WTO Twelfth Ministerial Conference: A Critical Opportunity to Strengthen the Global Trade and Health Agenda

The global biopharmaceutical industry,¹ which operates within a wide and interconnected innovation ecosystem, has long supported a strong international trading system rooted in the World Trade Organization's (WTO) core principles regarding openness, fairness, and predictability. These principles, as established by the WTO's key agreements, have played an essential role in helping to ensure that innovative pharmaceuticals, vaccines, therapies, and diagnostics can be developed, manufactured, and distributed to health systems and patients around the world. The WTO's Twelfth Ministerial Conference (MC12) presents an opportunity for WTO members to formalize and pursue a robust trade and health agenda that builds on these principles and further strengthens the open and rules-based international trading system in response to COVID-19 and future health crises.

Biopharmaceutical Industry Response to COVID-19

The world's innovative biopharmaceutical companies have developed, manufactured, and distributed billions of doses of vaccines, diagnostics and therapeutics to combat COVID-19. As of September 2021, 7.5 billion doses of COVID-19 vaccines had been produced, and it is estimated that 24 billion doses will be manufactured by June 2022.² These efforts have succeeded through more than 300 voluntary manufacturing and production agreements, including technology and knowledge transfer. Underpinning these innovations and voluntary agreements is a system of global innovation incentives, including strong and predictable intellectual property rights. Any weakening of these rights would significantly undermine innovation, collaboration, and access to vaccines, therapies, and diagnostics. Critically, COVID-19 vaccines have not equally reached all populations worldwide. To address this issue, the biopharmaceutical industry has committed to <u>five steps to urgently</u> advance COVID-19 vaccine equity: call for and support dose sharing, continue to optimize production, support country readiness, drive further innovation, and encourage the elimination of trade barriers.

Key Role of the WTO

As the primary global institution responsible for promoting and ensuring open and rules-based international trade, the WTO is playing and should continue to play a leading role in encouraging countries to eliminate trade barriers that impede the distribution of biopharmaceutical products, including COVID-19 vaccines and treatments, across borders. WTO Director General Ngozi Okonjo-Iweala has highlighted repeatedly the need for "[a]ction to further reduce export restrictions and supply chain barriers, and to facilitate logistics and customs procedures."³ The WTO Secretariat also has raised these issues, including in the context of "trade-related

Member companies composing The Association of the British Pharmaceutical Industry (ABPI), European Federation of Pharmaceutical Industries and Associations (EFPIA), International Federation of Pharmaceutical Manufacturers & Association (IFPMA), and Pharmaceutical Research and Manufacturers of America (PhRMA).
Airfinity, September 2021 Snap Shot COVID-19 Data, https://www.ifpma.org/wp-content/uploads/2021/09/Airfinity_September_2021_Snapshot_COVID-19_Data.pdf.

 ³ Speech – DG Ngozi Okonjo-lweala, Chair Summary following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" (14 April 2021), https://www.wto.org/ english/news_e/spno_e/spno7_e.htm.

bottlenecks and trade-facilitating measures on critical products to combat Covid-19."⁴ We welcome inclusive conversations among the WTO, its member states, and various stakeholders concerning these and related issues regarding trade and health.

By pursuing the global trade and health initiative at MC12, WTO members can strengthen existing trade policy environments and, in so doing, ensure a thriving innovation ecosystem, streamline regulatory frameworks, and strengthen the overall healthcare system, which in turn will better enable the world to combat the current and any future health crises.

WTO Trade and Health and MC12

Several proposals and initiatives that already are under consideration at the WTO provide a helpful basis for strengthening health-related trade policy. For example:

- In April 2020, New Zealand and Singapore announced trade-facilitative measures (including tariff elimination and commitments not to impose export restrictions) to ensure supply chain continuity and the removal of impediments to trade in products essential for the response to COVID-19.⁵
- The "Ottawa Group" submitted a "Trade in Health" initiative to the WTO's General Council in November 2020.⁶ This initiative proposes that WTO members limit export restrictions on essential medical goods, reduce tariffs, improve transparency, cooperate with other multilateral organizations, and share information and implement best practices concerning trade facilitation measures, standards, and technical regulations. This communication has evolved into a Draft General Council Declaration and now includes the formal support of over 50 WTO members.⁷
- The European Union's June 2021 communication to the WTO on "Urgent Trade Policy Responses to the COVID-19 Crisis" outlines constructive proposals concerning trade facilitation, regulatory cooperation, and disciplining export restrictions.⁸

These and other initiatives demonstrate a growing desire by WTO members to strengthen health-related trade policy measures. Illustrative of the urgent need to address these issues, additional support for such initiatives has been voiced in other important international fora. Under Italy's G20 Presidency, the May 2021 "Rome Declaration" acknowledges "the central role of the WTO, and the importance of open, resilient, diversified, secure, efficient and reliable global supply chains across the whole value chain related to health emergencies."⁹ Similarly, the September 2021 "Declaration of the G20 Health Ministers" recognizes the urgent need "to

5 Measures in Response to the COVID-19 Pandemic: Measures to Ensure the Free Flow of Trade in Essential Goods for Combatting the COVID-19 Pandemic, Communications from Singapore and New Zealand, G/C/W/777 and 778 (16 April 2020).

⁴ Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat Covid-19, Information Note (8 October 2021).

⁶ COVID-19 and Beyond: Trade and Health, Communication from Australia Brazil, Canada, Chile, the European Union, Japan, Kenya, Republic of Korea, Mexico, New Zealand, Norway, Singapore, and Switzerland, WT/GC/223 (24 November 2020).

⁷ Draft General Council Declaration, COVID-19 and Beyond: Trade and Health, JOB/GC/251/Rev.3 (30 June 2021).

⁸ Urgent Trade Policy Responses to the COVID-19 Crisis, Communication from the European Union, WT/GC/231 (4 June 2021).

⁹ Global Health Summit: The Rome Declaration (21 May 2021), https://www.governo.it/sites/governo.it/files/documenti/documenti/Approfondimenti/ GlobalHealthSummit/GlobalHealthSummit_RomeDeclaration.pdf.

eliminate WTO-inconsistent barriers that jeopardize the effective operation of the supply chains for essential medical goods."¹⁰ Finally, under the UK's G7 Presidency, the June 2021 "Carbis Bay Declaration" commits G7 members to pursue health objectives "based on the principles of open trade and transparency, including through terminating unnecessary trade restrictive measures and supporting open, diversified, secure and resilient supply chains."¹¹

Biopharmaceutical Industry Roadmap to Strengthen the Global Trade and Health Agenda

Building on the above-mentioned and similar proposals and initiatives, the biopharmaceutical industry urges WTO members to discuss and capitalize on MC12 to:

- take timely and critical actions to immediately liberalize trade of health products and the inputs and equipment required to develop and manufacture those products;
- confirm the central role of the WTO in strengthening and future-proofing the open and rules-based international trading system for the life sciences sector; and
- commit to advancing a robust trade and health agenda that will address health-related trade issues both immediately and more regularly in the future.

As partners in this fight against the pandemic and any future health crisis, the biopharmaceutical industry stands ready to work with WTO members and all stakeholders in advancing immediate and future working agendas to achieve these objectives. In doing so, industry encourages WTO members to consider the following:

1. Refrain from export restrictions: We urge WTO members to review and promptly eliminate export restrictions on health products, refrain from imposing new restrictions, and ensure that any export restrictions that WTO members deem necessary are consistent with WTO rules and procedures, including requirements that the restrictions be temporary, transparent, properly notified to the WTO and impacted parties, and applied only to prevent or relieve critical shortages of essential products.

COVID-19 and export restrictions: At the height of the first wave of the COVID-19 pandemic, governments around the world resorted to export restrictions intended to prevent shortages of critical goods. By April 2020, a total of 145 notified export restrictions had been imposed on medical goods. One year later, over 60 notified restrictions were still in place.¹² Rather than secure domestic supply, these restrictions hindered the global response to the pandemic by imposing barriers on companies coordinating global medical supply chains. At a time when companies most needed to dedicate their time and resources to increasing global supply, these restrictions disrupted supply chains and distribution routes, produced delays and additional costs, and increased the risk of supply shortages during the pandemic.

12 WTO members' notifications on COVID-19, https://www.wto.org/english/tratop_e/covid19_e/notifications_e.htm.

¹⁰ Declaration of the G20 Health Ministers (5-6 September 2021), https://reliefweb.int/sites/reliefweb.int/files/resources/G20_ltalia_2021_Health_Declaration_ final_05092021_OFFICIAL.pdf.

¹¹ Carbis Bay G7 Summit Communique: Our Shared Agenda for Global Action to Build Back Better (June 2021), https://www.g7uk.org/wp-content/uploads/2021/06/ Carbis-Bay-G7-Summit-Communique-PDF-430KB-25-pages-1-2.pdf.

2. Eliminate tariffs: We urge WTO members to eliminate tariffs on health products, including finished therapeutics, diagnostics, and vaccines, as well as the active pharmaceutical ingredients, raw materials, chemicals, other inputs and intermediaries, and specialty equipment used to invent, manufacture, and deploy these products.

COVID-19 and tariff elimination: Tariffs on vaccines and the inputs and equipment required to develop and manufacture them impose unnecessary material costs on the manufacture and distribution of COVID-19 vaccines. According to the Organisation for Economic Co-operation and Development (OECD), tariffs on vaccines exist in 22% of countries, with 8% of countries applying duties above 5%.¹³ Equally concerning are the numerous tariffs that governments impose on raw materials and other inputs necessary to produce medicines, including vaccines. According to the OECD, average world tariffs on vaccine ingredients such as preservatives, adjuvants, stabilizers, and antibiotics range between 2.6% and 9.4%.

3. Improve trade facilitation: We urge WTO members to take actions at their borders to improve trade facilitation measures for health products, including pharmaceutical products. Such actions may include enhancing customs clearance procedures, sharing best practices, developing and publishing national trade facilitation plans, and prioritizing full and immediate implementation of the WTO Trade Facilitation Agreement.

COVID-19 and trade facilitation: In response to COVID-19, certain WTO members implemented various measures, including green priority lanes and other expedited protocols and customs procedures, to facilitate the import and distribution of health products. Such initiatives have helped to strengthen supply chains and ensure that vaccines and other essential health products have reached global populations safely and efficiently.

4. Strengthen regulatory cooperation and capacity building: We urge WTO members to increase and improve regulatory cooperation, share best practices across borders, and expand mutual and unilateral recognition policies, as appropriate. In addition, WTO members may consider designing and implementing formal trade-related capacity building programs, including through resource sharing and the WTO's "Aid for Trade" initiatives.

COVID-19 and regulatory cooperation: COVID-19 has highlighted the importance of robust and consistent regulatory standards for health products and services, as well as the critical need for cooperation among countries in developing and applying those standards. Effective regulation boosts public trust in the safety of health products, including vaccines, and contributes to global supply chain resilience. Throughout the COVID-19 pandemic, coherent and consistent regulations, as well as regulatory agility, have helped to facilitate patient access to critical health products. Conversely, regulatory complexities and inefficiencies in certain markets have impeded supply chains and delayed patient access.









13 OECD: Using trade to fight COVID-19: Manufacturing and distributing vaccines (11 February 2021), https://www.oecd.org/coronavirus/policy-responses/using-trade-to-fightcovid-19-manufacturing-and-distributing-vaccines-dc0d37fc/?utm_source=Adestra&utm_medium=email&utm_content=Read%20More&utm_campaign=Trade%20May%20 2021&utm_term=tad.