

Medicines for Poland File a Petition to the European Parliament

The petition submitted by Medicines for Poland to the European Parliament in May this year to support the production of pharmaceutical ingredients for the manufacture of medicines in the EU has been accepted and will be considered this autumn.

80% of the active substances used in the production of medicines in Europe come from China or India. This increasing dependence has led to a partial loss of manufacturing capabilities. Until the mid-1990s, Europe and the US supplied 90% of the substances used globally to produce medicines. As recently as 20 years ago, there were about 170 manufacturers of active substances in Poland, while today there are only a dozen or so.

The SARS-CoV-2 pandemic has revealed the threats resulting from the reliance on Asia. As a result of disruptions in Asian manufacturing plants and global transport and increased demand for pharmaceuticals around the world, the principle of international solidarity was compromised, resulting in shortages of medicines and active ingredients.

In the "Petition on the need to support the production of active substances for medicinal products in the EU", Medicines for Poland has stressed the need for EU bodies to develop mechanisms to support the API production capabilities. Their shortage, combined with higher labour costs and the need to meet stringent environmental standards in Europe, make pharmaceutical production unviable. Investments will be needed to restore such production on the scale necessary to ensure EU security. Depending on the required pharmaceutical synthesis technology, the launch of production of a single active ingredient takes 3-6 years and is estimated to cost between EUR 50 and 180 million.

Germany, France and Spain are encouraging investment in pharmaceutical production at home. However, these actions will not be effective for the Community as a whole unless a coordinated effort is made to directly contribute to building new and maintaining existing production capacity in Europe.

"An example of such a coordinated strategy are the EU plans to strengthen the European semiconductor ecosystem¹ by attracting investment and increasing production capacity, as well as their testing and assembly in integrated plants and EU factories.² "Similarly to chips, establishing criteria to support pharmaceutical manufacturing facilities and opening EU production lines would help to ensure the security of the EU," points out Krzysztof Kopeć, President of Medicines for Poland.

¹ The Chips Act, COM/2022/46 final version, available at: https://eur-lex.europa.eu/resource.html?uri=cellar:ca05000a-89d4-11ec-8c40-01aa75ed71a1.0018.02/DOC_1&format=PDF (access on 5 May. 2022), hereinafter the "Regulation".

² Sec. 1.2.2 of the Regulation – Specific Objectives, p. 70-71.

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Another direction could be the establishment of a subsidy system for the production of such substances based on the model of direct subsidies for agricultural production. The support system should reduce manufacturing costs to enable the price of the pharmaceutical ingredients to be reduced and competitive against Asian products.

It is also necessary to provide immediate intervention and support for pharmaceutical substances which are currently still manufactured in the EU and prevent a reduction in the volume of production leading to irreversible closure of the technological line.

”Restoring this production in the EU will stimulate economic development and provide new jobs. It will increase the competitiveness of European manufacturers and improve the EU's resilience in the face of future medicine shortage crises. It will also help restore Europe's industrial leadership status. The strategic work has been done, now it is time for specific actions,” points out Grzegorz Rychwalski, Vice-President of Medicines for Poland.

The "Petition on the need to support the production of active substances for medicinal products in the EU" was submitted to the Petitions Committee of the European Parliament. In the petition, the Medicines for Poland also remind that one of the objectives of the European Parliament's November 2021 Resolution on pharmaceutical strategy is to strengthen the global competitiveness of the EU pharmaceutical sector worldwide, and that the EU Health Programme 2021-2027 aims to sustain the manufacturing³ active pharmaceutical ingredients and generic medicines, and to promote pharmaceutical products made in Europe⁴.

³ Par. 15 of the Preamble to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a programme of Union action in the field of health (the 'EU4Health Programme') for the period 2021-2027 and repealing Regulation (EU) No 282/2014.

⁴ Par. 33 of the Resolution.