

**WRITTEN SUBMISSION BY THE WTO SECRETARIAT
TO THE WHO INTERGOVERNMENTAL NEGOTIATING BODY
ON A PANDEMIC INSTRUMENT¹**

10 NOVEMBER 2023

1. The multilateral trading system has played an essential role in the response to COVID-19 and will inevitably play an influential role in preparations for and responses to future pandemics. The draft negotiating text of the WHO Pandemic Agreement accordingly includes multiple trade-related elements that intersect with WTO agreements and the ongoing work of WTO bodies. As mandated by Ministers in the 2022 WTO Pandemic Declaration², WTO Members have also been analysing lessons learned and challenges experienced during the COVID-19 pandemic and are working to build effective solutions to be prepared for and respond to future pandemics. We detail these efforts in Annex 1 to this submission to promote synergies and ensure complementarity with the work of the INB. We offer factual observations on the draft negotiating text below to support the effective implementation of the WHO Pandemic Agreement.

2. We appreciate continued efforts to articulate the relationship between the WHO Pandemic Agreement and other international agreements and instruments. We recognize in particular Article 25.2 of the draft negotiating text, which provides that the WHO Pandemic Agreement shall not affect the rights and obligations of any Party under other existing international instruments. We also note parallels with certain language in the draft negotiating text and that found in WTO instruments. The INB might consider, for example, including a reference to the Declaration on the TRIPS Agreement and Public Health³ in recital 10 of the Preamble, which addresses intellectual property rights, in order to provide greater context.

3. With respect to Article 11, we appreciate the recognition that TRIPS flexibilities may be usefully exercised both during and outside of pandemic periods. We wonder, however, if Article 11.2(c) might be more useful if the relevant flexibilities were left undefined, so as to not inadvertently limit their scope or prejudice the utility of some flexibilities over others. Additionally, with respect to Article 11.3(a), our experience over the past three years has shown that conversations surrounding the very general term "waivers of intellectual property rights" can raise questions about what practical mechanisms are intended, given that there is no common understanding of this specific phrase. The fact that intellectual property rights are granted and enforced at the domestic level, yet within the framework of international agreements, raises the question of what specific measures would be open to, or expected of, the Parties. If WHO Member States were to decide that this provision be retained, further clarification of the following points may be useful to facilitate its effective implementation in practice:

- a) in particular, how this provision would relate to the flexibilities referenced in Article 11.2(c); and
- b) which "relevant institutions" would frame such waivers, what mechanisms are intended at the domestic level, and how these may relate to existing rights and obligations.

4. We note with appreciation the emphasis on transparency throughout the draft negotiating text. To this end, Article 13.7 could benefit from acknowledging the significance of timely notifications to the WTO to improve the transparency of trade-restrictive measures. Such notifications are an essential tool to keep all actors informed of the availability of essential medical

¹ This document has been prepared under the WTO Secretariat's own responsibility as a factual overview and is without prejudice to the positions of WTO Members or to their rights and obligations under the WTO. It complements the WTO Secretariat's first written submission to the INB, dated 18 May 2022 (an updated version of which was circulated in WTO document [WT/MIN\(22\)/34](#) of 22 June 2022), and the second written submission to the INB, dated 22 September 2022.

² Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, adopted on 17 June 2022, document [WT/L/1142](#).

³ Document [WT/MIN\(01\)/DEC/2](#) of 20 November 2001.

goods and minimize uncertainty, as demonstrated during the COVID-19 pandemic.⁴ Similarly, many regulations pertaining to pandemic-related products are subject to notification requirements under the WTO SPS Agreement and the TBT Agreement at an early stage of their regulatory life cycle (i.e. when they are still in draft form). The publicly accessible "ePing SPS-TBT Platform" (<https://epingalert.org/>), jointly maintained by the WTO, ITC, and UN (UNDESA), tracks these measures, and can serve as a useful digital regulatory "early warning" alert system. The INB might therefore consider including a reference in Article 14 to multilateral regulatory transparency tools, such as ePing. This could, consistent with, *inter alia*, the general principles in Articles 3.6, 3.7 and the obligations in Article 16, further regulatory transparency, coherence, coordination, and cooperation.

5. We note that the WTO's 2022 Ministerial Pandemic Declaration mandates the WTO to work with the WHO on an international pandemic response, including on activities such as mapping manufacturing capacities and demand. We would welcome partnering in this effort to support sustainable production pursuant to Article 10.1(c) of the draft negotiating text and the operation of a WHO Global Supply Chain and Logistics Network, provided for in Article 13. Adding a reference to the WTO Pandemic Declaration to the Preamble or Article 13 of the WHO Pandemic Agreement could provide positive guidance to the Parties and promote collaboration.

6. The WTO Secretariat stands ready to support the Parties in strengthening coordination on issues related to public health, intellectual property, and trade, pursuant to Article 10.1(c) of the draft negotiating text. Indeed, such work is already underway within the existing trilateral cooperation framework. In September 2023, the Directors-General of WHO, WIPO, and WTO agreed to increase and broaden support for more effective and sustainable use of TRIPS flexibilities to increase access to health technologies and to be better prepared for future pandemics.⁵

7. Thank you for the opportunity to comment on the draft negotiating text and participate in this important process as an external stakeholder. The WTO Secretariat will continue to follow the work of the INB closely and remains available to lend its expertise on technical matters at the intersection of trade, intellectual property, and public health, as appropriate. Requests may be submitted to ipd@wto.org.

⁴ Document [G/MA/409](#) of 20 April 2023.

⁵ WHO, WIPO, WTO renew commitment to support integrated solutions to global health challenges, 12 September 2023. https://www.wto.org/english/news_e/news23_e/igo_13sep23_e.htm.

ANNEX

Indicative article(s) of the draft negotiating text	Related WTO work
Articles 10, 11	<p>Discussions are ongoing in the TRIPS Council on whether to extend, to COVID-19 therapeutics and diagnostics, the 2022 Ministerial Decision on the TRIPS Agreement⁶, which includes a single targeted waiver of TRIPS Article 31(f).⁷</p> <p>The General Council, the TRIPS Council and the Working Group on Trade and Technology Transfer are considering Member proposals to facilitate technology transfer, research collaboration across borders, and geographical diversification of manufacturing capacity, particularly in developing and LDC Members.⁸ WTO Members have discussed, among other topics, factors surrounding the creation of global partnerships, developed country Member incentives for technology transfer pursuant to TRIPS Article 66.2, and the role of intellectual property rights and TRIPS flexibilities in research and development and technology transfer.</p>
Articles 13, 14, 16	<p>The Council for Trade in Goods is currently considering a draft report that takes stock of the work that has been undertaken by all its 14 subsidiary bodies with respect to the COVID-19 pandemic and seeks to capture lessons learned with a view to improving preparedness for future pandemics. The draft text, which will be considered on 30 November, addressed work relating to a wide range of issues, including export restrictions, regulatory requirements, international coordination, transparency, trade facilitation, and sanitary and phytosanitary measures. The draft also includes lessons learned which relate to improved coordination and cooperation, better understanding of trade-related measures imposed during crises, enhancing transparency and experience sharing at the WTO, improving data collection and information sharing, and the role of digitalization.</p> <p>The TBT Committee, one of the 14 subsidiary bodies mentioned above, agreed to examine and compile best practices for future pandemic preparedness, including streamlining conformity assessment procedures during pandemics, and enhancing international regulatory cooperation, to facilitate trade in select essential medical goods like vaccines.⁹ A compilation of these discussions was circulated in 2022.¹⁰ The TBT Agreement (and SPS Agreement) strongly supports regulatory harmonization by requiring regulations be based on international standards, which is in line with various provisions of the draft negotiating text containing similar goals. In this respect, one of the best practices contained in the TBT Committee 2022 compilation was the "use of relevant international standards as a basis for technical regulations or standards on select essential medical goods, as well as relevant international standards, guides or recommendations</p>

⁶ Document [WT/L/1141](#) of 17 June 2022.

⁷ The Council for TRIPS has before it a proposal to extend the Ministerial Decision on the TRIPS Agreement *mutatis mutandis* for the production and supply of COVID-19 therapeutics and diagnostics. See document [IP/C/W/694](#) of 6 December 2022. On 28 September 2023 the Council held an Informal Thematic Session for External Stakeholder Input. Over 20 speakers from intergovernmental organizations, civil society, industry and academia shared facts, evidence, and experience relevant to the manufacture and supply of COVID-19 vaccines, diagnostics, and therapeutics. A Report by the Chair on the session is available at document [IP/C/W/706](#) of 23 October 2023.

⁸ Communication from the African Group, Policy Space for Industrial Development - A Case for Rebalancing Trade Rules to Promote Industrialization and to Address Emerging Challenges such as Climate Change, Concentration of Production and Digital Industrialization, document [WT/GC/W/868](#) of 1 March 2023; Communication from Australia; the European Union; Hong Kong, China; Japan; Singapore; Switzerland; Chinese Taipei; the United Kingdom and the United States of America, Intellectual Property and Innovation: Research Collaboration Across Borders, document [IP/C/W/699](#); Communication from the African Group, The Role of Transfer of Technology in Resilience Building: Reinvigorating the Discussions in the WTO on Trade and Transfer of Technology, document [WT/GC/W/883](#) of 5 July 2023; Communication from the African Group, The Role of Transfer of Technology in Resilience Building: The TRIPS Agreement, document [WT/GC/W/884](#) of 5 July 2023; and Communication from the United Kingdom, Intellectual property, voluntary licensing and technology transfer, document [IP/C/W/704/Rev.1](#) of 2 October 2023.

⁹ Document [G/TBT/46](#) of 17 November 2021, para. 8.4.

¹⁰ Information Note, Overview of Discussions in the Committee on Technical Barriers to Trade Relating to COVID-19, 27 October 2022. Available at: https://www.wto.org/english/tratop_e/covid19_e/tbt_report_e.pdf.

Indicative article(s) of the draft negotiating text	Related WTO work
	<p>as a basis for conformity assessment procedures associated with those [pandemic-related] measures."¹¹</p> <p>The INB may also benefit from considering concrete actions undertaken by the Committee on Market Access (CMA) in collaboration with the World Customs Organization (WCO) on improved classifications of essential medical goods in the Harmonized System (HS) that could be relevant for future pandemics. On the basis of a May 2022 communication from the CMA to the HS Committee of the WCO, the WCO negotiating body agreed on a new classification for ambulances and mobile clinics and is currently negotiating more specific customs classifications for facemasks and respirators used in health emergencies. The WTO, WCO and WHO have also worked together to develop a classification proposal for vaccines in view of their classification within the HS, in order to improve public health outcomes and align trade policies with public health objectives.</p>
Articles 4, 5	<p>Work in the SPS Committee pursuant to the SPS Declaration on Responding to Modern SPS Challenges¹² covered new opportunities and emerging challenges for international trade in food, animals, and plants, such as expanding global populations, innovation in tools and technologies, environmental challenges, shifting pressures due to the spread of pests and diseases, the increasing threat of antimicrobial resistance, and emerging infectious diseases linked with the human-animal-environment interface. A draft report on this work is being prepared by the SPS Committee, recognizing that aligning SPS measures and procedures with the SPS Agreement, in particular with its provisions on international standards, scientific principles, and risk assessment, remains of fundamental importance.¹³</p>

¹¹ Ibid. p. 11.

¹² Document [WT/L/1138](#) of 17 June 2022.

¹³ Document [G/SPS/W/344/Rev.2](#) of 27 October 2023.