

LIF feedback on EU Commission “Roadmap to Pharmaceutical Strategy”

LIF, the research-based pharmaceutical industry in Sweden, welcomes the Commission Roadmap to Pharmaceutical Strategy. It is an important initiative and can be a key mean to the end that the Pharmaceutical Industry within EU “remains an innovator and world leader”, as outlined in President von der Leyen’s Mission letter to Commissioner Kyriakides.

The strategy can potentially strengthen the research eco-system, enhance resilience in case of health-crises, ensure a healthy productive population and address long-term health threats within EU.

The roadmap is acknowledging the value of the pharmaceutical industry. LIF, member companies and other industry representatives are committed to work for patient access to innovative treatments. The possibility to give feedback is important, as the roadmap needs to be amended with necessary drivers of innovation to realize its ambition of supporting the industry in Europe to be a world leader in innovation.

The pharmaceutical industry within EU is innovative and strong, though fiercely challenged internationally. And the development since the millennium has been to the advantage of countries like the US and China. Therefore, the Pharmaceutical Strategy is a possibility for the Commission to safeguard and strengthen the industry with reforms needed. LIF refers to necessary steps outlined previously by Efpia after the publication of the EU industrial strategy, including alignment to EU trade strategies.

EU needs a world-class IP framework to attract investment into the development of future treatments for the benefit of patients, including patients with rare and paediatric diseases. Developing incentives to further address unmet medical needs and seize advances in science is critical to tackling issues like AMR and pandemic preparedness. SPC harmonisation and strong IP systems can increase certainty and predictability for innovators and investors alike.

EU also needs a fast and stable regulatory framework that is globally competitive, and EU needs regulatory approval times on par with other regions or better. EMA needs further strengthening, to be able to deliver on its 2025 regulatory science strategy.

We share the concern over inequalities of access to new treatments. Faster, more equitable access for citizens is a shared goal. Though, to really understand and analyse access and affordability, distribution, wholesale, and retail must be included in the analysis, alongside with reimbursement and procurement. The concern shall not be solved by inhibiting development and access to new better treatments. A solution that stimulates & improves both must be found.

As the set up and organization of healthcare differs between countries there are no single solution to the access problems. Instead several issues need to be analysed and discussed, including late start of market access assessment, duplicative evidence requirements, national pricing and reimbursement policies and companies’ behaviours responding to these and other factors.

A High-Level Forum on Better Access to Health Innovation can identify and develop multi-stakeholder solutions for introducing new technologies that can broaden access, reduce delays, and mitigate the impact of shortages. This collaborative dialogue must be evidence-based, requiring an EU-led analysis of the root causes, and it has to be action-oriented, agile and dynamic.

Effective pharmaceuticals are many times used for decades, and we need to have a thorough understanding of the long product cycle of medicines in the discussion of access and affordability. But at the same time there is absolutely a need for novel pricing models for new classes of innovative treatments under development today. We see an obvious need for bridging the EU discussion on ATMP and precision medicine with national pilots and initiatives.

LIF looks forward to the dialogue on the Strategy and will come back with a more extensive response to the roadmap during the public consultation.

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