

A Pharmaceutical Strategy that benefits EU citizens, protects healthcare systems and fosters EU competitiveness

AESGP reaction to European Commission's Communication on the EU Pharmaceutical Strategy

AESGP welcomes the European Commission's Communication proposing a patient-centred Pharmaceutical Strategy ensuring the quality and safety of medicines, while boosting the sector's global competitiveness. This holistic strategy is much appreciated at a time where the world struggles amidst the COVID-19 pandemic. The global public health and economic situation has further highlighted the **need for greater resilience of supply chains and health systems, and for global crises preparedness.**

A strategy that considers the value of self-care pharmaceutical products

Maintaining uninterrupted access to non-prescription medicines throughout this global crisis has been at the core of the European Self-Care Industries mission. Self-care and **responsible use of non-prescription medicines, as the first line of response to common health conditions, has allowed rational use of health system resources** during its worst hours.

AESGP suggests that the Pharmaceutical Strategy should seize upon learnings from the global pandemic and look into the socio-economic benefits of improving non-prescription medicines' availability. The benefits of wider availability of non-prescription medicines in Europe were already well recognised in the strategy of the Heads of Medicines Agencies 2020, but currently this is far short of being fulfilled. Hence, AESGP believes that, when implementing the European Pharmaceutical Strategy and reviewing the system of incentives, **it is important to acknowledge the specificities of regulatory pathways to market for non-prescription medicines and to consider effective incentives that aim to increase their availability and accessibility.**

A strategy that fosters EU competitiveness and attracts investment

The pharmaceutical sector in Europe, which includes many SMEs, has been vital for the European growth and prosperity. European regulatory framework is recognised globally for its quality and sustainability. Pharmaceutical Industry in Europe is a significant employer of skilled workforce. AESGP finds positive the Commission's intention to keep an EU competitive level playing field and to prioritise skills investment. **A stable, integrated, predictable, coherent and proportional legislation, is crucial for business certainty and to attract EU and foreign investment, including for SMEs.**

A strategy that can enable digital transformation

AESGP welcomes the **urgency to develop capabilities of the pharmaceutical regulatory network in the digital space.** AESGP thinks that industry, regulators, legislators and society at large have to work together to accelerate the effort if we really want to see **Europe become a leader in the digital health space.** Europe must ensure **a fit for purpose regulatory framework so that people can safely enjoy the benefits** brought by digital transformation and new technologies, without leaving anyone behind.

A strategy that balances environment, sustainability and healthcare needs

AESGP members, along with other pharmaceutical industry stakeholders have been concerned with the climate urgency, addressing knowledge gaps in the effects of pharmaceuticals in the environment, and adapting manufacturing to encompass greener practices. Furthermore, AESGP considers the Pharmaceutical Strategy to be an **opportunity for Europe to align sustainable action with a competitive industry**.

A strategy that can enhance smart regulation and regulatory efficiency to benefit access

In line with this Commission's commitment for a sound and flexible regulatory system, AESGP agrees that **it is crucial to pursue a better regulation agenda for a modern pharmaceutical sector, to reduce red tape and improve access and timelines**, after an impact assessment that addresses the specificities of the assorted range of pharmaceutical products.

A strategy that can address shortages with risk-balanced and proportional measures

AESGP welcomes the step-wise approach proposed by the Commission. AESGP considers it important for the European Commission to address shortages of medicines taking into account a diverse internal market and protectionist measures taken by third countries as part of their national business agendas, and even by some EU member states in times of crises. **Europe needs to address root causes of shortages while balancing it with a risk-based approach to maintaining access to affordable medicines**, that often rely on supply from third countries. For this purpose, **the EU needs to work with WTO members and ask for the international respect of trade rules, prices, tariffs and duties and establish partnerships for market access and business opportunities**.

AESGP is looking forward to the dialogue with the Commission, European Parliament, Member States and European Medicines Regulators on the proposed actions, in **implementing an ambitious Pharmaceutical Strategy that serves all citizens, while addressing current challenges with science-based, risk-balanced and proportional measures**. AESGP is committed to actively contribute to the development and implementation of an EU pharmaceutical policy that ensures the sustainability of health systems, respecting environmental concerns, and that is able to foster a successful industrial sector in Europe.

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