**Position of Medicines for Poland for public consultation on a *new EU instrument guaranteeing the functioning of the Single Market in emergency situations* by the European Commission**

The pandemic has demonstrated the importance of having a strong European and national pharmaceutical industry and has revealed the weaknesses of an economy that has created a complex system of global interdependence. The EU's dependence on the supply of pharmaceutical products from outside Europe, the long supply chains, the loss of manufacturing competences - these have all threatened the security of Europeans. It has become clear that EU solidarity is very important, but it must be built on strong foundations - the capabilities and competences of EU countries. It is therefore necessary to support the building of national production capacities that will contribute to the EU's health security, which is just as important as energy or military security.

The European pharmaceutical sector uses more than 60% of raw materials from China and India to produce medicines. 30% of generic medicines used in Europe come from Asia. The pandemic has highlighted the need to increase Europe's strategic autonomy.

1. **The European Union institutions recognise the need to strengthen European sovereignty in the manufacture of active substances and finished medicines, based on the existing pharmaceutical industry but also on new economic initiatives. This is reflected in the formulation of draft documents or resolutions calling for action in this area.**

Documents worth referring to in this context includes:

* Recovery plan for Europe,
* European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address the emerging problem (2020/2071(INI),
* Regulation of the European Parliament and of the Council on the establishment of a programme of Union action in the field of health for 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU Health Programme"),
* Pharmaceutical strategy for the European Union, and
* Versailles Declaration .

European Parliament Resolution of 17 September 2020 on the shortage of medicines – how to address the emerging problem (2020/2071(INI) underlines the role of the pharmaceutical in this issue:

* ”M.   whereas the generic and biosimilar medicines industry supplies the majority of medicines to EU patients (almost 70 % of dispensed pharmaceuticals);
* N. whereas the entry of generics and biosimilars into the market is an important mechanism for increasing competition, reducing prices and ensuring the sustainability of healthcare systems; whereas their market entry should not be delayed;
* O.  whereas the EU-based manufacturers of generics have an important role to play in satisfying the growth in demand for affordable medicines in the Member States;
* AI. whereas a strong, innovative and competitive pharmaceutical industry in Europe is in the vital interest of the EU and its Member States;
* AJ. whereas the pharmaceutical industry needs the right legal framework to undertake research, development and production for pharmaceuticals within the EU;
* 1.  Stresses the geostrategic imperative for the Union to regain its independence with regard to healthcare, to secure rapidly and efficiently its supply of affordable medicines, medical equipment, medical devices, active substances, diagnostic tools and vaccines, and to prevent shortages thereof, prioritising the interest and safety of patients; stresses the importance of ensuring that all Member States have fair access to the supply chain;

highlights, to that end, the need for the Union’s pharmaceutical industry to have a diversified supply chain and a medicine shortage risk mitigation plan to cope with any vulnerabilities and risks to their supply chain;

* 20.   Urges the Commission and the Member States, if needed for the public interest, to consider the introduction of measures as well as financial incentives in line with State aid rules and sustainable policies in return for commitments, to protect Europe’s strong pharmaceutical industrial base and to encourage the industry to locate its operations in the EU, from the production of APIs to medicine manufacturing, packaging and distribution; urges the Member States to secure existing operations, for example by rewarding investments in the quality of medicines and in the security of supply; emphasises the strategic significance of this sector and the importance of investing in European companies in order to diversify resources and encourage the development of innovative production technologies capable of enhancing the responsiveness of entire production lines; recalls that all public funding must be made conditional on the full transparency and traceability of investments, on supply obligations on the European market, and on facilitating the best outcome for patients, including in terms of accessibility and affordability of manufactured medicines;

In a statement adopted on 10 March 2022 at the informal meeting of EU Heads of State in Versailles on Russian military aggression against Ukraine, EU leaders acknowledged that, in the face of increasing instability and threats, it is necessary to take greater responsibility for the security of the Union and to take further decisive steps towards building European sovereignty, reducing dependence and developing a new model for growth and investment. EU leaders pledged to focus, among other things, on supporting sustainable production of affordable medicines, funding research and development and building capacity for critical products to respond to health crises. This is also needed from the perspective of developing the EU and national pharmaceutical industries and building strategic autonomy in the area of medicines.

Given that depending on the type of API, different production technologies with specially adapted synthesis lines must be available and all processes are subject to validation, targeted, long-term investment programmes need to be implemented to produce key API in Poland and Europe and ensure long-term return on investment. Increasing the volume of APIs manufactured will reduce their production costs and increase competitiveness against Asian producers.

**It is essential to implement instruments to support domestic pharmaceutical manufacturers. The development plans prepared by the European Commission should be based on the potential of the existing pharmaceutical industry, and the measures planned should focus on developing it and forming new competencies.**

To this end, stable economic, industrial and regulatory policies need to be implemented. Investments in the manufacture of API, excipients and medicines in Europe require the support of national governments and the EU. The location of these investments must be geographically balanced and ensure uninterrupted supply chains in cases of emergency, as in this year's pandemic. It is necessary to ensure a flexible registration process using digitalisation and to shorten the registration procedure for European producers. Legislative and non-legislative measures are needed to instruct national reimbursement policy makers to give preference to products manufactured in the EU or from intermediates and APIs made in Europe and to move away from the lowest price criterion used to date, which gives an advantage to Asian manufacturers. Support should follow the model employed in the case of the common agricultural policy and should consist in subsidising production and products which guarantee security of the citizens.

1. **Building the EU pharmaceutical safety**

The pandemic has shown that in crisis situations, when demand for medicines soars worldwide and national borders are closed, the only guarantee of a country's health safety is to produce medicines in its own territory. When the pandemic broke out, pharmaceutical companies operating in the EU immediately declared that the European market would be their priority and that they would provide medicines to Europeans first. With great organisational effort, they increased production to meet the growing demand for medicines.

It is worth emphasising that basic drug safety should be based on medicines that are commonly used by patients, medicines that have the highest turnover, essential medicines defined by the competent authorities and medicines used in surgery.

Strengthening the pharmaceutical industry in the EU is also extremely important because of the increase in demand for medicines. In Poland alone, one in four Poles is over 60 years of age, and in the middle of the 21st century as many as 40% of our country's population will be seniors, so the consumption of medicines will increase, especially those that are used in the treatment of lifestyle diseases. A guarantee of their uninterrupted supply at affordable prices is to have a domestic and European pharmaceutical industry.

**With this in mind, we request for the implementation of the following regulations:**

* Investments in the manufacture of APIs, excipients and medicines in Europe require the support of national governments and the EU. Support from the EU for the production of APIs and medicines at all stages of the production cycle through mechanisms modelled on the Common Agricultural Policy should be considered. Their production is associated with huge inputs due to environmental standards, high electricity and water consumption. In this way, the higher costs of manufacture in Europe can be offset, which is the price that has to be paid for building the EU's pharmaceutical safety.
* Development plans prepared by the EC should be based on the potential of the already existing pharmaceutical industry, and planned actions should focus on its growth and the development of new competencies. To this end, it is necessary to have in place stable economic, industrial and regulatory policies.
* When choosing the locations for such investments, it is important to maintain geographical sustainability and ensure uninterrupted supply chains in emergency situations, such as this year's pandemic.
* It is necessary to ensure a flexible, digitised registration process and to shorten the registration procedure for European manufacturers.
* Non-legislative measures should also be implemented, recommending that national authorities responsible for reimbursement policies give preference to products manufactured in the EU or from intermediates and APIs made in Europe and abandon the lowest price criterion, which has so far given an advantage to Asian manufacturers.
* An important pillar of EC actions should be to increase access to medicines and to even out differences in this regard between EU members.