European Industrial Pharmacists Group
Groupement des Pharmaciens de l'Industrie en Europe

E.I.P.G. Comments on

Proposals for a Critical Medicines Act: Call for Evidence

- EIPG members fully support the objectives and ongoing efforts to ensure sustainable and reliable access to critical medicines.
- The participation of a heterogeneous group of stakeholders to submit ideas and contributions to support the development of the draft law to integrate proposals from a wide range of perspectives and expertise is surely the most appropriate approach. It is essential that all stakeholders adopt a patient-centric approach.
- Managing distribution during disruptions and crises by prioritising the medicines identified as critical is a key competence. In the past, we have noticed that national medicine authorities have been very reluctant to provide a list of critical medicines because they fear it touches on a competitively sensitive area where one manufacturer's medicine could be on the critical list and another's not, potentially causing competitive inequality. In the future, there must be clarity on who created the list and the potential role of the national medicines authority.
- When compiling its list, the EMA needs to consider country-specific differences, treatment practices, and clinical guidelines more. Additionally, careful consideration should be given to potential market dynamics and disruptions regarding stockpiling. Many countries are already building their own crisis stockpiling models.
- There is a significant difference between the origin of Europe's active pharmaceutical ingredients (APIs) in the supply chain for innovative products and those for generic medicines. The majority of all APIs for innovative products come from Europe whereas the vast majority of all APIs come from Asia. It seems that a large number of APIs for critical medicines are generics. Off-patent medicine pricing is competitive, so extra care is needed with procurement procedures.
- Strengthening the manufacturing capacity in the EU (reshoring APIs from Asian countries) is likely to take many years, despite the availability of financial incentives. This is mainly because of technical and environmental issues in

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both regions. A particular focus should be placed on developing a coordinated plan, including the agreement on a list of API priorities.

- For many years, in most European countries, the European Medicines Verification System (EMVS) could have made available levels of finished product stock in the supply chain. Large numbers of industrial staff and their necessary resources and many healthcare practitioners have spent their time and effort inputting data, allowing packs to be dispensed and exported, and recording the stock available for prescription products. EMVS should provide information on finished products as soon as there is a critical shortage.
- If the EU introduces broadly applicable obligations for critical medicines, the "stockpiling period" must be extended to avoid new and significant availability issues in the market as everyone stocks up simultaneously.
- It is essential to understand well in advance what the critical product list will entail and what new obligations it will impose at the manufacturer/wholesale level. The expectations of authorities and marketing authorisation holders (potentially considering commercial services and functionalities in their ERPs and other systems) should be clear

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