

Non-paper by Austria, Belgium, Croatia, Cyprus, Estonia, Finland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Slovenia, Spain, Sweden and The Netherlands on a joint vision for a Pharmaceutical Strategy for Europe

Access to medicines is crucial for the health of the European people and for the security and autonomy of the Union. Medicinal products are not only essential interventions that restore the health of our patients and ensure the wellbeing of our citizens, they are also of strategic importance to the EU's industrial landscape. The European pharmaceutical industry plays a valuable role in the research and development of innovative treatments and in the production of key enabling technologies. It is in a position to stimulate **green and digital transformations**. Ensuring the **supply of high quality, safe, efficacious and affordable medicines** in our region is urgent and decisive to the future of the European Union.

To ensure the long-term sustainability of healthcare systems, it is of the utmost importance to engage in actions to implement an effective policy framework that ensures a well-functioning EU pharmaceutical industry. This would ultimately contribute to more sustainable access to medicines for European patients.

The Covid-19 crisis has had a severe impact on society and has made the European Union realise that **health is paramount to the welfare and wellbeing of its citizens**. The crisis highlighted **existing vulnerabilities** in medicines' availability as well as **one-sided dependencies** on raw materials and product supply from a few third countries. While a formal evaluation of the extent of the ongoing crisis is yet to take place, and many Member States are still in the midst of tackling its effects, this is a timely moment to call for action in this field. We need a **joint holistic and comprehensive approach** to the pharmaceutical strategy to strengthen both the preparedness and resilience of European healthcare systems when facing present and future challenges.

The current context has increased the urgency to develop a renewed pharmaceutical strategy, one that will adapt the EU regulatory framework as required, using new digital tools while focusing on the needs of health systems and patients.

During the Health Ministers Council meeting on 9 December 2019, the Council called for a **European agenda on pharmaceutical policy** for the legislative period of 2020-2024. This agenda would address, in a consistent and structured manner, major concerns and challenges in the EU's pharmaceutical system. It would strengthen the delicate balance between marketing authorisation and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment of medicinal products.

In March 2020, in its **New Industrial Strategy for Europe**, the Commission announced the forthcoming publication of a New Pharmaceutical Strategy. We propose linking the various components of the industrial strategy, the upcoming pharmaceutical strategy as well as of the EU recovery plan and the EU4Health programme, to duly align overarching objectives and strategic measures.

We call upon the Commission to merge the Council's plea for an agenda with the pharmaceutical strategy to create a long-term Strengthened Partnership **between the European Commission and the Member States** guided by the principles of **availability, affordability, sustainability and security of supply** of medicines. Such a partnership would entail enhanced dialogue and interaction between the European Commission and the Member States with a mutual understanding of their distinct competencies, guaranteeing respect to the competencies of the Member States. It should also build on the activities of the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) joint working groups and taskforces, strengthening coordination and incorporating the vision of the competent authorities in regulatory decision-making. It would also involve defining a joint programme of objectives and activities, engaging Member States in the planning and development process, defining coordination roles, and establishing clear and transparent programme

governance and procedures. All this while ensuring proactive exchange of information between the Member States and the Commission. We believe that the existing collaboration mechanisms in the EU should be strengthened and streamlined for this purpose.

We look forward to building a long-term strengthened Partnership with the European Commission and the Member States and to contributing to a pharmaceutical strategy that meets the needs of our countries, our citizens and that benefits the European Union at large.

This non-paper is without prejudice to the national position papers submitted by individual Member States.