U.S. CHAMBER OF COMMERCE

Comments on the European Commission's Pharmaceutical Strategy for Europe

September 2020

The U.S. Chamber of Commerce ("Chamber") appreciates the opportunity to respond to the European Commission ("Commission") on its Pharmaceutical Strategy.

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. The Chamber is a longtime advocate for strong commercial ties between the United States and the European Union. According to a recent Chamber study the U.S. and EU are jointly responsible for more than one-third of global gross domestic product, and transatlantic trade and investment supports 16 million jobs on both sides of the Atlantic.[1]

This submission complements the Chamber's ongoing support for the Commission's work to remove trade barriers and to protect intellectual property (IP) in the European Union (EU) and internationally[2].

The world's current capacity to innovate is unrivaled in human history. Moreover, it is increasingly clear that the COVID-19 pandemic and associated economic challenges will only be overcome through close partnerships between governments and business that equally leverage and respect the social and economic value created by private sector innovators and creators.[3]

The businesses we represent have been instrumental in supporting and enabling the unprecedented worldwide response to COVID-19. Firms small and large have diverted funding and human resources away from other activities to quickly accelerate the research, development, and manufacture of protective equipment, advanced diagnostics, disinfection products, medical devices, and potential treatments and vaccines. Innovative biopharmaceutical firms in particular have been central to this response and have assumed great business risk with no assurance that they will recoup the costs associated with this extraordinary expenditure of time and resources.

To accelerate the European economic recovery, reinvigorate the European pharmaceutical industry, and ensure patients have access to the medicines they need, the Chamber believes that EU policies must foster a world-class ecosystem for innovation. This would necessarily build on a stable IP system, but should also include targeted incentives to attract capital, remove trade barriers, enable investment in new and existing enterprises, and create high-value, highly paid, long-term jobs.[4]

The Chamber welcomes the Commission's recognition of the significant contributions that the innovative biopharmaceutical sector makes. Innovative medicines can increase efficiency and improve the sustainability of healthcare systems by bringing the right medicines to the right

[1] U.S. Chamber of Commerce & AmCham EU, The Transatlantic Economy 2020.

[2] https://www.uschamber.com/report/2020-international-ip-index

[3] Global Business Associations Recommendations on COVID-19 response Open Letter to Government Leaders.

[4] EPO & EUIPO (2019), IPR-Intensive Industries and Economic Performance in the European Union, pp. 89-90.

patient at the right time, and health systems can avoid additional costs that can have a significant impact on national health budgets (e.g. palliative care, transplants). In short, innovative medicines are therefore a key component to a resilient modern health care system, one that is built on prioritizing healthcare as an investment rather than a cost.

As framed currently, the EU's proposed Pharmaceutical Strategy does not adequately recognize these benefits nor does it properly address the need to reaffirm Europe's global leadership in this high-value, technologically driven sector. The EU must strengthen, rather than undermine, key conditions that would boost European competitiveness and its ability to attract investment in the next generation of innovation.

When announcing the development of the Pharmaceutical Strategy, Health Commissioner Stella Kyriakides rightly set out a high level of ambition, saying: "(T)he EU needs a pharmaceutical strategy that makes essential medicines available to all and cements our global leadership on innovation in pharmaceuticals." The Chamber agrees that Europe should be ambitious, and the COVID-19 crisis has shown that the world depends on life science innovation to fight emerging global health threats and to tackle existing health challenges. [5]

After careful consideration of the Pharmaceutical Strategy Roadmap, we believe the Commission's plans lack the necessary tools to put Europe back at the vanguard of medical discovery. In recent years, 47 percent of new treatments originated in the U.S., compared with just 25 percent from Europe (2014-2018). Yet, 25 years ago the opposite was the case, when almost 50 percent of new medicines originated in Europe. Europe's share of global research and development (R&D) investment is also falling. Over the past twenty years, the EU's R&D base has gradually eroded, with new cutting-edge technology research transferred out of Europe, largely to the U.S., and more recently to countries like China. The United Kingdom's recent departure from the EU is likely to accelerate these trends.

While COVID-19 will have myriad negative consequences, it also represents an opportunity for the EU to respond to the strategic vulnerability created by the erosion of Europe's R&D base. The Pharmaceutical Strategy provides a timely opportunity to do so, by rebuilding Europe's medical research ecosystem, enhancing the region's resilience to global health threats, and positioning it as a key driver for the EU's economic recovery. The Strategy should also be considered in the context of key international alliances with strategic partners, including the United States. In the absence of this kind of action, the loss of Europe's competitiveness will continue—and could accelerate—given fierce global competition for life science investment. Europe risks becoming simply a consumer of medical innovation originating beyond its borders.

The Chamber respectfully offers several suggestions for how Europe can begin to reclaim a leadership role and become a more attractive investment destination for biopharmaceuticals and ensure Europeans can access the very latest innovative medicines.

1. **Develop a World Class Innovation Ecosystem by boosting incentives, enabling technology transfer, and facilitating better access to capital for SMEs.** Such measures would help Europe to build on its impressive record on basic research and enable Europe-based enterprises to grow and attract investment into the development of future treatments for patients, including rare and pediatric diseases.

[5] https://www.theglobalipcenter.com/report/innovation-creativity-access-barometer/

2. **Access to Affordable Medicines – Undertake an evidence-based analysis of the root causes and drivers of access, supply, and shortage issues**. It is important to acknowledge that inequalities of access to new treatments and vaccines across Europe are multifaceted and can only be addressed by stakeholders working together.

3. **Ensure Europe's regulatory system can meet global challenges** such as COVID-19.

4. **Ensure Europe's research, data, supply chain and manufacturing infrastructure is fit for purpose,** resilient, diverse, and environmentally sustainable**.**

1. Develop a World Class Innovation Ecosystem by– boosting incentives, enabling technology transfer and facilitating access to capital for SMEs

We are entering a period of substantially slower growth across much of the world. To accelerate our collective economic recovery, the Chamber is calling on governments to ensure all policies are focused on promoting and innovation.[6] This includes fostering an R&D ecosystem based on a stable intellectual property regime; providing incentives for unmet medical needs, educating qualified scientific staff; enacting research and innovation-inducing tax measures; and developing strong public research institutes.

Strong intellectual property rights (IP) and regulatory protections—including patents, supplementary protection certificates (SPCs), regulatory data protection, trade secrets, and other IP—are the most effective measures to support innovative research and development of new medicines. These temporary protections facilitate timely access to the latest medicines and drive the discovery of tomorrow's new treatments and cures. Effective IP rights and enforcement mechanisms provide innovators with the predictability and legal certainty they need to take on risk, access financing, collaborate with partners, and launch new medicines.

Thanks to such protections and incentives, including those for orphan and pediatric medicines, more than 160 treatments are now available to address previously unmet needs.[7] Today innovators, including those in Europe, are racing to develop safe and effective COVID-19 medicines and vaccines. If the EU were to continue weakening its intellectual property protections, it would risk falling even further behind China, the U.S., and the UK in the development and use of new advances like cell and gene therapies, novel vaccines, and artificial intelligence. Should this occur, the value of European investment would continue to be captured elsewhere. Therefore, alongside maintaining and, where necessary, improving IP protection, the Commission should consider *new* incentives to generate greater private investment in order to address significant challenges such as anti-microbial resistance (AMR).

Patents, regulatory protections and incentives, plus market-based pricing policies, all promote competition and more effective treatment options. In exchange for the temporary period of protection patents provide, innovators must fully disclose their inventions to the world. That public disclosure accelerates innovation and empowers potential competitors to build on those inventions. Today, biopharmaceutical innovators face that competition faster—from other

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[6] Global business associations open letter, *Ibid.*

[7] https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/help-us-make-rare-disease-even-rarer/

innovators, generic drug companies, and even health services seeking to facilitate the manufacture, supply, and use of unlicensed medicines.

Previously, a new medicine might remain the only innovative treatment available in its therapeutic class for ten years or more. By the 2000s however, that period had declined to around two years.[8] Indeed, less than a year after the launch of an innovative treatment for Hepatitis C in 2013, multiple additional treatments became available, competing on both price and clinical benefits. Moreover, generic competitors now challenge patents earlier and more frequently—even as early as four years after the launch of an innovative medicine.[9] Today, more than 94% of innovative medicines experience at least one patent challenge prior to generic entry—compared to 25% in 1995.[10]

The biopharmaceutical sector, with its high failure rate of successful drug discovery, large associated R&D, and lengthy approval processes for new products across multiple markets, is particularly reliant on the temporary protections of IPR. Biopharmaceutical innovators rely on the predictable protection and enforcement of patents, regulatory test data, and safeguards against unfair commercial use of IP as a basis for long-term, high-risk, capital-intensive investments. The Chamber recommends the Commission promote the use of SPCs, and the creation of a unitary SPC, as well as ensure that implementation of the SPC export waiver does not cause undue harm to investment in European innovation.

Europe, despite year-on-year growth, is increasingly lagging behind the U.S. in creating a mature biotech funding ecosystem. This results in significant capital leakage and innovation drain to regions outside Europe.[11] To promote the wider uptake and use of the IP system as a driver of economic and social value, we recommend the EU promote public-private cooperation, to ensure that academic discoveries translate into effective innovations available to consumers. In this respect, we suggest the introduction of measures to enable universities and research institutions to play a more important role, by increasing the entrepreneurship of scientists and technical transfer offices. The Bayh-Dole Act in the United States provides a useful model of encouraging greater IP commercialization based on university research underpinned by public sector funding.[12]

Another key aspect of a flourishing innovation ecosystem is a well-functioning capital market. There is significant public research funding available in Europe such as the public-private partnership Innovative Medicines Initiative (IMI), the European Commission's Horizon 2020 program, and InnovFin. These are generally seen as good funding vehicles for SME biotech companies, however existing funding mechanisms are insufficient for many inventions to be brought to market—more effective private investment partnerships are necessary.

Taking into account the investments needed to develop biopharmaceutical products for market launch, the total amount of European Venture Capital (VC) money is too low to finance European biotechs throughout the whole product development process. Mature biotech companies that can develop, launch, and sell a medicinal product independently are lacking in Europe. Such companies are essential for a confident biotech investment ecosystem. Most

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[8] Tufts Center for the Study of Drug Development, "First-in-class drugs in competitive development races with later entrants," Impact Report, Dec. 2015, View here

[9] Grabowski, H., G. Long et al., "Updated trends in US brand-name and generic drug competition," Journal of Medical Economics, Sep. 2016, View here

[10] *Ibid.*

[11] https://vitaltransformation.com/2018/10/investing-in-eu-biotech-ip-what-works/

[12] https://bayhdole40.org/

companies do not find their funding in Europe, but instead move to the U.S., seeking a listing on the NASDAQ or acquisition by a larger, often U.S.-based company. We are also increasingly seeing China-based entities as a route for European biotech to secure funding through acquisition.

The EIB and EIF are important bodies within the EU to provide long-term financing, including the funding of venture capital firms, but as with the IMI, funding is spread too thinly. Both EIB and EIF, when financing investment funds, could provide funding with the aim of creating larger funds that can invest across Europe.[13]

Additional incentives to stimulate greater investment, currently available at national, or sub-national level—such as tax credits for research or specific commercialization agreements for IP developed at European universities through investors in biotech start-up companies—can present strong incentives to biotech companies and assist in obtaining longer term funding.[14]

There are many examples across Europe of flourishing innovation hubs. Nevertheless, approaches are fragmented and the Commission should consider promoting the most successful examples of such incentives in a manner that creates synergies across Europe. A European Commission supported and member state implemented exercise to promote best practices to incentivize innovation would provide additional support to establishing and maintaining successful biopharma businesses across Europe.

2. Access to Affordable Medicines – Undertake an evidence-based analysis of the root causes and drivers of access, supply, and shortage issues

Chamber member companies share the goal of ensuring that patients in Europe can access leading edge treatments and cures. New, novel medicines are revolutionizing how we fight disease, but too often the way we value them has not kept pace. Many EU member states have restrictive government pricing and reimbursement policies that may contribute to delaying market access for biopharmaceutical innovators, thereby preventing timely patient access to medicines that have received regulatory approval.

Advances in the treatment of diseases typically are not driven by large, dramatic developments, but more commonly build on a series of continuous advancements over time. The full value of a particular therapy typically emerges years after initial approval as further research is conducted and physicians and other health care providers gain real-world experience. The optimized use of medicinal products and the further development of therapeutic classes of medicines often lead researchers to explore new treatments in related areas—restarting the research and development cycle.

Indeed, nearly a quarter of existing therapeutic indications are treated by medicines initially developed to address a different concern.[15] And more than 60% of therapies on the World Health Organization's (WHO's) Essential Medicines List relate to improvements on older

[13] https://www.ebe-biopharma.eu/publication/the-european-biotech-ecosystem-ebe-position-paper-recommends-how-to-make-funding-go-further/

[14] https://internationalbiotech.org/wp-content/uploads/2018/11/BIO-2018-report-Final.pdf

[15] Jin, G. and S. Wong, "Toward better drug repositioning: prioritizing and integrating existing methods into efficient pipelines," Drug Discovery Today, Jan. 2014, www.sciencedirect.com/ .

treatments.[16] This step-by-step transformation in knowledge has led to increasing longer lives, improved outcomes, and enhanced quality of life for many patients.[17] There should be mechanisms to encourage and reward such innovation and adequate protections responding to the necessary investment.

Correlating medicine prices with costs related to development and manufacturing, as a means to bring down healthcare costs may seem simple on the surface but suffers from several serious flaws—and does not properly capture all elements to be factored in when looking at the price of a medicine. For a start, policies that require disclosure of costs such as R&D and manufacturing (cost-plus) fail to account for the complex nature of biopharmaceutical R&D. Such a narrow approach is also likely to discourage future investments in cutting-edge innovation. Cost-plus pricing rewards high-cost manufacturing and inefficient R&D, rather than high-value products. Value-based approaches—where a medicine's price is based on how well it works for patients—present a new option that would more appropriately provide a fairer value for innovation and a reasonable return on investment. Moreover, greater disclosure of the costs individual states pay for specific medicines could undermine a tiered pricing approach, which allows poorer states access to therapies. The Commission should take care to ensure that any actions taken in the context of the Pharmaceutical Strategy do not, in fact, have inadvertent consequences that would ultimately be to the detriment of patient access.

For these reasons, the Chamber supports the EU Health Coalition's call for the creation of a High-Level Forum on Better Access to Health Innovation, which would bring together stakeholders and evidence to address the barriers to access and to find new solutions to overcome them.[18] Biopharmaceutical companies seek to work with governments and payers to develop innovative and flexible ways to value medicines that focus on results, lower patient costs, prevent shortages, and enable timely access to the medicines patients need.

3. Ensure Europe's regulatory system can meet global challenges

COVID-19 underscores the importance of an adaptive regulatory environment to enable global, innovative research and development and provide access to novel therapies. The EU regulatory system should align with the evolving international environment to assess real world data, complex innovative clinical trial designs, and digital health technologies, including AI and advanced therapy medicinal products. The EU should ensure a public policy environment that is transparent and predictable, allowing industry stakeholders to participate meaningfully in developing rules and regulations that support market efficiency.

Cell-based advanced therapies are innovative treatments which can pave the way for for future scientific developments. A treatment which cures disease can not only dramatically change the lives of patients but also significantly enhance the efficiency of healthcare systems. In this respect, we call on the Commission to pay attention to the current legal framework for the development of Advanced Therapy Medicinal Product (ATMPs) in hospitals (the 'Hospital Exemption') as set out in Article 3(7) of Directive 2001/83/EC. The Hospital Exemption has a legitimate role to play in areas of unmet medical need, as long as it is used appropriately and consistently. However, the Hospital Exemption has been interpreted differently across member states, creating unhelpful variation and market fragmentation. In response, the Chamber believes

[16] See Cohen, J. and K. Kaitin, "Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice," American Journal of Therapeutics, Jan.-Feb. 2008, journals.lww.com/americantherapeutics/).
[17] Goss, T.F., E.H. Picard, and A. Tarab, Recognizing the Value in Oncology Innovation, Boston Healthcare Associates, June 2012, link to article
[18] https://www.euhealthcoalition.eu/recommendations/

there is a need for clear and harmonized guidelines to clarify the scope and requirements, including a clear definition of 'non-routine' preparation.

Separately, as companies respond to calls for COVID-19 vaccines and other treatments, we welcome the enhanced flexibility that regulators are showing through their willingness to explore adaptive and appropriately accelerated regulatory approval procedures. To ensure society's confidence in the vaccines being developed and the high standards that the European Medicines Agency and national regulators require for any vaccine candidate, clear and consistent communication between regulators, industry, and patient groups is essential.

Moreover, current circumstances offer a significant opportunity to enhance existing international regulatory cooperation efforts. The Commission should work closely with partner countries, including the United States, to share regulatory testing data to encourage faster adoption of effective medicines. Doing so will require effective ongoing coordination across the Commission and with partner governments to ensure the continued viability of cross-border data flows, including strengthened protections for the commercial transfer of data to different regulatory bodies, paired with sufficient patient privacy protections. Moreover, policymakers should build on the successes of the EU-U.S. mutual recognition agreement on pharmaceuticals, and efforts should be made to expand regulatory cooperation to cover vaccines along with veterinary medicine.

4. Ensure Europe's research, data, supply chain and manufacturing infrastructure is fit for purpose

The Chamber recognizes and appreciates the EU's concern regarding the security of the global pharmaceutical products supply chain.

Governments have an opportunity—and a responsibility—to work closely with businesses to identify and remove obstacles to swift approval and distribution of COVID-19 technologies, including removing unnecessary regulatory requirements, approval delays, and barriers to the efficient distribution of materials, including: export bans, excessive stockpiling or allocation requirements, taxes, and tariffs. Indeed, the Chamber has expressly outlined a number of principles that should limit and guide the use of any export restrictions—which we emphasize must be "targeted, proportionate, transparent, and temporary" as agreed by the G20.[19]

The Commission, EU member states, and many others are already taking significant steps to maintain distribution channels and to prepare for the swift approval and distribution of safe and effective medicines and vaccines, recognizing that expedited regulatory pathways must not compromise our mutually held goal of safe and effective solutions. We hope the Commission continues to pursue such actions, and that you will encourage other governments to do the same. Again, active cooperation and regulatory data sharing with other governments will be key.

As the Commission's "Roadmap" on Pharmaceutical Strategy rightly recognizes, responses to new and emerging health crises do not happen in a vacuum but have an important international dimension. To enhance patient access to innovative medicines, the EU and its member states should institute or strengthen policies that encourage the development, manufacturing, and trade of important treatments and cures through pro-innovation policies. The Chamber has developed

[19] https://www.uschamber.com/issue-brief/international-principles-export-restrictions-the-covid-19-pandemic

a series of policy recommendations on supply chain security, the importance of stockpiling critical materials, and keeping trade open..[20]

The unprecedented volume and progress of R&D collaborations to advance development and deployment of COVID-19 treatments and vaccines highlights the importance of mechanisms for efficient and expeditious licensing of intellectual property rights. Governments should coordinate efforts and work transparently to ensure uninhibited trade in medicines, medicine inputs and ingredients, and other life-saving products. They should also partner with the private sector to enhance patient access. In terms of creating a more robust manufacturing supply chain, there is also a need for stronger regulatory oversight in third countries. This could be acheived through the promotion and adoption of high Good Manufacturing Practice (GMP) standards, and an expansion of existing Mutual Recognition Agreements on GMP.

Chamber member companies work in partnership with universities, clinical researchers, patient organizations, health care providers, and others to bring new treatments and cures to patients who need them around the world. Our companies have introduced nearly 650 new therapies since 2000[21] and are actively investing in many of the over 8,000 new drugs currently in development worldwide, with about three quarters having the potential to be first-in-class treatments.[22] These collaborations are predicated on strong, transparent, and predictable IPRs. When parties mutually license rights on the basis of these IPRs, it prompts them to reach agreement on the relative value of the resources that each brings to the collaboration. Such contractual agreements are fundamental to the allocation of private sector resources, in particular.

Biopharmaceutical innovation is necessarily global. According to an April 3 report on trade in medical goods from the World Trade Organization (WTO), global production of medicines, medical supplies and equipment, and personal protective equipment (PPE) is broadly distributed around the world.[23] Rather than incentivizing the production of pharmaceuticals solely in the EU, efforts should be made to remove domestic and global trade barriers and to stimulate international partnerships—particularly with trustworthy partners. Diversifying supply chains to avoid overreliance on non-market economies may be a reasonable goal, but the EU should work together with partners like the U.S., Canada, UK, Australia, and Japan to ensure robust and geographically diverse sources of supply in case of future shocks. Research, development, and distribution of innovative medicines increasingly involve collaboration and the exchange of commercially sensitive information between multiple partners across borders and around the world.

Strong intellectual property protection and enforcement enable innovators to license their patented inventions with the certainty that valuable information remains secure. In addition, fair and transparent access to overseas markets provides a powerful incentive that drives and sustains substantial investment in valuable treatments and cures. Where markets are open and intellectual property is protected and enforced, biopharmaceutical innovators have the predictability and certainty they need to collaborate with partners, accelerate the launch of new medicines and compete successfully. Competition means more medicines in the same therapeutic class, more

[20] https://www.uschamber.com/issue-brief/learning-the-right-lessons-safeguarding-the-us-supply-of-medicines-and-medical-products

[21] U.S. Food and Drug Administration, "New Drugs at FDA: CDER's new molecular entities and new therapeutic biological products," View here ; and U.S. Food and Drug Administration, "Biological approvals by year," View here

[22] Long G., The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, Analysis Group (2017), available at View here

[23] https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf

options for patients, and lower prices. In a time where global health threats can develop quickly and unexpectedly, robust international cooperation and open markets are prerequisites for stability in the global pharmaceutical products supply chain.

Conclusion

The U.S. business community is proud of its longstanding and significant contributions to the transatlantic commercial relationship and to Europe's thriving innovation economy. Our member companies are eager to help Europe respond to the pandemic, help provide advice on best practices to ensure Europe remains competitive and continues to thrive as an attractive destination for biopharmaceutical investment. The Chamber appreciates the opportunity to share these comments, and we look forward to continuing our constructive engagement with the Commission as the Pharmaceutical Strategy develops.

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