U.S. Chamber of Commerce

Response to the European Commission's Consultation on the Revision of the General Pharmaceutical Legislation

December 21, 2021

The U.S. Chamber is the world's largest business federation, representing the interests of more than three million enterprises of all sizes, across all sectors, and is made up of both U.S. and internationally headquartered companies. The Chamber is a longtime advocate for strong commercial ties between the U.S. and EU.

Chamber members are heavily invested across Europe, and we hope that the Commission uses the revision of the pharmaceutical legislation an as opportunity to set the appropriate conditions for the EU-based biopharmaceutical sector to regain its leading international position, in such a way that it recognizes the complexity of medicinal product development, avoids weakening IP rules, or conditions incentives with increased obligations.

Maintaining a system that rewards innovation and encourages investment in new technologies would help to meet this goal.

Looking Back

Q1: In your opinion, are there any other issues that should be addressed in this revision?

- Modernize the pharmaceutical regulatory environment in Europe to learn from advances made during the pandemic, as well as account for the next generation of medicines and vaccines.

- Guarantee strong IP protections to ensure a stable, predictable and transparent regulatory regime for rights holders; focus on maintaining—and avoiding the further erosion of—the European research base.

- Maintain (and extend) a robust framework of incentives to spur R&D that specifically tackles high unmet needs, for example against AMR, to reverse Europe's declining share of global investment in innovative healthcare.

- Recognize the complexity of medicinal product development and avoid the reduction of incentives coupled with increasing obligations for researchers and manufacturers.

- Champion novel approaches to clinical trial design and support the ability of the European Medicines Agency (EMA) and national authorities to modernize and increase uptake of interoperable and cloud-based systems, encourage international research collaboration facilitated by cross-border data flows.

- Preserve open global supply-chains for medicines in collaboration with international partners & stakeholders. For example, focus on strengthening and ensuring continued integrated supply chain connectivity with trusted trading partners through existing bilateral and multilateral efforts including the U.S.-EU Trade and Technology Council and by furthering the work of the WTO Trade and Health Initiative.

Q2: Is there any other aspect you would like to mention, including positive or unintended effects of the legislation, or would you like to justify your replies?

Looking Forward

Unmet Medical Needs

Q3: Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined elements, or would you like to justify your replies?

First, it should be noted that the U.S.—through a willingness to support an IP-enabled innovation ecosystem, including by providing for fair value for investment in innovation—drives most global drug development, including for orphan drugs. A strengthened European industry would help contribute to expanded drug discovery

worldwide. The Commission should use this opportunity to drive European competitiveness and attract investment.

We understand the Commission's intention to define novel and flexible approaches to tackle un-met needs (UMN), but we would warn against the adoption of too narrow a definition, which would neither increase the number of medicines or indications eligible for incentives, nor increase investment or development output. Challenges on the development of novel antibiotics are clear examples of how more, and not fewer, incentives are needed. We do not believe an approach designed for specific patient populations would be optimal to identify UMN in all disease areas. A patient centered UMN approach that considers the severity and burden of disease on patients, families and caregivers is more appropriate. We would also recommend that point 4 not be included as a key criterion to define UMN, as access is dependent on variables associated with specific national markets.

Incentives for Innovation

Q4: Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

Any methodology put forward to capture R&D costs is unlikely to reflect the true industry investment, as developing products is a highly complicated process with a high failure rate. Such debate risks prioritizing expensive R&D programs, rather than high-value products. Policies tying incentives to R&D transparency for a single product perpetuate a mindset focused exclusively on reducing healthcare costs—which itself is a significant reason why Europe's innovative industry is weaker today than in the past.

A robust and predictable regulatory framework is needed to promote investment and undertake a long and uncertain development process. Complementary incentives e.g., additional supplementary protection certificates (SPCs) and regulatory exclusivity focused on underserved areas could be effective drivers to prioritize the development of treatments for high unmet needs. These new incentives should, however, be added to the current framework, not replace it.

Future Proofing: Adapted, Agile, and Predictable Regulatory Framework for Novel Products

Q6: How would you assess the following measures to create an adapted, agile and predictable regulatory framework for novel products?

Regulatory pilots in a 'sandbox' environment would provide the opportunity to test the pharmaceutical framework for development of new cutting-edge products. We recommend the Commission work with industry to provide more clarity on the application of the sandboxes for various types of products.

Moreover, the Commission should take into account the experience of the past two years during the pandemic and work with stakeholders and healthcare providers to ensure the benefits of digital health tools, including telemedicine and increased international research collaboration, continue to flourish.

Q7: Do you think that certain definitions and the scope of the legislation need to be updated to reflect scientific and technological developments in the sector (e.g. personalised medicines, bedside manufacturing, artificial intelligence) and if so what would you propose to change?

The EU should put in place a framework to accommodate tomorrow's innovation, with the regulatory flexibility to adapt as and when the technology does. Broadly speaking, the use of technology in the health sector should be encouraged, as it promotes better health outcomes, lowers costs, and ensures healthcare providers have more time and flexibility to treat more patients more effectively.

For key emerging technologies like artificial intelligence, it is critical that the Commission take a fully risk-based approach, rather than deeming the entire health industry as "high-risk." Patient-facing uses of artificial intelligence like assisted surgery should not be treated the same as processes that automate anonymized patient data entry for clinical trials, for example.

Generally speaking, a flexible regulatory environment that enables innovation while maintaining effective guardrails to protect public health is the best way forward. This environment must be allowed to evolve with technological development, and continued stakeholder engagement is essential.

Rewards and Obligations Related to Improved Access to Medicines

Q8: Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

The introduction of additional obligations on industry would have an immediate negative economic impact (as already foreseen by the Commission itself). Additionally, such measures would not achieve their intended goal of improving European healthcare systems and society. New obligations would rather put the EU at an even bigger competitive disadvantage compared to other markets, such as the U.S. and China.

These potential regulatory changes ignore the central role of member-states on pricing and reimbursement, and the fact that marketing authorization holders only have so much say on member-state launch. Additionally, there may not be demand for certain products in certain member-states.

The root causes of unequal access are multifactorial and require a holistic approach at the EU level. Also, in the case of complex technologies, significant new infrastructure needs to be introduced, making it challenging for companies to launch in most member-states. Requirements that require companies to share launch plans ahead of time ignore such facts and would introduce uncertainty into the entire marketing and reimbursement processes. Undermining IP rights or related additional incentives for underserved populations will not improve access to medicine across Europe. Instead, this would threaten to further erode the EU research base, however unintentionally.

Enhancing the Competitive Functioning of the Market to Ensure Affordable Medicines

Q9: Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

Competition can play a role in relation to affordability, but a level playing field should be ensured, to balance both generics and innovators' interests. Plans to harmonize the Bolar exemption should not be broadened to de facto (pre-) commercial activities. An expansion of the Bolar exemption beyond activities needed for regulatory approval would increase uncertainty, invite unnecessary litigation, and stop or delay innovative investments.

There may be disagreements as to the actual moment of 'patent expiry' so we suggest the creation of an early resolution mechanism, such as exists in the U.S., China, and in other markets. Such clarity could also help with incentives for biosimilars. This incentive could be based upon lessons from the U.S., which show the 180-day exclusivity period for the first approved small molecule drug leads to multiple generic drugs – which ultimately make up 90% of the U.S. market.

Finally, we recommend EU-level procurement be pursued only as an emergency tool, as done with COVID-19 vaccines, not as a standard mechanism to procure therapies due to practical challenges.

Q10: What measures could stimulate the repurposing of off-patent medicines and provide additional uses of the medicine against new diseases and medical conditions? Please justify your answers.

Innovative companies already engage with academia and other entities involved in drug R&D. We suggest the Commission investigate the merits of incentives and consider how they could support repurposing, e.g. indication-based pricing and reimbursement models that could make the repurposing of off-patent products more attractive.

Security of Supply of Medicines

Q11: Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your

replies?

Flexibility and resilience of supply chains are achieved as part of a global and risk-based approach, in collaboration with international partners and stakeholders, following agreed trade rules and obligations. More harmonization across member-states on import/export requirements could encourage greater security of supply. Transparency of stock held e.g., at the manufacturer level, will not alleviate any issues, and given the fragmented real time multi-stakeholder environment, it will be hard to generate meaningful data. Trading partners need to take their obligation to ensure supply seriously. Adequate supply also depends on the variability of demand. Manufacturers should have the right to manage their supply chains with the ability to release products for a specific member-state to cover changing demand on a realistic scale.

Quality and Manufacturing

Q12: Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the outlined measures, or would you like to justify/elaborate your replies?

There is already sufficient oversight of manufacturers. However, there may be a need to strengthen regulatory oversight or due diligence requirements on stakeholders further downstream in the supply chain, such as agents, brokers, distributors, and wholesalers.