SANT Committee prioritises manufacturing competitiveness in draft report on the Critical Medicines Act

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Today, the European Parliament's Rapporteur Tomislav Sokol presented his draft report on the Critical Medicines Act to the Committee on Public Health.

The report pushes strongly to improve the competitiveness of the EU pharmaceutical manufacturing sector and better coordination of contingency stocks as additional objectives of the Regulation. It also expands the Act's scope by broadening the definition of medicinal product of common interest and making the Investments Chapter also applicable to such medicinal products, as well as to critical medicines.

Medicines for Europe is committed to Europe's health security and supports an ambitious Critical Medicines Act. The draft Parliament report builds on the Commission proposal to clarify the importance of EU solidarity for stockpiling, to support more investment in EU manufacturing and to strengthen security of supply criteria in medicine purchasing. The Regulation should be further strengthened to ensure that security of supply is ensured for all medicines in the list. Only 40% of medicines in the general pharmaceutical market go through procurement and, while for critical medicines it is likely that the figure rises to around 50% by not making pricing and reimbursement a mandatory part of national plans supporting security of supply, the Act fails to address half of the medicines in the list. The Critical Medicines Act must include security of supply criteria in both public procurement and pricing and reimbursement policies.

The report also:

- Strengthens support for manufacturing with regulatory, administrative and technical support and a one-stop-shop for the designation and funding for strategic projects.
- Clarifies that Member States and the Commission should ensure that environmental and chemical legislation do not have unintended consequences for the availability of critical medicines.
- Builds on security of supply measures in medicine markets by mandating multi-winner tenders and Commission guidelines for the application of non-price criteria as well as the revision of cost containment measures in national pricing and reimbursement policies which cause industry consolidation and shortages.
- Calls for more control over national hoarding through provisions on stockpiling, including stricter solidarity requirements, regulatory flexibility, monitoring of stock levels by the Commission, and regular reporting by Member States.
- Strengthens international partnerships by requiring the Commission to assess the possibility of including health security provisions in free trade agreements and supporting accession countries in this regard.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at https://www.medicinesforeurope.com/ and on LinkedIn and X @medicinesforEU.