AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

Evaluation and revision of the general pharmaceutical legislation

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 €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Executive summary

The American Chamber of Commerce to the EU (AmCham EU) is committed to the development of a regulatory environment which furthers the capabilities of European healthcare, improving accessibility and ensuring a crisis-resistant medicines regulatory system. The following outlines our key viewpoints at the outset of this evaluation and revision process:

- Modernise the pharmaceutical regulatory environment in Europe to account for the next generation of medicines and vaccines;
- Maintain a robust framework of incentives that specifically tackles high unmet need, for example in the fight against antimicrobial resistance;
- Recognise the complexity of medicinal product development and avoid reduction of incentives coupled with increasing obligations. This will undermine innovation without improving access and does not serve to establish the EU as a leader in biopharmaceutical innovation;
- Guarantee strong IP protections to entice long-term global investment in European R&D capabilities;
- Champion novel approaches to clinical trial design and support the ability of European Medicines Agency (EMA) and national authorities to modernise the European Medicines Regulatory Network and increase uptake of cloud-based systems to enable real time information sharing between industry and regulators;
- Preserve an open, globally calibrated supply-chain for medicines in collaboration with international partners and stakeholders.

Our response - evaluation and revision of the general pharmaceutical legislation

As the voice of American business invested in Europe, AmCham EU aims to be a key partner in designing the revision of the EU general pharmaceutical legislation which provides an environment for the biopharmaceutical sector to flourish and to contribute to the overall EU competitiveness. In 2021, 46% of companies active in pharmaceutical R&D are based in the US, with just 19% in the EU; some 55% of medicines globally are developed in the US life sciences ecosystem.[1] As companies invested in Europe, we would like to be in a situation where the EU ceases to be at a comparative disadvantage to the US.

The biopharmaceutical industry continuously works to further ground-breaking science. It is essential for the EU to maintain a solid framework to support the next generations of medicines and vaccines. We understand the Commission's intention to define novel and flexible approaches to tackle high unmet need (UMN), but would like to warn against measures resulting in fewer medicines or indications eligible for incentives, as this will not increase investment or development output. Challenges around the development of novel antibiotics are clear examples of how more – not less – incentives are needed. In this context, defining the concept of 'unmet medical need' may be a challenging exercise. Accordingly, we understand that the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) is working on an UMN concept possibly including a principle-based (criteria) approach and addressing more than orphan and paediatric products. We do not believe an approach designed for specific patient populations would be optimal to identify UMN in all disease areas. A

[1] PharmaIntelligence, 'Pharma R&D Annual Review 2021', 16

patient-centred UMN approach that considers the severity and burden of disease on patients, families and caregivers should be preferred. Such an exercise should be carried out through constructive dialogue with stakeholders and should ensure a suitable level of flexibility as to what type of data could be accepted to meet the definition.

For the EU to still be a leader in innovation, a world class IP and incentives framework is crucial. Any erosion of existing incentives will undermine the attractiveness of Europe as a market for investment without expanding access. Proposals tying incentives to obligations to launch products in all/most EU markets and on R&D transparency for a single product perpetuate a mindset that healthcare innovation is a cost, not an investment and do not address the complexity of the issue (eg, whether there is demand for certain products in a Member State, or that complex technologies (eg, advanced therapy medicinal products) require significant manufacturing and distribution infrastructures).

The obstacles represented by affordability and availability of medicines are multi-factorial. Developing products is a highly complicated process with a high failure rate, any methodology put forward to capture R&D costs is unlikely to ever capture the true investment of industry. Moreover, it opens up a risk that expensive R&D programmes, not high-value products, are prioritised. Plans to harmonise the Bolar exemption should not be broadened to de facto (pre-)commercial activities. After the Supplementary Protection Certificate waiver, this would send further negative signals to US investors.

We are concerned that the current approach is not fully aligned with the sentiment of the Industrial Strategy: to use the green and digital transformations to empower industry and small businesses, and to ensure that all policies are innovation conducive. The forecasted immediate negative economic impact that the EU Commission expects from the additional obligations it intends to introduce will not contribute to achieving the goal of harnessing Europe's industry for the improvement of our healthcare systems and society. It would also put the EU at a competitive disadvantage compared to other geographies, such as the US and China, who are on a trajectory to achieve a V-shaped recovery.

While this would not counterbalance the above-mentioned negative measures, we welcome proactive approaches to the European regulation for medicines that can respond to new technologies quickly. Regulatory pilots in a 'sandbox' environment would provide the opportunity to test the pharmaceutical framework for development of new cutting-edge products. A Complex Clinical Trial (CCT) pilot programme would facilitate use of CCT design approaches in drug development, promote innovation and allow more timely and iterative regulatory advice. Participation of Clinical Trials Facilitation and Coordination Group experts is critical to facilitate consistent scientific advice and evaluation by EMA Scientific Advice Working Party and national clinical trial assessors. We also encourage a forward-looking policy initiative on personalised medicines and the creation of an integrated evaluation pathway for drug-device/diagnostic combination products sufficiently underpinned in legislation.

We reiterate previous calls to provide sustained support to EMA and other regulators. We encourage establishing a European Medicines Regulatory Network (EMRN) regulatory modernisation initiative, to execute alongside regulatory science programmes, with measurable outcomes negotiated between regulators and industry. There is the opportunity to shorten time to Committee for Medicinal Products for Human Use (CHMP) opinion by streamlining steps of assessment process and including rolling review features and to normalise the availability of regulatory tools, such as accelerated assessment and rolling reviews. Build EMA and Network infrastructures to support a cloud-based system enabling real time information sharing between industry and regulators. In addition, collaborations with FDA and other international regulatory partners must intensify so Europe can maintain a position of excellence.

Supply-chain flexibility and resilience should be achieved as part of a global approach, in collaboration with international partners and stakeholders that follows internal trade rules and obligations. Transparency of stock held (eg, manufacturer level) will not alleviate any issues and given the fragmented real time multi-stakeholder

environment this may not be an effective approach as it will be hard to generate meaningful data. Partners in trade need to take their obligation to ensure supply seriously. In this regard the launch of structured dialogue between the Commission and industry including stakeholders in the trade area after the first economic customer is an appropriate step forward. To alleviate future supply disruptions efficient scale-up of production can be achieved within a diverse global network.

AmCham EU remains committed to the on-going process to modernise the EU's regulatory environment for pharmaceuticals, ready to contribute to the structured dialogue and further the shared agenda of industry and the European Commission to improve the health and well-being of EU citizens.