AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

European Commission's public consultation on the Pharmaceutical Strategy Roadmap

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2018, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Response

As the voice of American business invested in Europe, AmCham EU aims to be a key partner in designing a Pharmaceutical Strategy which realises both of the Roadmap's objectives: 1) Addressing availability and affordability challenges; 2) Support innovation and a globally competitive pharmaceutical industry. To this end we want to emphasize the following points:

Innovation leadership

- The EU needs a world-class innovation ecosystem, including a globally competitive IP framework, to attract investments driving the development of future treatments for the benefit of all patients.
- Innovation leadership is also important when looking at the impact of COVID-19, to ensure Europe is prepared to face any future health crises and governments are equipped with resilient health systems, looking at healthcare as an investment rather than a cost.
- We believe this can be best achieved by targeted, non-legislative initiatives and warn against any erosion or tampering of existing incentives that have proven to be a success story, e.g. the OMP Regulation.
- Measures are needed to stimulate R&D in areas of high unmet need and market failure such as antimicrobials, notably with the introduction of a robust EU-level AMR 'pull' incentive via specific legislation.
- The Strategy should promote public-private cooperation in Europe, to ensure that academic discoveries translate into effective medicines available to patients.

Access and affordability

- Current obstacles to affordability and availability of medicines are multi-factorial. They cannot and should not be addressed by tampering with the EU's regulatory and IP incentives framework, integral to the EU's stated objective to be a world leader in innovation.
- We support the EU Health Coalition's call for a High-Level Forum on Better Access to Healthcare Innovation, enabling multi-stakeholder dialogue to co-design solutions to access issues.
- We encourage the adoption of innovative payment and funding models that help address affordability concerns and healthcare systems sustainability, while fully capturing the value of innovative medicines.

Regulatory procedures and scientific advances

- The Roadmap lacks concrete tools to foster clinical development in Europe putting it on par with other world regions.
- Shorter approval times, reduced administrative burden and more flexible and simplified post-approval processes for medicines are needed, while ensuring quality and safety. This is particularly necessary in the case of innovative therapies such as ATMPs.
- By implementing the EMA's 2025 strategy and the Network Strategy, regulatory improvements would be achieved efficiently without the need for legislative change.
- Advancing the EU Health Data Space will be key to deliver high quality, interoperable, real word data to optimize treatments for patients.

- To increase the use of health digital technologies in Europe, a regulatory framework on the development and implementation of digital solutions and initiatives is needed, including guidelines to national agencies.

Resilience and shortages

- More collaboration between the EU, its partners and industry is needed to improve supply chain flexibility and resilience as part of global, rather than fragmented, approach. Our shared goal should be to quickly and efficiently scale up the production of quality medicines and vaccines, to reflect demand and accommodate any regional supply disruptions.
- This can be achieved by removing tariffs and other trade barriers to ensure multiple sources of supply; fighting trade in counterfeit medicines; transparent and harmonized regulations; real time data sharing on availability and demand needs; and support investment in innovative manufacturing, rather than mandating localization.
- The upcoming EC analysis of root causes of medicines shortages should include the role of parallel trade.
- Harness the benefits of digital and emerging science and technologies for manufacturing and supply.