Trade and Health Agenda: A Meaningful World Trade Organization Roadmap to Strengthen Global Health

The World Trade Organization is a key institution to promote global health

The global biopharmaceutical industry,[1] which operates within a wide, 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 ensuring that innovative biopharmaceuticals, vaccines, and therapies can be developed, manufactured, and distributed to health systems and patients around the world.

WTO members should formalize and pursue a robust trade and health agenda that builds on these principles, expands the scope and utility of existing initiatives, and further strengthens the open and rules-based international trading system that underpins and supports global health.

By pursuing a meaningful and proactive global trade and health agenda that reduces barriers to exports and imports of biopharmaceuticals and their inputs, WTO members can help ensure a thriving innovation ecosystem, streamline regulatory frameworks, strengthen supply chain resilience, and improve healthcare systems for the benefit of patients and economies around the world. As the primary global institution responsible for promoting and ensuring open and rules-based international trade, the WTO should play a leading role in encouraging countries to eliminate trade barriers that impede the distribution of biopharmaceutical products across borders.

In a changing international context, some WTO members are pursuing national and regional policies that align with the proposals in this paper, to make their supply chains for critical medical goods more resilient. A significant opportunity exists to build towards a global consensus, taking forward the momentum of the WTO's Thirteenth Ministerial Conference (MC13) to support diversified and reliable global supply chains[2] and safeguard the development, trade of, and access to vital health products against future economic and health challenges.

A WTO roadmap to strengthen global health through meaningful trade policies

Ahead of the WTO's Fourteenth Ministerial Conference (MC14), WTO members should formalize and pursue a robust trade and health agenda that confirms the central role of the WTO in strengthening and future-proofing the open and rules-based international trading system that enables life sciences innovation and access to medicines for patients worldwide. This agenda should seek to resolve immediate challenges and provide a framework to address more effectively health-related trade issues in the future.

Furthermore, with several multilateral and regional organizations discussing and negotiating how to strengthen healthcare systems to prepare for future global health emergencies, the WTO

[1] 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).

[2] Abu Dhabi Ministerial Declaration, MC13, Paragraph 6. *We underscore the importance of open, inclusive, resilient, sustainable, diversified and reliable global supply chains, and their role in ensuring that production and trade can more easily recover from crisis and disruptions. We note the work being done in WTO bodies, especially on transparency including information sharing, and welcome efforts to promote the resilience of global supply chains.*

is best positioned among such organizations to ensure that the multilateral trading system contributes to these objectives. It is therefore critical that WTO members lead these discussions and negotiations at the WTO.

This proposal builds on work that already is underway or has been proposed at the WTO and by its members.[3] In particular, the global biopharmaceutical industry encourages WTO members to prioritize the following objectives: (1) strengthen the innovation ecosystem and protect intellectual property (IP) rights; (2) eliminate tariffs and limit export restrictions; (3) strengthen supply chains and improve trade facilitation; and (4) enhance quality and effectiveness of regulatory policies and procedures. Industry stands ready to engage on these issues and share relevant experiences, best practices, evidence, and data.

1. Strengthen the innovation ecosystem and protect IP

WTO members should take actions at the WTO to ensure that key global policies to incentivize medical innovation and promote essential research, development, production and distribution of medicines are respected. Such policies include those that promote adherence to the rule of law, development of skilled workforces, health-related data flows, and implementation of robust IP and other pro-innovation regulatory frameworks. At a minimum, WTO members should fully implement and enforce their obligations under all WTO agreements, including the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The TRIPS Agreement has created the policy environment necessary for the world's technological advancement over the last three decades. For the biopharmaceutical industry, WTO members that lead global innovation have high standards of IP protections, significantly invest in domestic healthcare, and promote a strong, robust and predictable innovation ecosystem.

In any review or discussion regarding the TRIPS Agreement, WTO members should recognize and embrace the vital role of robust and predictable IP protections in enabling innovation and investment. In addition, WTO members should ensure that transfers of technology occur at all times in accordance with existing WTO rules and on a voluntary basis and mutually agreed terms.[4] Any WTO discussions concerning technology transfer, including in the Working Group on Trade and Transfer of Technology, should reflect and respect these policies. Together, these rules and policies concerning IP, innovation, and technology transfer play a critical role in facilitating medical innovation. The biopharmaceutical industry has a research and development (R&D) intensity level of 30%, invests more in R&D than any other R&D-intensive industry, and supports a pipeline of approximately 12,700 medicines in different phases of clinical development globally.[5] In 2022 alone, the top 50 biopharmaceutical companies alone invested $167 billion in R&D.[6] Through robust support for the WTO's foundational obligations and collaboration to promote an innovative global ecosystem, WTO members can ensure that their policy and legal frameworks incentivize medicine discovery and commercialization and strengthen global health.

To support the WTO's trade and health agenda, discussions in the **TRIPS Council** should focus on promoting the implementation and enforcement of IP commitments, and discussions in the **Working Group on Trade and Transfer of Technology** should focus on ensuring that transfers of technology occur on a voluntary basis and mutually agreed terms.

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[3] E.g., Committee On Market Access, Lessons Learned from the Experience–Sharing Sessions on Trade in Covid-19 Related Goods, GA/MA/409, April 2023.
[4] https://www.ifpma.org/publications/technology-transfer-a-collaborative-approach-to-improve-global-health/; https://www.ifpma.org/events/how-different-partnership-models-supported-the-response-against-covid-19/.
[5] IFPMA Always Innovating, https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures/.
[6] Id.

2. Eliminate tariffs and limit export restrictions

WTO members should reduce and ideally eliminate tariffs on health products, including finished therapeutics and vaccines and the active pharmaceutical ingredients, raw materials, chemicals, other inputs, and specialty equipment used to invent, manufacture, and deploy these health products. Tariffs on health products and the inputs and equipment required to develop and manufacture those products impose unnecessary material costs on the production and distribution of medicines. More pointedly, such tariffs are excess costs imposed by governments on purchases of medicines by their own citizens. For example, 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%.[7] Equally concerning are the numerous tariffs that governments impose on raw materials and other inputs necessary to produce medicines. According to the OECD, average world tariffs on vaccine ingredients range between 2.6% and 9.4%.[8]

As part of this effort, WTO members should restart discussions to improve and expand the Agreement on Trade in Pharmaceutical Products.[9] As an initial step, WTO members that have not already done so should accede to the Agreement. Furthermore, the existing parties should begin negotiations to expand the product scope of the Agreement, with the aim of achieving comprehensive coverage of finished biopharmaceuticals and inputs used in their production. In addition to reducing tariffs on biopharmaceuticals and inputs, WTO members should commit to refrain from imposing tariffs on such products in the context of measures related to trade disputes or trade balances, given the importance of ensuring reliable access to medicines for patients.

Similarly, WTO members should significantly reduce import and export restrictions on health products, refrain from imposing new restrictions, and ensure that any import and export restrictions that WTO members deem necessary are consistent with WTO rules and procedures, including requirements that the restrictions be proportionate, temporary, transparent, properly notified to the WTO and impacted parties, and applied only to prevent or relieve critical shortages of essential products. Rather than securing domestic supply, export restrictions hinder global health promotion by imposing barriers on companies, governments, and other actors coordinating global medical supply chains. Such restrictions result in disrupted supply chains and distribution routes, increased costs and product delays, and heightened risks of supply shortages. During the COVID-19 pandemic, such restrictions resulted in countries holding excess supply of critical health products that could have been exported to countries with high demand for the products.

As part of the trade and health agenda, WTO members should hold discussions on these matters in the **Committee on Market Access**.

3. Strengthen supply chains and improve trade facilitation

WTO members should take domestic actions to strengthen or reinforce supply chains and improve trade facilitation measures for health products, including biopharmaceutical products. Such actions may include improving healthcare infrastructure and procurement systems, resolving last-mile delivery concerns, enhancing customs clearance procedures, instituting expedited protocols and customs procedures for medicines, sharing best practices, developing and publishing national trade facilitation plans, and prioritizing full and immediate

[7] OECD, Using trade to fight COVID-19: Manufacturing and distributing vaccines (Feb. 11, 2021), https://www.oecd.org/coronavirus/policy-responses/using-trade-to-fight-covid-19-manufacturing-and-distributing-vaccines-dc0d37fc/.
[8] Id.
[9] https://www.wto.org/english/tratop_e/pharma_ag_e/pharma_agreement_e.htm.

implementation of the WTO Trade Facilitation Agreement.[10] Such actions are crucial to foster open, secure, diverse and resilient supply chains, as envisioned in the MC13 Declaration, and to ensure that medicines are able to reach patients efficiently, consistently, and especially during global health emergencies.[11] Moreover, such actions would help to address inefficient distribution infrastructure and logistics constraints and improve the monitoring and restriction of the production and distribution of substandard and counterfeit medicines. Such measures also ensure efficient access to safe, effective, and high-quality health products.

Actions to improve trade facilitation may occur unilaterally, in accordance with WTO rules, and, as needed, with WTO or member technical support. In addition, WTO members should work with the World Customs Organisation (WCO) to streamline customs procedures for medical goods and to enact polices that strengthen the customs workforces of WTO and WCO members. The WTO Committee on Market Access identified a range of trade facilitation and customs challenges in an April 2023 report that WTO members should use as a basis for action.[12]

As part of the trade and health agenda, WTO members should hold discussions on these matters in the **Committee on Trade Facilitation**.

4. Enhance quality and effectiveness of regulatory policies and procedures

WTO members should take actions to enhance the quality and effectiveness of domestic regulatory policies and procedures. Safe and timely delivery of medicines to patients requires robust, developed, and consistent regulatory standards for health products and services, as well as cooperation among countries in developing and applying those standards, including through appropriate regulatory initiatives that aim to harmonize and converge regulatory approaches. Coherent and consistent regulations help to facilitate patient access to medicines, while regulatory inefficiencies, approval delays, and unnecessary complexities in many WTO members disrupt supply chains and significantly limit patient access.

Actions to enhance domestic regulatory systems may occur unilaterally, in accordance with WTO rules, and through increased and improved bilateral or multilateral cooperation. The WTO Technical Barriers to Trade Agreement explicitly recognizes the value of WTO members accepting, for example, the results of comparable conformity assessment procedures from other Member States. Cooperation between WTO members with equally robust regulatory frameworks, and trusted partnerships help strengthen supply chains for medical products by reducing duplication of activity (e.g., redundant facility inspections to ensure good manufacturing practices), simplifying administrative processes, and enhancing regulatory clarity and efficiency. WTO members should share best practices across borders and implement procedures for regulatory reliance, expand unilateral and mutual recognition policies, as appropriate, including by increasing participation in Mutual Recognition Agreements and expanding the scope of activities covered by such agreements.

In addition, WTO members should consider extending and utilizing technical support, including by designing and implementing formal trade-related regulatory capacity building programs, such as through resource sharing and the WTO's "Aid for Trade" initiatives. Furthermore, the WTO and its members should engage, as appropriate, with relevant international organizations to enhance the quality and effectiveness of domestic regulatory policies and procedures. Such organizations include the World Intellectual Property Organisation (WIPO), the International Coalition of Medicines Regulatory Authorities (ICMRA), the International Council for

[10] https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm.
[11] Abu Dhabi Ministerial Declaration, WT/MIN(24)/DEC, Mar. 4, 2024.
[12] Committee On Market Access, Lessons Learned From The Experience–Sharing Sessions On Trade In Covid-19 Related Goods, GA/MA/409, April 2023.

Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and other entities.

As part of the trade and health agenda, WTO members should hold discussions on these matters in the Committee on **Technical Barriers to Trade**.

The WTO should build on existing strong international support for meaningful global trade and health initiatives

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

- 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 global response to COVID-19.[13]
- November 2020: Many geographically diverse WTO members, at various levels of economic development, proposed a "Trade and Health Initiative" to the WTO's General Council.[14] This initiative advocates 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 initiative has evolved into a Draft General Council Declaration supported by over 50 WTO members: **Australia**; **Brazil**; **Brunei**; **Canada**; **Chile**; **China**; **European Union**; **Hong Kong**; **Iceland**; **Japan**; **Kazakhstan**; **Kenya**; **Korea**; **Mexico**; **Moldova**; **Montenegro**; **New Zealand**; **North Macedonia**; **Norway**; **Singapore**; **Switzerland**; **Taiwan**; **United Kingdom**; **Uruguay**; and **Vanuatu**.[15]
- June 2021: The **European Union** submitted a communication to the WTO outlining appropriate trade policy responses to address COVID-19, including in the areas of trade facilitation, regulatory cooperation and export restriction disciplines.[16]
- July 2021 and October 2021: The **WTO Secretariat** published papers detailing "trade-related bottlenecks and trade-facilitating measures on critical products to combat COVID-19."[17]
- June 2022: WTO members issued a **WTO Ministerial Declaration** acknowledging the importance of limiting export restrictions, enhancing trade facilitation measures, streamlining customs procedures, reducing tariffs, and enhancing regulatory cooperation.[18]
- April 2023: The **WTO Committee on Market Access** published a report summarizing trade-related lessons learned from the COVID-19 pandemic, including the need for WTO members to reduce tariffs, discipline export restrictions, improve customs

[13] 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).
[14] 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).
[15] Draft General Council Declaration, COVID-19 and Beyond: Trade and Health, JOB/GC/251/Rev.3 (30 June 2021).
[16] Urgent Trade Policy Responses to the COVID-19 Crisis, Communication from the European Union, WT/GC/231 (4 June 2021).
[17] Indicative list of trade-related bottlenecks and trade-facilitating measures on critical products to combat COVID-19; and Update: Indicative list of trade-related bottlenecks and trade-facilitating measures on critical products to combat COVID-19.
[18] Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, WT/MIN(22)/31 (22 June 2022).

procedures, eliminate burdensome administrative procedures, and implement other "trade easing measures."[19]

- July 2023: The **United Kingdom** submitted a communication that outlined a growing need to identify how trade can help facilitate voluntary licensing and/or technology transfer partnerships as part of collective efforts to address pandemic preparedness and equitable access.[20]
- December 2023: The **WTO Council for Trade in Goods** issued a report that discusses various issues that positively affect pandemic preparedness, including the reduction or elimination of tariffs and non-tariff measures.[21]

Illustrative of the urgent need to address these issues, additional support for such initiatives has been voiced consistently in other important international fora. For example, one of the 2024 priority areas of the **Group of 7** (G7) is the strengthening of the global health architecture and enhancement of healthcare systems. To this end, in February, the **G7** leaders agreed to "implement the principles on resilient and reliable supply chains" and committed "to safeguarding the global research ecosystem … and work to prevent covert and forced transfer of IP, data, and sensitive technology."[22]

Similarly, the **OECD** issued a report in 2024 that concluded that "reliable medical supply chains are a cornerstone of resilient health systems"[23] and the **Asia-Pacific Economic Cooperation** issued non-binding guidelines in 2023 that promote enhanced trade facilitation, improved customs procedures, and good regulatory practices.[24]

The **Group of 20** has issued declarations in 2021 acknowledging the importance of open and efficient health supply chains and highlighting the need to eliminate trade barriers that impede medical supply chains.[25] Similarly, the **G7** issued a declaration committing its members to pursue health objectives based on principles of open trade, including the elimination of unnecessary trade restrictive measures.[26]

Individual WTO member governments and expert bodies have expressed similar support for such initiatives. For example, in the **United States**, proposed legislation would authorize the U.S. Trade Representative to negotiate trade agreements with trusted trading partners to promote strong regulatory standards and eliminate tariffs and other trade barriers in the medical sector.[27] Meanwhile, in a study requested by the U.S. Congress, the National Academies of Sciences, Engineering, and Medicine has recommended improving medical supply chain resilience through the negotiation of "a plurilateral treaty under the World Trade Organization that prohibits export bans and restrictions on key components of global medical product supply

[19] Committee On Market Access, Lessons Learned from the Experience–Sharing Sessions on Trade in Covid-19 Related Goods, GA/MA/409, April 2023.
[20] 23-4911 General Council – Intellectual property, voluntary licensing and technology transfer – Communication from the United Kingdom, 19 July 2023.
[21] Report on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, G/L/1521 (1 December 2023).
[22] https://www.g7italy.it/wp-content/uploads/Apulia-G7-Leaders-Communique.pdf.
[23] OECD (2024), Securing Medical Supply Chains in a Post-Pandemic World, OECD Health Policy Studies, OECD Publishing, Paris.
[24] APEC Non-Binding Guidelines on Logistics-related Services that Support the Movement of Essential Goods During a Public Health Emergency, https://www.apec.org/meeting-papers/annual-ministerial-meetings/2023/2023-apec-ministerial-meeting/apec-non-binding-guidelines-on-logistics-related-services-that-support-the-movement-of-essential-goods-during-a-public-health-emergency.
[25] Global Health Summit: The Rome Declaration (21 May 2021), https://www.governo.it/sites/governo.it/files/documenti/documenti/Approfondimenti/. GlobalHealthSummit/GlobalHealthSummit_RomeDeclaration.pdf; and Declaration of the G20 Health Ministers (5-6 September 2021), https://reliefweb.int/sites/reliefweb.int/files/resources/G20_Italia_2021_Health_Declaration_ final_05092021_OFFICIAL.pdf.
[26] 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.
[27] Medical Supply Chain Resiliency Act, S.2115 and H.R.4307, 118th Congress (2023), available at https://www.congress.gov/bill/118th-congress/senate-bill/2115 and https://www.congress.gov/bill/118th-congress/house-bill/4307.

chains."[28] In the **United Kingdom**, the Critical Imports and Supply Chain Strategy[29] recognizes medicines as critical products and has received broad support for the clear principles it sets out for how to ensure resilient and secure supply chains that protect both businesses and consumers who rely on them. The **European Union** established the Critical Medicines Alliance in January 2024, aiming to identify key areas and priorities for action, proposing solutions to strengthen the supply of critical medicines, ultimately enhancing efforts to prevent and address shortages effectively. Other WTO member governments are pursuing or considering similar initiatives.

These and other initiatives demonstrate a growing desire by WTO members to strengthen health-related trade policy measures.

Call to Action: WTO Members should formalize and pursue a robust trade and health agenda ahead of MC14

The COVID-19 pandemic underscored the need to eliminate unnecessary trade barriers that impede the development, production, and distribution of biopharmaceutical products. Though other international organizations are discussing ways to strengthen healthcare systems to prepare for future global health emergencies, the WTO is best positioned among such organizations to strengthen the open and rules-based international trading system that enables life sciences innovation and access to medicines for patients worldwide.

As explained above, a broad and diverse set of WTO members have embraced this opportunity by advancing constructive proposals to strengthen health-related trade policy. Ahead of MC14, a renewed and coordinated effort is necessary to ensure that WTO members build and ultimately deliver on these ambitions to incentivize medical innovation and improve patient access to medicines. The global biopharmaceutical industry therefore urges WTO Members to formalize and pursue a robust trade and health agenda that focuses on enhancing IP rights, eliminating tariffs and export restrictions on medicines and inputs, improving trade facilitation policies, and enhancing the quality and effectiveness of regulatory policies and procedures.

[28] National Academies of Sciences, Engineering, and Medicine. 2022. Building resilience into the nation's medical product supply chains. Washington, DC: The National Academies Press. https://doi.org/10.17226/26420.
[29] Critical Imports and Supply Chain Strategy, HM Government, Department for Business and Trade, January 2024 UK critical imports and supply chains strategy - GOV.UK (www.gov.uk).

Supporting associations