A Pharmaceutical Strategy for Europe

2021/2013(INI) - 24/11/2021 - Text adopted by Parliament, single reading

The European Parliament adopted by 527 votes to 92, with 70 abstentions, a resolution on a pharmaceutical strategy for Europe.

Health is fundamental to the well-being of Europeans and equitable access to healthcare is a cornerstone of the EU and Member States' national health policies. **40 % of medicinal end products marketed in the EU originate in non-EU countries**, while 60 % to 80 % of active pharmaceutical ingredients are produced in China and India. The disruption of the global supply chain ensuing from the COVID-19 pandemic has highlighted the EU's dependency on third countries in the health sector.

Putting patients at the centre of all health policies

Recognising the existence of inequalities in access to quality health services between and within Member States, Members called for national and European measures, including legislation, to address these disparities and ensure **patients' right to universal, affordable, effective, safe and timely access to essential and innovative medicines**.

Particular attention should be paid to people in vulnerable situations, including pregnant women, children, the elderly, people with disabilities, patients with chronic diseases and comorbidities, patients in intensive care units and people on long-term treatment.

Antimicrobial resistance (AMR)

Considering that AMR constitutes a serious threat to public health, Members recommend that the Commission introduce an **EU therapeutic guide for antimicrobials**, setting up traceable antimicrobial use reduction targets at EU level, and that communication campaigns on AMR be coordinated through a single calendar at EU level.

Research in pharmaceuticals

Parliament called on the Commission to assess, and revise where appropriate, the system of incentives to promote research into and the development of new medicines for **unmet diagnostic and therapeutic needs**, prioritising public interests and patient safety when assessing projects promoted by the pharmaceutical industry to combat cancers, including paediatric cancers, rare diseases and neurodegenerative diseases. Members suggested that an EU framework should be created to guide and regularly evaluate the implementation of national plans to fight these diseases.

Pricing and costs of pharmaceuticals

Members called on the Commission to:

- promote dialogue with the Member States and all relevant stakeholders to promote **'Made in Europe' pharmaceuticals** by strengthening manufacturing and supply resilience;

- promote information sharing among Member States on net medicine prices through the European Integrated Price Information Database (EURIPID) collaboration;

- introduce measures to increase transparency in the area of research into and the development and production of medicinal products;

- explore the possibility of establishing, subject to conditionalities, an EU fund, co-financed by the Member States, for negotiating and purchasing orphan medicines and other new medicines;

- address the root causes of shortages of pharmaceuticals and propose sustainable solutions and mitigations plans;

- be alert to anti-competitive conduct and investigate anti-competitive practices in the pharmaceutical industry.

Role of generic and biosimilar medicines

Parliament stressed the importance of generic, biosimilar and value-added medicines for consistently increasing equitable access for patients and making healthcare systems sustainable in a European Union where access is still uneven. It called on the Commission to ensure **healthy competition after the expiry of intellectual property exclusivities** by ensuring access to biosimilar medicines from day one and removing all barriers to access to competition.

Parliament also recommended, inter alia, to:

- address the differences in the average number of days between the approval of a medicine and the moment it becomes available to patients in the EU, and implement solutions to **reduce delays to the market entry of medicines**;

- facilitate the launch of large **clinical trials** conducted in a harmonised and coordinated manner at EU level;

- reassess the system that leads from conditional marketing authorisation to standard marketing authorisation or exceptional renewal of authorisation, based on robust clinical data;

- develop an **early warning system** for drug shortages based on a European digital platform;

- ensure full and harmonised application of the **General Data Protection Regulation** (GDPR) with regard to the conduct of clinical research across the EU;

- establish a structured dialogue on manufacturing and the supply chain and a broader, high-level **political pharmaceutical forum** to share the lessons learned from the COVID-19 emergency and to define an effective policy framework to prevent long-term shortages;

- ensure **quality and environmental sustainability standards** for active pharmaceutical ingredients imported from non-EU countries and address the problem of pharmaceutical household waste, through measures to reduce packaging.