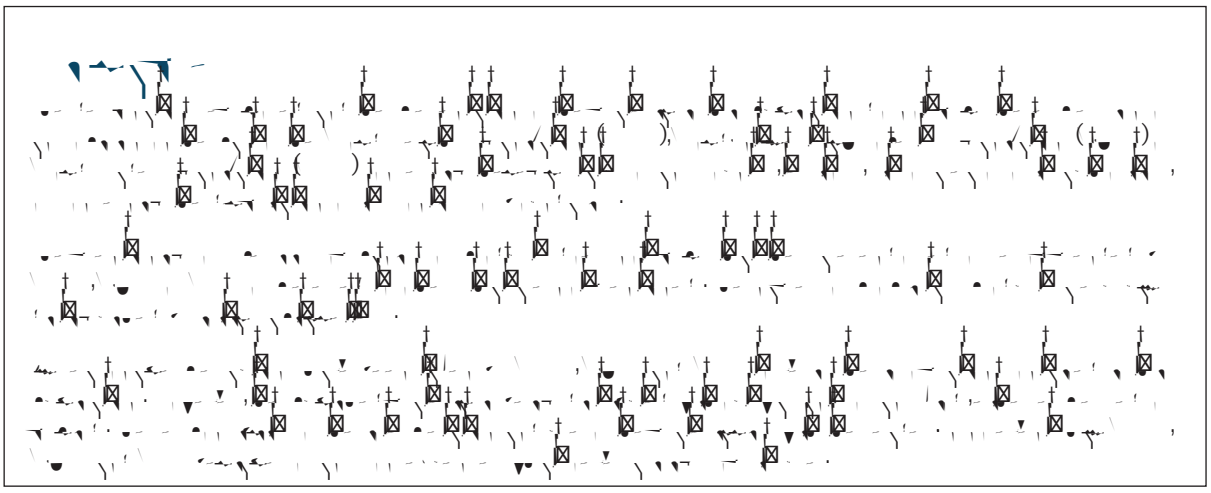
An Integrated Health, Trade and IP Approach to Response to the COVID-19 Pandemic

Second Update, May 2023



World Health Organization

World Intellectual Property Organization

World Trade Organization

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The second edition of the joint WHO, WIPO and WTO publication *Promoting Access to Medical Technologies*

of a pre-negotiated platform for tools and supplies and the adoption of a pandemic framework convention using powers under the WHO Constitution.[17]

Six months after issuing its main report, the former co-chairs of the IPPPR published a progress report to assess steps taken to implement the recommendations in its May 2021 report. They highlighted the need for a vaccines-plus strategy that combines measures such as vaccination, masks, social distancing, improved ventilation and contact tracing systems with access to diagnostic tests and therapies.[18] In May 2022, the co-chairs issued a second progress report that called for, *inter alia*, rapid financing of the Access to COVID-19 Tools Accelerator (ACT-A) to ensure ongoing access to the tools available to tackle COVID-19 in low- and middle-income countries.[19]

Working Group on Amendments to the International Health Regulations (2005) (WGIHR)

The Working Group on Amendments to the International Health Regulations (2005) (WGIHR) was established by the 75th WHA, in 2022, to replace the prior Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).[20] The WGPR previously assessed and reported on the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response.[21] The report led to the establishment of the Intergovernmental Negotiating Body (INB) in December 2021.[22]

The WGIHR continues the WGPR's work with a revised mandate of working exclusively on consideration of proposed targeted amendments to the IHR (2005), consistent with the WHO Executive Board decision 150(3) (2022), for consideration by the 77th WHA in 2024.[23] As of February 2023, the WGIHR had published proposed amendments submitted by member states.[24]

Intergovernmental Negotiating Body

The INB was created to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response with a view to adoption under appropriate provisions of the WHO Constitution.[25] It commenced its work in February 2022.[26] The INB agreed that the instrument should be legally binding and contain both legally binding as well as non-legally-binding elements.[27] Following consultations with WHO member states and submissions from relevant stakeholders, the INB published a conceptual zero draft in November 2022.[28] The draft proposed text on:

- substantive issues for pandemic prevention, preparedness, response and recovery, including achieving equity;
- strengthening and sustaining capacities;
- health system recovery coordination, collaboration and cooperation;

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most up-to-date information on the impact of SARS-CoV-2 variants on the effectiveness of different vaccines. This is an area where the evidence remains preliminary and develops quickly. Measures to reduce transmission continue to work against new variants by reducing the amount of viral transmission and therefore also reducing opportunities for the virus to mutate. Such measures apply not only to threats posed by epidemics and pandemics but also to the ongoing threat of antimicrobial resistance.

The importance of effective national infection, prevention and control programmes is a shared priority of the international community for addressing public health threats of international concern. Ensuring access to affordable vaccines, diagnostic tests and therapeutics is a critical way of protecting people from the virus and the spread of new variants.[33] Inequitable access to vaccines and other health products contributes to the continued spread and emergence of new variants, risking the effectiveness of current tools and threatening to unravel progress everywhere.[34]

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Disease Outbreak News

The WHO Disease Outbreak News provides up-to-date information on the impact of SARS-CoV-2 variants on the effectiveness of the different vaccines.[35] As of early 2023, the BA.5 Omicron variant remained the dominant variant of concern circulating globally.[36] Protection through vaccines, however, appears to be retained against severe disease for all variants, although the available evidence remains limited.[37] Booster shots of the COVID-19 vaccine, approved in 2021, are doses administered to a vaccine population that has completed a primary vaccination series (currently one or two doses of COVID-19 vaccine depending on the product) when, with time, the immunity and clinical protection has fallen below a rate deemed sufficient in that population.[38] Studies have shown that booster shots could make up for at least part of the reduced protection and efficacy of vaccines against new variants; hence some countries mandated booster shots.

Four bivalent variant-containing vaccines targeting the Omicron variant and related sub-lineages have been authorized by stringent regulatory authorities, including the United States Food and Drug Administration and the European Medicines Agency.[39]

Polic challenge po ed b he pandemic

The COVID-19 pandemic has generated sudden, far-reaching impacts on health systems, and has prompted significant social and economic repercussions around the world. The head of the International Monetary Fund (IMF) warned that while there was strong economic recovery in wealthy countries, developing countries were being held back by slow vaccination rates, which is a "danger for the coherence of growth and it is also a danger for global stability and security."[40] World Bank data indicates that the pandemic has stimulated a steep increase in debt, especially in emerging markets and developing economies.[41] Statistical briefs published by the Committee for the Coordination of Statistical Activities analyse the social and economic impact of the pandemic and suggest that an additional 71 to 100 million people are being pushed into extreme poverty as a result of the pandemic.[42]

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This extraordinary threat to people's health and livelihoods has required urgent action to:

- monitor and contain the spread of the virus and new variants;
- understand relevant virology and epidemiology;
- mobilize and coordinate the requisite resources;
- deploy the necessary health-care system infrastructure;
- ensure that health-care products, technologies and protective equipment are available and can be accessed equitably in sufficient quantities worldwide;
- develop, test, manufacture and ensure equitable access to diagnostics, vaccines and therapeutics, medical devices and other relevant technologies;
- ensure the free flow of vaccines and inputs, as well as therapeutics and diagnostics; and
- address the economic repercussions resulting from the pandemic and measures to contain it, which may, in turn, also impact people's health.

Mee ing he demand for heal h echnologie and medical er ice

The pandemic triggered a massive global demand for vaccines and existing health technologies to respond to COVID-19, including diagnostics, medicines, ventilators and other medical devices, as well as for consumables used in hospitals, such as personal protective equipment (PPE). This put pressure on public procurement systems and led to shortages and other supply and access challenges for certain products in developed and developing countries.[43]

Expanding and diversifying manufacturing

Government priorities have included ensuring sufficient access to vaccines, intensive care equipment such as ventilators, and PPE to minimize infection risk to front-line workers, and ensuring access to testing services and products. Governments in a number of countries have taken steps to enhance and adapt manufacturing capacity to meet a surge in demand for hospital equipment and PPE, including through redirecting production lines to manufacture essential products. Bangladesh's Beximco Pharmaceuticals is producing a generic version of remdesivir, a pharmaceutical that is patented in a number of countries to treat COVID-19, thus benefitting from the transition period under the TRIPS Agreement, which currently exempts least-developed countries from implementing patent protection for pharmaceutical products and from protecting clinical trial data.[44] Beximco later obtained a sub-licence from the Medicines Patent Pool (MPP).[45]

Expanding and diversifying manufacturing capacity for vaccines, as well as diagnostics and therapeutics, has been and continues to be a key part of the debate around global equitable access to COVID-19 health products. A number of governments have invested in ensuring that sufficient manufacturing capacity is available to produce the necessary volumes of vaccines for COVID-19. Publicly available data and information on global manufacturing capacity include:

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IHR (2005).[56] Telemedicine may be used to overcome geographical limitations and physical distancing requirements.[57]

Expediting procurement

Authorities in many jurisdictions have expedited the procurement of essential products via emergency procedures, such as shortening public procurement timelines and issuing direct contract awards. A number of countries have put in place transparency mechanisms with regard to emergency procurement following best international practices. Some countries and regional groupings have used pooled procurement for select goods.

Safeguarding supply chains

To safeguard essential supply chains during the COVID-19 pandemic, numerous competition authorities exceptionally allowed some level of cooperation between manufacturers, distributors and purchasers. Among others, the European Commission and competition agencies from Canada, China, Japan, the Russian Federation and the United Kingdom published COVID-related guidance on permissible collaboration.[58] Some competition authorities have eased the rules applicable to specific sectors by issuing "comfort letters"[59] or introducing sector exemptions which apply to entire industries[60]. The European Competition Network has issued guidance[61] on the application of competition policy in times of urgency and limited supply and clarified whether and when coordination between firms to respond to crisis needs can be permitted, at least temporarily.[62]

At the same time, to ensure that companies are not taking advantage of the exceptional market situation, competition agencies have made it clear that they will be vigilant for cartels (i.e. firms colluding to avoid "ruinous" competition or to take advantage of increased demand and emergency public purchasing by engaging in bid rigging). For example, the United Kingdom Competition and Markets Authority has emphasized that it "will not tolerate unscrupulous businesses exploiting the crisis as a 'cover' for non-essential collusion", and the United States Department of Justice "has reminded firms that they could be prosecuted for collusion, especially where it relates to the provision of public health products … to government agencies".[63] In the area of merger control, competition authorities also paid attention to the impact of the COVID-19 pandemic. For example, guidance has been issued to clarify that the emergency will not affect the standard of merger review (e.g. in the United Kingdom).[64]

2021[74]. More recently, the share of medical goods in total merchandise trade has reverted to pre-pandemic levels, declining to 6.9 per cent in 2022.[75] Preserving the integrity of global trade is therefore critical to ensure equal access to needed health technologies and will support countries in recovering from the crisis and building health systems that foster greater resilience against future pandemics.[76]

> **Ensuring equal access to needed health technologies will support countries in recovering from the crisis and foster greater resilience against future pandemics.**

While recognizing that governments may take emergency measures to address public health challenges, including shortages of technologies to respond to COVID-19, G20 trade ministers[77] have repeatedly called upon countries to ensure that any trade-restrictive measure taken to promote public health be targeted, proportionate, transparent and temporary, points echoed by leaders of the World Customs Organization (WCO), the WHO and the WTO.[78]

WTO resources

Ensuing declarations and statements by a wide range of WTO members have underscored the importance of a predictable, transparent, non-discriminatory and open global trading system for pandemic response and recovery. In particular, they have emphasized the importance of well-functioning supply chains and the need to facilitate cross-border flows of vital medical supplies and services Tw 0 -1.333 Td[(the W)62 (orld Customs0.5 0.e9c26(-)uiw 0centc/Spansn)et1.95 0 2333 023441

of December 2022, 443 COVID-related trade and trade-related measures in the area of goods had been implemented by WTO members and observers, of which 56 per cent were of a trade-facilitating nature and 44 per cent were trade restrictive.

In the second half of 2022, the number of new COVID-related support measures to mitigate the social and economic impacts of the pandemic fell sharply. Furthermore, according to information received by the WTO Secretariat as of mid-October 2022, 79.2 per cent of the COVID-related trade restrictions

Innovation Index, with almost 90 per cent being first filed in the United States or Europe. Most patent grants, mainly relating to mRNA and viral vector technologies, have been made in Australia, Canada, China, European Patent Office member states, Israel, Japan, the Republic of Korea, New Zealand, the Russian Federation, South Africa and the United States. Little information was available on whether patent applications that correspond to these 74 patent families have been filed in most developing countries.

On 10 March 2022, WIPO published a Patent Landscape Report, *COVID-19-related Vaccines and Therapeutics: Preliminary Insights on related Patenting Activity during the Pandemic*.[105] It finds, among other things, that universities and research organizations were highly active in vaccine patenting during the pandemic's early days. While only a modest percentage of COVID-19 vaccines and therapeutics patent filings reflects collaboration in patent filing, the analysis of the COVID-19 therapeutic tracker data generated by the Milken Institute and Regulatory Affairs Professionals Society, as well as related vaccine information from the WHO, shows collaboration between different organizations to facilitate development and distribution of both vaccines and therapeutics. The report finds that the level of collaborations among pharmaceutical companies, biotechnology start-ups, universities and public research institutions across different regions is even higher in the product development, clinical trial and manufacturing stages. Building on the insights discussed in the first report, WIPO published a second Patent Landscape Report on COVID-19, which provides observations based on a comprehensive review of the patenting activity that took place in the field of COVID-19 vaccines and therapeutics.[106]

Innovation and access: flexibilities in the IP system

Well-functioning IP systems should consider the interests of a wide range of stakeholders, such as start-ups, universities, R&D institutions – both public and private – and corporations, as well as the interests of public and private funders and of the public at large, including patients, who ultimately benefit from innovation that meets their needs. To achieve this delicate balance, each country can tailor its domestic IP system to its particular needs and circumstances, including through the implementation of the provisions of the TRIPS Agreement, and subsequent instruments which provide flexibility for public health purposes and the application under national law.

Domestic intellectual property laws

The IP system has a number of features that support and facilitate R&D and access, including certain exclusions from patentable subject matter and limited exceptions to patent rights. These options are available to support countries' access to medical technology and innovation policies.[107] For example, national IP systems have certain options with respect to patenting material that exists in nature. Patentability may have relevance for

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In 2020, compulsory licences were issued in Hungary and the Russian Federation for local production of remdesivir.

Also in 2020, Israel issued a government-use licence for the import of generic lopinavir/ritonavir in COVID-19 treatment.

The United States Government utilized powers under 28 USC Section 1498(a) in 62 government contracts for the production of COVID-19 countermeasures including vaccines, treatments and diagnostic tests.[115] Whenever a manufacturer acting as a government contractor uses a patented invention for the United States, without the licence of the patentholder, with the authorization or consent of the US Government under 28 USC Section 1498, this section could limit the owner's remedy to compensation by the US Government.[116] Federal Acquisition Regulations Clause 52.227-1 adds that the Government can provide authorization and consent to a contractor to use any patented invention and the Government assumes liability for infringement of the patent to the extent of the authorization and consent granted.[117] This clause was referred to in the US Government R&D contract with Moderna for the manufacture of its COVID-19 vaccine (Spikevax).[118] In a recent patent infringement lawsuit filed by Arbutus Biopharma Corporation against Moderna, Moderna asserted that it acted as a government contractor/supplier and the claim should be brought against the US Government in the Court of Federal Claims. A district court judge in Delaware in November 2022 rejected Moderna's request to deny jurisdiction pending full adjudication of the merits of that assertion.[119]

In April 2021, at the peak of the second wave in India, the Delhi High Court found that there is a basis for the central government to issue compulsory licences and government use authorizations to address shortages of COVID-19 treatments.[120] At the same time, the Supreme Court of India, taking note of the unprecedented humanitarian crisis, also flagged the availability of compulsory licensing powers under the Indian Patents Act, 1970, and under the TRIPS Agreement for the Government's consideration to ensure access to patented COVID-19 treatments.[121] As of the time of writing, the Indian Government has not issued compulsory licences for COVID-19 health products.

Further, the European Commission has proposed a Regulation establishing a framework for compulsory licensing for crisis management at EU level. It proposes the introduction of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-critical products within the European Union in the context of a Union crisis or emergency mechanism.[122] While national compulsory licencing schemes in EU member states would not be affected, the objective is to ensure coherence with other crisis and emergency instruments at EU level.

Special Compulsory Licensing System

The TRIPS Council's regular review of the Special Compulsory Licensing System for manufacture and export of pharmaceutical products[123] in October 2020 made reference to the relevance of the System for the global health crisis.[124] However, questions have also been raised as to whether the System can provide an effective and expeditious response to the COVID-19 pandemic[125] and concerning the choice of developed country WTO members to exclude themselves from using the System as importers.[126]

According to the information note *The TRIPS Agreement and COVID-19*[127], while it remains a challenging task to forecast the System's role to help addressing the pandemic, its mere existence may be helpful in facilitating access, whether or not a compulsory licence is ultimately issued to procure the needed vaccines or treatments. For exe

well as the immediate addition of COVID-19 vaccines, diagnostics and treatments to Schedule 1 of the Patents Act.[133]

The Spanish National Research Council (CSIC) granted a global, non-exclusive license to C-TAP for a COVID-19 serological antibody technology in November 2021.[174] This licence was the first transparent, global, non-exclusive licence for a COVID-19 health tool, and the first test licence signed by MPP and included in C-TAP. Licences granted to C-TAP are described as transparent due to the public disclosure of the full text of the licensing agreement. The agreement covers all related patents and the biological material necessary for manufacture of the test. The C-TAP/MPP subsequently granted a sub-licence to Biotech Africa, under which the CSIC shared all proprietary know-h(i)-119.79(h t)-6.4 (h)-0.72(o)-12.6 (o)- gh A-8.1 (f)-11a.7 (o381 0 Td[(h(i)19.79(h t)-6.42 (3)-

are also existing challenges for the implementation of each of them. That is why they should be explored simultaneously according to the different needs of the countries and their ability to implement them at the national level.

WIPO initiatives

The WIPO Program of Work and Budget 2022/23[186]

Access to COVID-19 Tools Accelerator (ACT-A)

In 2020, the WHO together with private sector partners and other stakeholders, launched ACT-A, a collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.[206] ACT-A is organized around three main pillars of work (diagnostics, therapeutics, vaccines) and a cross-cutting pillar to support health systems strengthening during the pandemic (Health Systems and Response Connector) and the Access and Allocation workstream to ensure the equitable allocation of COVID-19 tools. As of March 2023, COVAX – the vaccines pillar – has been allocated 1.94 billion COVID-19 vaccine doses since the beginning of the pandemic.[207] The diagnostics pillar has delivered 182.1 million tests to 182 countries. The therapeutics pillar has delivered US$28.5 million worth of COVID-19 medicines. Other major achievements of ACT-A include funding R&D of new therapeutics, diagnostics and vaccines, as well as supporting the market entry of new, affordable rapid tests. ACT-A operations are currently transitioning to support countries for long-term COVID-19 control. The next phase of ACT-A's work will focus on three main areas:

R&D and market shaping activities for new COVID-19 tools;
longer-term institutional arrangements for sustained access to COVID-19 tools; and
new product introduction and protection of priority populations in line with national and international targets.

and not constrained by existing contracts, and enable low

COVID-19 Resources for Global Results,' fact sheet, April 2022, https://www.cdc.gov/budget/documents/covid-19/COVID-19-Global-Response-fact-sheet.pdf."

The United States reportedly invested at least $31.9 billion of public funds directly into the development, production and procurement of mRNA COVID-19 vaccines.[233] While the vast majority of this investment

respond to pandemics.[257] In the zero draft developed by the INB Bureau for an international instrument on pandemic prevention, preparedness and response (WHO CA+), transparency in cost and pricing, and regarding information about funding for R&D of pandemic response products are considered essential to achieving equity in pandemic prevention, preparedness, response and recovery of health systems. International solidarity with countries that report public health emergencies is also encouraged to promote transparency and timely reporting of public health events.

The WHO Director-General has noted the lack of transparency as the main disadvantage of bilateral technology transfer through voluntary licensing.[258] In addition, resolution WHA72.8, *Improving the transparency of markets for medicines, vaccines, and other health products*[259], requests the WHO Director-General to take a number of actions toward improving transparency, including toward improving public reporting of patent status information and the marketing approval status of health products. As part of the actions taken, C-TAP is set to promote transparency by supporting member states in collecting and analysing information on economic data across the value chain for health products, and data for relevant policy development and implementation towards achieving universal health coverage.

COVID-19 Law Lab database

The WHO, together with partners, maintains the COVID-19 Law Lab database, launched in July 2020.[260] The database gathers and shares legal documents from over 190 countries in response to the COVID-19 pandemic. It includes information on disease surveillance and technology, quarantine and isolation measures, and legal measures relating to lockdowns, mask-wearing, social distancing, access to medication and vaccines.

WIPO COVID-19 IP Policy Tracker

The WIPO COVID-19 IP Policy Tracker[261] online listing provides information on measures adopted by IP offices in response to the COVID-19 pandemic, such as the extension of deadlines to ensure continued operations. In addition, it provides information on legislative and regulatory measures taken by governments, to improve access, as well as on voluntary actions of a broad range of stakeholders. It relies on information provided by IP Offices, member states and other entities, hence is not an exhaustive list of all actions taken regarding COVID-19.

WTO trade monitoring

To promote transparency, the WTO monitors and reports on trade-related measures pertaining to goods, services and IP rights implemented by its members in response to the pandemic.[262] The WTO has issued a number of information notes and reports on trade in the context of COVID-19, including updated notes on trade in medical goods, transparency, export prohibitions and restrictions, the treatment of medical products in regional trade agreements, standards and regulations, trade in services and how WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services.[263]

The information note *Developing and Delivering COVID-19 Vaccines Around the World*[264] as well as the infographic *The Global Race to Vaccinate*[265] examine trade impacts and explore how trade policy can play its part in ensuring the rapid roll-out of COVID-19 vaccines.

The a for ard

The COVID-19 pandemic has placed immense pressure on health systems and trade systems around the world. The urgent search for technologies that may help to control the pandemic has mobilized unprecedented research efforts, investments and partnerships. Moreover, it has given rise to new models of working, which have led to rapid and efficient innovation.

National and international responses to the pandemic reflect policymakers' growing experience in tackling pressing health needs, with initiatives considering health, trade and IP elements in a holistic manner. Responses to the pandemic span such a wide range of technical areas that nearly every section of the WHO-WIPO-WTO trilateral study is relevant to addressing the global response to COVID-19.

The Directors-General of the WHO, WIPO and the WTO have emphasized the need to leverage lessons learned during the first three years of the COVID-19 pandemic and build on and expand the cooperation that has emerged from this health crisis.[266]

Indeed, the global health crisis caused by the COVID-19 pandemic has highlighted the importance of keeping the momentum and securing global equitable access to new technologies to effectively respond to future health emergencies. Adequate management of IP is central to achieving these goals. In 2022, important milestones were put in place at the multilateral level. They can lay the ground for and frame the work on pandemic preparedness and response.

At the WTO's 12th Ministerial Conference in June 2022, ministers unanimously adopted the WTO's pandemic response, i.e. the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics[267] and the Ministerial Decision on the TRIPS Agreement[268] with regard to COVID-19 vaccines. The Declaration provides a framework to guide the WTO's work in order to render the multilateral trading system more resilient and better prepared for future crises. It calls on relevant WTO bodies, based on proposals by members, to analyse the lessons learned and challenges experienced during the COVID-19 pandemic in a wide range of areas, including export restrictions, food security, IP, regulatory cooperation, services, tariff classification, technology transfer, trade facilitation and transparency.

The WTO's General Council is due to take stock of this work annually until the end of 2024. The Declaration also mandates the WTO to cooperate with the WHO and other international organizations on an international pandemic response. This lays the foundation for continuing and further intensifying the collaboration between the WHO, WIPO and the WTO, as well as other stakeholders, including as regards technical support to make full and effective use of policy options available to WTO members under the TRIPS Agreement and subsequent instruments.

In parallel, the Ministerial Decision on the TRIPS Agreement

37 See https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5/episode-34---vaccines-variants-mass-gatherings.

38 See https://www.who.int/news/item/04-10-2021-interim-statement-on-booster-doses-for-covid-19-vaccination.

39 See: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Variants-2022.1; https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccine-boosters; and https://www.ema.europa.eu/en/news/ecdc-ema-statement-booster-vaccination-omicron-adapted-bivalent-covid-19-vaccines.

40 See https://www.reuters.com/article/global-trade-idUKP6N28J045.

41 See https://datatopics.worldbank.org.

42 *How COVID-19 is changing the world: A statistical perspective*, Volume II, 2020, available at https://unstats.un.org/unsd/ccsa/documents/covid19-report-ccsa_vol2.pdf.

43 For further information on determinants of access, see the Trilateral Study, chapters II (section A) and IV. See also https://www.bbc.com/news/world-asia-india-55571793.

44 *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with respect to Pharmaceutical Products*, WTO document IP/C/73, 6 November 2015.

45 Available at https://medicinespatentpool.org/licence-post/molnupiravir-mol.

46 Available at https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines.

47 Available at https://www.unicef.org/supply/covid-19-market-dashboard.

48 Available at http://vaxmap.org.

49 Available at https://launchandscalefaster.org/COVID-19.

50 See https://cepi.net/news_cepi/survey-launched-by-cepi-to-track-multinational-vaccine-manufacturing-capacity-for-use-in-future-epidemics-and-pandemics and https://cepi.net/wp-content/uploads/2021/03/Landscape_of_current_C19_supply_chain_manufacturing_capacity.pdf.

51 Available at https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.

52 See https://msfaccess.org/africa-south-korea-roundtable-working-together-local-production-diagnostics for further information.

53 See https://africacdc.org/news-item/african-union-and-africa-cdc-launches-partnerships-for-african-vaccine-manufacturing-pavm-framework-to-achieve-it-and-signs-2-mous and https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action.

54 For further information on health services under the WTO General Agreement on Trade in Services (GATS), see the Trilateral Study, chapter II section B.3(c).

55 See https://www.who.int/publications/m/item/covid-19-virtual-press-conference-transcript---12-july-2021.

56 *Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response*, available at https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_9Add1-en.pdf.

57 See the Trilateral Study, chapter II, section B.1.(e)(v) Software licensing and eHealth.

58 Anderson, D., Apfel, P., "COVID-19 Maps: The Global Impact of COVID-19 on Competition Law Enforcement", *e-Competitions Antitrust Case Laws e-Bulletin*, 23 July 2020, 95551.

59 For example, see European Commission, "The EU Commission Issues a Temporary Framework Communication on Allowing Limited Cooperation among Businesses, and a Comfort Letter Especially for Critical Hospital Medicines during the COVID-19 Pandemic", *e-Competitions*, 8 April 2020, 94176.

60 For example, South Africa has issued block exemptions in the health-care, banking, retail and hotel sectors. Competition authorities from Bulgaria, Italy, the Netherlands, Portugal and

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145 See Mitchell, A.D. and Taubman, A., "Practical Means of Applying the TRIPS Agreement's Flexibilities to Spur Vaccine Production: Special Series on Trade and Health", *ARTNeT Working Paper No. 225*, 5 January 2023, available at https://www.unescap.org/kp/2023/practical-means-applying-trips-agreements-flexibilities-spur-vaccine-production-special.

146 Available at https://www.who-wipo-wto-trilateral.org.

147 See the Trilateral Study, chapter IV, section C.2 Pre-grant and post-grant review procedures.

148 *Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp*., No. IPR2019-00554, 2020 WL 4237232, 23 July 2020.

149 See https://cafc.uscourts.gov/opinions-orders/20-1184.OPINION.12-1-2021_1872445.pdf and https://cafc.uscourts.gov/opinions-orders/20-2329.OPINION.12-1-2021_1872458.pdf.

150 In Argentina, Fundación GEP opposed Gilead´s patent application on remdesivir (see https://www.redlam.org/argentina-fundacion-gep-opposed-gileads-patent-application-on-remdesivir). Pre-grant oppositions have been filed in India against patents on molnupiravir, a compound investigated for use to treat COVID-19 (see https://www.patentoppositions.org/en/drugs/molnupiravir-mk-4482).

151 See https://www.patentoppositions.org/en/drugs/molnupiravir-mk-4482/patent_oppositions/60c9d050d2708f00059d0fdc.

152 See https://www.patentoppositions.org/en/drugs/remdesivir-gs-5734/patent_oppositions/636b6638d2708f0005ea114e

153 See https://twn.my/announcement/CALL%20FOR%20REVOCATION%20OF%20RDV%20PATENTS%20IN%20INDIA.pdf and Wu, X. and Khazin, B.P., "Patent-related Actions Taken in WTOated A42 (EV)20 (O)-21 (C)20 (A)82 (TI)-21 (O)-28-Capeutii(din, B.P)10dot.TIF%20d2708f00059d0fdc.P oppo09tentP oppo

222 See https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/recipients-of-mrna-technology-from-the-who-mrna-technology-transfer-hub.

223 See https://www.who.int/news/item/23-02-2022-moving-forward-on-goal-to-boost-local-pharmaceutical-production-who-establishes-global-biomanufacturing-training-hub-in-republic-of-korea.

224 See https://www.who.int/initiatives/who-biohub.

225 See https://www.wto.org/english/news_e/news21_e/heal_29jun21_e.htm.

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