# #Prescription4EU – Five remedies for a Pharmaceutical Strategy for Europe catering for national health systems and patients' needs

** Austria, Belgium, Croatia, Estonia, Finland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Slovenia, Sweden and the Netherlands have identified the following common priorities and next steps, which need to be further discussed at the European level in the context of the strategy implementation and the long term partnership[1] between the European Commission and the Member States [2].*

1. To **tackle Shortages** collectively and **build a European response**.

*Points to be discussed as soon as possible are:*

- Encourage more solidarity and cooperation by agreeing to common principles towards building sustainable stocks at different levels of the supply chain. Consider strategic reserves at EU level for medicines for human use and medical devices, foreseeing mechanisms for access and equitable distribution.
- Coordinate measures at national and European level to: (1) generate best practices in monitoring and data management as well as in stakeholder interaction and communication, and (2) improve early notification of supply disruptions and investigating their root causes. This includes evaluating the effectiveness of joint EU public procurement and its potential use for better distribution of medicines.
- Emphasize obligations of marketing authorisation holders and wholesalers to ensure the security of supply and explore tools available to uphold such obligations, for example discussing mandatory risk mitigation measures.

2. To **define** clear criteria for '**Unmet Medical Needs'**, appropriately **stimulating and rewarding innovation** while securing a healthy pharmaceutical market and the sustainability of healthcare systems.

*Points to be discussed as soon as possible are:*

- Identify the target conditions, technologies or patient groups that new therapies are to focus on over a given timeline.
- Evaluate ongoing private and public innovation incentives and funding to drive future clinical R&D to meet patients' needs.
- Tackle the global health threat of antimicrobial resistance (AMR), by stimulating prudent use, strengthening incentives for R&D of new antimicrobials, their alternatives and diagnostics; using the potential of EU instruments, structures and policies to explore new models for research, development, production and purchasing, to stimulate the availability of (new) antimicrobials.
- Stimulate pharmaceutical companies to maintain older medicinal products on the market by creating better incentives for medicines' repurposing, reducing the regulatory burden and stimulating the introduction of electronic product information and multi-language packaging.

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[1] See joint Non-paper by Austria, Belgium, Croatia, Cyprus, Estonia, Finland, Ireland, Italy, Lithuania, Luxemburg, Malta, Norway, Portugal, Romania, Slovenia, Spain, Sweden and the Netherlands on a joint vision for a Pharmaceutical Strategy for Europe.

[2] The content of this declaration is without prejudice to national positions. The above-mentioned points are to be discussed in greater detail and therefore Member States reserve the right to submit additional and/or other viewpoints, subject to the actual content of the pharmaceutical strategy for Europe to be published on 24 November 2020.

3. To **redesign** the **framework** for **Advanced Therapy Medicinal Products (ATMPs) and create a system equipped** to **respond to** scientific and technological **developments**.

*Points to be discussed as soon as possible are:*

- Review and update the regulatory framework for ATMPs. The two available routes - central registration and hospital exemption – play an important role with certain ATMPs, but respond inadequately to all scientific and technological developments.
- Discuss thoroughly whether current marketing authorisation procedures are fit for personalized medicines.
- Share best practices in hospital exemption procedures; discuss whether the hospital exemptions would benefit from review and harmonization across the EU, also in regards to pharmacovigilance.

4. **To create a Pharmaceutical Hub in Europe** to **reinforce** the region's **capacity.**

*Points to be discussed as soon as possible are:*

- Emphasise EU's role in the global pharmaceutical production and supply chain, considering how to stimulate R&D, optimise the supply chains, diversify sourcing and suppliers, tackle environmental and waste water aspects, and stimulate innovative, cleaner and sustainable local pharmaceutical production.

**5.** To **foster International Cooperation -** while bearing in mind national competences - to **achieve** equally **accessible, affordable medicines.**

*Points to be discussed as soon as possible are:*

- Encourage information exchange throughout the product's lifecycle between regional collaborations and individual Member States, paving the way to coordination and collaboration in the field of HTA and pricing and reimbursement, thereby promoting better alignment in the measurement and analysis of health outcomes of interest and achieving a more balanced pharmaceutical market.
- Look into legislative and non-legislative actions at EU level aiming to reduce asymmetries in access across the single market and encourage healthy competition.