Spanish Presidency set to advance medicines supply resilience for European strategic autonomy

Brussels, 3rd of July 2023

Medicines for Europe welcomes the Spanish Presidency of the Council of the European Union and the trio with Belgium and Hungary to advance healthcare and pharmaceutical initiatives for Europe.

We support the Spanish Presidency objectives to reindustrialise the EU and ensure open strategic autonomy and to press for sustainable pharmaceutical policies for access, availability, and affordability.

As stressed by Heads of State and Government on 30th June, the Commission should move forward with "*an initiative for urgent measures to* ***ensure sufficient production and availability of the most critical medicines and components in Europe and to diversify international supply chains*** *while pursuing, in parallel, the reform of pharmaceutical legislation*".

Our priorities for the Spanish Presidency are the following:

1. DELIVER ON EQUITABLE AND TIMELY ACCESS FOR PATIENTS

Generic, biosimilar, and value-added medicines contribute materially to the **sustainability of healthcare budgets** and substantially increase access to medicines for patients across the European Union.

We need predictability and legal certainty to guarantee **timely access to generic, biosimilar and value added medicines on day-1 of intellectual property expiry. The EU pharma legislation must put an end to gamesmanship delaying competition**

2. LEADERSHIP IN MEDICINES MANUFACTURING

Open Strategic Autonomy is one of the key drivers of European trade and industrial policy in the post Covid 19 period.

The time has come to move introduce a **Critical Medicines Act** to:

- **encourage investment** in medicine and active pharmaceutical ingredient **manufacturing in the EU**.
- **Reform the public procurement systems and pricing of medicines** to guarantee the long-term sustainability of the industry and avoid shortages which harm the patients and the healthcare systems in general

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3. A RESPONSIBLE INDUSTRY IN A RESPONSIVE REGULATORY FRAMEWORK

An efficient regulatory environment is key to deliver on safe and high quality medicines while preventing shortages. We need a:

- A **digitalised, flexible and harmonized regulatory framework** will help more generic, biosimilar and value-added-medicines reach patients sooner. Patients can be informed with the latest information concerning their medicines with an **electronic patient information leaflet**.

- A green transition that enable critical long-term investments in manufacturing and **safeguard patient access to pharmaceutical treatments**, recognising the specificities of the off-patent sector that supplies the essential medicines for Europe's population.

We are committed to work alongside the Spanish Presidency and the trio to achieve these vital objectives - **delivering for patients and strengthening the resilience of off-patent medicines and active pharmaceutical ingredients** manufacturing in Spain and across Europe.

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 and invest up to 17% of their turnover in R&D investment. 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 www.medicinesforeurope.com and on Twitter @medicinesforEU.