STATEMENT

RESEARCH-BASED BIOPHARMACEUTICAL INDUSTRY ON THE TRIPS WAIVER DISCUSSIONS AT WTO MINISTERIAL CONFERENCE 12

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The associations representing the global research-based biopharmaceutical industry reaffirm that weakening the intellectual property (IP) framework as proposed in the "Quad compromise" is unnecessary and harmful to innovation. An IP waiver does not address inequitable access to COVID-19 vaccines and will put global health security at risk. It will undermine innovation and industry's ability to partner, invest at risk, and respond quickly to future pandemics.

Industry has worked around the clock, taking a "business NOT as usual" approach to tackling the COVID-19 pandemic, focusing significant resources to push the boundaries of science, develop workable solutions and secure the capacity to scale up manufacturing once solutions were found, while at the same time ensuring patients would continue to receive existing medicines. This resulted in the fastest ever vaccine development and authorization (in just 326 days).

Despite these strides in science and manufacturing, for the past 18 months, the World Trade Organization (WTO) Member States have been discussing various ways to weaken the IP framework. To this day, there is no evidence that IP has been a barrier to COVID-19 vaccine production or access, nor acknowledgment of the critical role IP has played in the research, development, and production of novel, safe, and effective vaccines and therapeutics.

From the outset of the pandemic, industry knew that it would need to scale up quickly, seeking to build capacity before approvals were granted, partnering wherever possible, all while pledging to not compromise on quality, safety and efficacy[1]. To date, industry has entered into 381 partnerships for COVID-19 vaccines and 150 for COVID-19 therapeutics, of which over 88% and 79%, respectively, involve technology transfer. IP protections allowed for years of research and investment at risk to bear fruit and today we have 11 vaccines with WHO Emergency Use Listing and 36 therapeutics approved across the world.[2] Biopharmaceutical companies continue to research and invest. Academia and industry have 659 (192 in clinical phase) vaccine candidates and 1,706 (885 in clinical phase) therapeutic candidates in the pipeline.[3]

By May 2021, less than six months after the first vaccine authorization, monthly production output was close to a billion vaccine doses;[4] enough to vaccinate the world if countries were

[1] https://www.ifpma.org/wp-content/uploads/2020/09/COVID-19_Vaccine_Maker_Pledge.pdf
[2] https://covid19.trackvaccines.org/agency/who/
[3] https://www.efpia.eu/media/637039/efpia-vaccines-infographic-may-2022-1.pdf
[4] Note: Global monthly production of COVID-19 vaccines reached 0.83 bn doses in May 2021, 1.2 bn doses in June 2021, 1.2 bn doses in July 2021. Source: IFPMA analysis based on Airfinity data, available at: https://science.airfinity.com/

willing and able to share. At that time, industry called on governments to remove trade restrictions, share doses and prepare health systems to roll out vaccinations ("*5 steps to urgently advance COVID-19 vaccine equity*"), a message repeated in March 2022 when critical bottlenecks in vaccine delivery and administration, often linked to weak healthcare systems, were becoming even more evident ("*Three Priorities to Urgently Increase COVID-19 Vaccine Access*"). Today, it is universally recognized that COVID-19 vaccine supply is not the barrier to access with global vaccine production capacity vastly exceeding demand and doses needed to inoculate and provide boosters to the world.

During this pandemic, there have been many lessons learned that can improve equitable access for future pandemics.[5] We must redouble our collective efforts to achieve health equity, while ensuring health systems and delivery infrastructure are strengthened. COVID-19 vaccines and treatments were only possible because of decades-long investment in research and an enabling IP framework that encouraged swift, voluntary partnerships across the private, public, and academic sectors.

The TRIPS waiver discussion lacks evidence and the IP framework has fallen victim of political posturing. This week, as the WTO meets for the 12th Ministerial Conference, leaders must keep in mind that weakening the IP framework will jeopardize global health security. A much better approach is to focus on the real challenges to COVID-19 vaccine access including removing trade barriers, addressing distribution challenges, strengthening healthcare systems, and partnering to drive innovation and access.

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About

ABPI exists to make the UK the best place in the world to research, develop and use new medicines. We represent companies of all sizes who invest in discovering the medicines of the future. Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

The **Biotechnology Innovation Organization** (BIO) is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

The **European Federation of Pharmaceutical Industries and Associations** (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

The **International Council of Biotechnology Associations** (ICBA) is a coalition of nonprofit, national biotechnology trade associations formed to promote public understanding of, and to advocate for, public policies that support the growth of the innovative biotechnology industries. The ICBA represents the

[5] https://www.ifpma.org/wp-content/uploads/2022/05/IFPMA_COVID-19_Pandemic_Lessons_Learned_May_2022.pdf

global voice of the industry in international fora with the goal of promoting continued innovation in the human health, agriculture, and industrial and environmental sectors.

The **International Federation of Pharmaceutical Manufacturers and Associations** (IFPMA) represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

The **Japan Pharmaceutical Manufacturers Association** (JPMA) is a voluntary association comprising 73 research-oriented pharmaceutical companies. JPMA has been contributing to advancing global healthcare through the development of innovative ethical drugs, facilitating sound development of the pharmaceutical industry through proactively establishing policies and recommendations in response to globalization and enhancing public understanding of pharmaceuticals.

The **Pharmaceutical Research and Manufacturers of America** (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1 trillion in the search for new treatments and cures, including $91.1 billion in 2020 alone.

Vaccines Europe was created in 1991 to provide a voice for the vaccine industry in Europe. The group represents vaccine companies of all sizes operating in Europe, and currently includes all the major global innovative and research-based vaccine companies, including small and medium-sized enterprises.