint procurement as a strategy to achieve lower prices for innovative medicines rather than ensuring availability.
- Joint procurement should only be considered for critical medicines and only if the marketing authorization holder (MAH) is not interested in marketing them in the relevant countries.
- The provisions for collaborative procurement may hinder the market from functioning effectively and infringe on national procedures.
- This is connected to products going through the EU joint clinical assessment process and therefore covers the most highly innovative and newest medicines coming to the market. Joint procurement of these medicines will not lead to lower prices.There is an assumption that Member States want to purchase these medicines.

Imposition of New Criteria in National Procurement Processes

- The new criteria imposed in national procurement processes may affect the choice of suppliers and manufacturing sites, thereby limiting companies' freedom of choice.
- We would particularly like to highlight Articles 18/19, where new criteria regarding environmental and social rights should be carefully considered.

National Stockpiles

- The maintenance of national stockpiles continues to impact Companies' stock management, and threatens access and supply chain resilience across other EU markets. Maintenance of national stockpiles as finished product (packaged and labelled), ties up inventory and restricts the ability of industry to respond to shortages wherever they may occur across the EU. There is a concern that some Member States may be seen to “hoard” critical medicines, to the detriment of other member states. MSD takes the view that stockpiling can be an important tool in supply resilience for some medicines, but this approach is best deployed in a way that maintains flexibility – i.e. stockpiling of critical intermediates, of drug substance or unlabelled / unpackaged bulk drug product, maintained at an above-country level..
- The regulation does not take into account the potential impact these measures may have on the overall supply of medicines to third countries, focusing solely on the EU.

Publicly Funded Projects

- Companies receiving public funding for strategic projects, either from the EU or individual Member States, will be required to prioritize the supply of their medicines within the EU and the funding Member States. This means that companies should carefully evaluate accessing this type of funding to avoid committing to subsequent obligations that may affect their global inventory management.
- Additionally, this type of proposal may create a sense of competition among Member States.

Regulatory Flexibility

- We see a missed opportunity to address regulatory flexibilities, such as packaging and other mechanisms that could address shortages, including labeling and electronic package leaflets.

- Simplified labeling (for example, enabling increased pack sharing across markets), permitting English packs across countries, and electronic product information can have a significant impact on the prevention and mitigation of shortages.

About MSD

For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We follow the science where we can make the greatest difference, now and in the future. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in humans and animals.

Electronically signed by:
Birgitta Wikman Erlandson
Reason: Approved
Date: Jun 23, 2025 21:34 GMT+2

Birgitta Wikman Erlandson
Managing Director
Merck, Sharp & Dohme (Sweden) AB

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