



The U.S. Chamber of Commerce (Chamber) is the world's largest business federation, representing the interests of more than three million enterprises of all sizes and sectors and a longtime advocate for strong commercial ties between the U.S. and EU. The Chamber and its Global Innovation Policy Center appreciate the opportunity to respond to the European Commission (Commission) IIA on revision of general pharmaceuticals legislation, consistent with our ongoing support for the Commission's work to remove trade barriers and protect IP.

The Chamber shares Europe's goal of ensuring patients with unmet medical needs have timely access to the latest therapies. To accelerate economic recovery, reinvigorate the European pharmaceutical industry, and ensure patients have access to medicines requires a world-class European innovation ecosystem. COVID-19 with its myriad negative consequences is an impetus for the EU to address the strategic vulnerability created by the erosion of its R&D base. Absent bold action, Europe's pharmaceutical sector will continue to lose competitiveness to fierce global competition.

#### Incentivizing Innovation for Unmet Need

A world class IP and incentives framework is a prerequisite for leadership in bio-pharma innovation. Weakening of existing incentives will undermine Europe as an investment destination, without expanding access to medicines.

It is essential for the EU to support the next generations of medicines. In its drive for novel and flexible approaches to unmet need, the Commission should avoid measures leading to fewer medicines or indications eligible for incentives, as it would negatively effect investment and the R&D pipeline. More broadly, to avoid undermining innovation incentives extreme caution should be taken to ensure that amendments to IPRs for competition policy purposes (such as in relation to "Bolar" exemption) strictly adhere to the end goal – e.g., to facilitate clinical testing limited to purposes of generating safety and efficacy data for regulatory purposes.

#### Ensuring Equitable and Affordable Access to Medicines Across the EU

The Chamber supports industry calls for a High-Level Forum on Access to Health Innovation. Differences in access to medicines across the EU largely depend on how and when individual Member States (MS) reimburse medicines. While the provision of health care is a MS competency, the Commission should work to ensure swift MS reimbursement, consistent with the Transparency Directive. Moreover, MS should remove barriers to access, such as international reference pricing. Proposals tying incentives to obligations to launch products in all/most EU markets and on R&D transparency for a single product perpetuate the misperception that healthcare innovation is a *cost*, when in reality it is an *investment*.

The Commission can strengthen the financing of local biotech ecosystems, and promote best practices across the EU. The Commission forecasts immediate economic loss due to the additional obligations it intends to introduce. The effects are likely to be particularly onerous for smaller European biotechs and academic partnerships, putting the EU at a further disadvantage to competitors, such as the U.S. and China.



### Bolstering Supply Chains

The Chamber recognizes the Commission’s concerns regarding the continuity of the global pharmaceuticals supply chain. To enhance access to innovative medicines we suggest the Commission institute and strengthen policies that encourage and facilitate their development, manufacturing and open trade. It is especially important to reaffirm the EU’s commitment to integration and interdependence with like-minded, fellow democratic partner countries. Attempting to “reshore” entire supply chains, especially for medical supplies, would not only dramatically increase costs, but actually undermine supply chain resilience in case of a natural disaster or disruption in Europe’s home market. We therefore encourage the EU to demonstrate international leadership – unilaterally through trade agreements and in multilateral organizations – to promote uninterrupted global supply chains and open trade.

### CONTACT

Robert Grant, Sr. Director, International Affairs

Global Innovation Policy Center, U.S. Chamber of Commerce

[RGrant@uschamber.com](mailto:RGrant@uschamber.com)