

## ESIP feedback to the Pharmaceutical Strategy Roadmap

ESIP welcomes the initiative to help ensure Europe's supply of safe and affordable medicines to meet patients' needs and support the European pharmaceutical industry remain an innovator and world leader. However, we stress the need for a balanced approach that takes due consideration of access to innovation that addresses real unmet medical need and the financial sustainability of health systems as laid out in the Council Conclusions of 2016.

### Access and availability

ESIP welcomes a broader review of the current regulatory framework governing pharmaceuticals and intellectual property rights, with a view to incentives for innovation and market failures. Incentives need to be targeted to innovative therapies that addresses a high unmet medical need, which should be consistently defined across the legislation. They should also be linked to market launch obligations that ensure equitable access across the EU as well as continuous supply, through stricter enforcement of Directive 2001/83/EC.

Abusive behaviour to extent monopoly position that restricts availability should be prevented through stronger enforcement of competition law, as foreseen in the Industry Strategy.

We welcome the current discussion on medicine shortages and possible solutions. A European initiative to ensure availability needs to strike a balance between diversification and measures to relocate production back to Europe. Greater transparency and timely information exchange throughout the supply chain is also crucial.

### Affordability and financial sustainability of health systems

While emphasising that pricing and reimbursement decisions are a Member State competence, ESIP welcomes the aim of the future strategy for enhanced cooperation related to cost-effectiveness, pricing and reimbursement decisions and procurement practices, which should build upon existing regional initiatives such as Beneluxa, Finose, and Valetta. This could also include exchange of best practice on innovative and reimbursement models. Such actions go hand in hand with the closer cooperation on health technology assessment as proposed in the draft Regulation.

As to affordability of medicinal products, the initiative should equally include a review of how EU investment in its funding programmes e.g. Horizon 2020 has been reflected in the prices set by marketing authorisation holders. Funding through future EU research programmes such as Horizon Europe should be subject to conditionality clauses that guarantee public return on public investment.

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The EU should also promote developing global market mechanisms for innovative new products to increase their availability to all patients in need, currently underdiagnosed and undertreated in many countries, and lower their cost per patient.

### Enabling innovation for unmet medical needs

EU investment in research and innovation must have a clear orientation to the needs of European health systems by explicitly involving downstream stakeholders - healthcare professionals, patients and payers - in setting the research priorities.

The use of real-world data in market authorisation procedures should be applied only in exceptional, well-described cases complementing clinical trial data. Quality standards for this kind of data need to be developed according to their intended use and the regulator should provide a clear statement why these data have been considered fit for purpose. Strict adherence to post-authorisation evidence requirements by the market authorisation holder needs to be ensured.

### Competitiveness

In the context of competitiveness, high social and occupational health standards need to be considered along with quality, safety and environmental standards for medicines marketed in the EU.

As a key stakeholder, representing the European social healthcare payers, we urge the Commission to closely involve ESIP at every future stage of the development of the strategy.

