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

Second update, May 2023

Extract from *Promoting Access to Medical Technologies and Innovation* (Second Edition)

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World Health Organization
Department of Public Health, Innovation and Intellectual Property
Avenue Appia 20
CH-1211 Geneva 27
Switzerland
Tel: + 41 22 791 21 11
Fax: + 41 22 791 31 11
Email: gspoa@who.int
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World Intellectual Property Organization
WIPO Publications
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World Trade Organization
WTO Publications
154 rue de Lausanne
CH-1211 Geneva 21
Switzerland
Tel: + 41 22 739 53 08
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Introduction

The second edition of the joint WHO, WIPO and WTO publication *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (the Trilateral Study),* published in 2020, included a special insert that mapped the challenges posed by the COVID-19 pandemic in relation to the integrated health, trade and intellectual property (IP) policy framework set out in the Trilateral Study.

The Trilateral Study and the special insert were designed to serve as background reference for policy-makers in the widest sense – lawmakers, government officials, delegates to international organizations, non-governmental organizations and researchers who seek a comprehensive presentation of the full range of issues, including institutions and legal concepts with which they may be unfamiliar. They were also designed to serve as a factual resource for the three organizations' technical cooperation activities.

This update revises the information contained in the last version, launched in October 2021**, in the light of more recent developments as of 17 May 2023.

* Available at https://www.who.int/publications/i/item/9789240008267, https://www.wipo.int/publications/en/details.jsp?id=4511 and https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm.

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A dramatic impact on health systems and responses at the global level

The coronavirus disease 2019 (COVID-19) pandemic constitutes an extraordinary global public health crisis. It has created a pressing need for intensified global cooperation to respond to the current pandemic and be better prepared for future health emergencies. From the outset, the pandemic raised issues at the crossroads of public health, trade, and IP policy and the framework for and the management of innovation and access, including those relating to the transfer of technology.

According to the WHO Coronavirus Dashboard,[1] globally, as of March 2023, more than 761 million confirmed cases of COVID-19, including almost 6.9 million deaths, had been reported to WHO. However, there is likely a significant undercount of total deaths directly and indirectly attributed to COVID-19. WHO estimated the number of excess deaths due to COVID-19 worldwide to be 14.9 million (in the range of 13.3 to 16.6 million) between January 2020 and December 2021, as compared to the reported 3 million excess deaths due to COVID-19 estimated in 2020.[2]

COVID-19 disproportionately impacts vulnerable populations. It has exposed persistent inequalities by income, age, race, sex and geographic location. Despite recent global health gains, across the world people continue to face complex, interconnected threats to their health and well-being rooted in social, economic, political and environmental determinants of health.

> **COVID-19 disproportionately impacts vulnerable populations, exposing persistent inequalities by income, age, race, sex and geographic location.**

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – first recognized in December 2019 – causes COVID-19. A systematic review of 79 studies and published in 2020 found that 20 per cent of people who become infected with SARS-CoV-2 remain asymptomatic.[3] Those who become symptomatic develop mild (40 per cent) or moderate (40 per cent) disease. Approximately 15 per cent of people with COVID-19 develop severe disease that requires oxygen support and 5 per cent have critical disease with complications including respiratory failure and/or multi-organ failure.[4]

Based on notifications to the WHO under the International Health Regulations (IHR) (2005)[5], the WHO Director-General declared a public health emergency of international concern on 30 January 2020. Since then, the WHO has been issuing temporary recommendations under Article 18(2) of the IHR (2005) relating to trade, including recommendations pertaining to travel, cargo and goods. On 11 March 2020, the WHO Director-General characterized the COVID-19 outbreak as a pandemic. On 5 May 2023, the WHO Director-General declared that COVID-19 no longer constituted a public health emergency of international concern given the decreasing trends in COVID-19 deaths and hospitalizations, and the high levels of population immunity to SARS-CoV-2.[6]

United Nations resolutions in response to the COVID-19 pandemic

Resolution 76/175

General Assembly resolution 76/175, *Ensuring equitable, affordable, timely and universal access for all countries to vaccines in response to the coronavirus disease (COVID-19) pandemic*[7], recognizes the importance of international cooperation and effective multilateralism in ensuring that all states have affordable, timely, equitable and universal access to COVID-19 vaccines. It underscores that equitable access to health products is a matter of global priority and that the availability, accessibility, acceptability and affordability of health products of assured quality are fundamental to tackling the pandemic, and it expresses concern that the unequal distribution of vaccines delays the end of the pandemic.

Resolution 74/274

General Assembly resolution 74/274, *International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19*[8], underscores that equitable access to health products is a global priority and that the availability, accessibility, acceptability and affordability of health products of assured quality are fundamental to tackling the pandemic.

Resolution WHA73.1

World Health Assembly (WHA) resolution WHA73.1, *COVID-19 response*[9], is concerned, *inter alia*, with the continued functioning of the health system and universal health coverage, the promotion of R&D, including through open innovation, as well as timely, equitable and affordable access to health technologies. It calls on international organizations and other stakeholders to work collaboratively at all levels to develop, test and scale-up production of safe, effective, quality, affordable

diagnostics, therapeutics, medicines and vaccines for the COVID-19 response. This includes existing mechanisms for voluntary pooling and licensing of patents, in order to facilitate timely, equitable and affordable access to the technology, medicines and vaccines needed to respond to COVID-19, consistent with the provisions of relevant international treaties, including the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health.[10] It also calls for restrictions on the movement of medical equipment and medicines to be temporary and specific, for sharing of knowledge, lessons learned, experiences, best practices, data, materials and commodities, and for collaboration to promote both private-sector and government-funded R&D.

Resolution WHA74.6

Resolution WHA74.6, *Strengthening local production of medicines and other health technologies to improve access*[11], signals WHO member states' commitment to distribute production capacity more equitably. It recalls the Doha Declaration, which affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the right of member states to protect public health and, in particular, to promote access to medicines for all, and recognizes the importance of IP protection for the development of new medicines, as well as the concerns about its effects on prices. The resolution requests the WHO Director-General to continue to provide technical support, as appropriate and upon request, in collaboration with other competent international organizations, in particular WIPO and the WTO. This includes support to policy processes and to countries that intend to make use of the provisions contained in the TRIPS Agreement, including the flexibilities affirmed by the Doha Declaration to promote access to pharmaceutical products.

Resolution WHA74.7

Resolution WHA74.7, *Strengthening WHO preparedness for and response to health emergencies*[12], requests the WHO Director-General to collaborate with member states, other international organizations, civil society and the private sector, based on lessons learned from the COVID-19 response and prior health emergencies, to propose strategies to enable rapid research, development, production and global equitable distribution of quality, safe, effective and affordable medical and other countermeasures and commodities at national, regional and global levels to respond to future health emergencies.

Resolution 49/25

The Human Rights Council resolution 49/25, *Ensuring equitable, affordable, timely and universal access for all countries to vaccines in response to the coronavirus disease (COVID-19) pandemic*[13], calls upon states and other relevant stakeholders to take appropriate measures to guarantee the fair, transparent, equitable, efficient, universal and timely access and distribution of safe, quality, efficacious, effective, accessible and affordable COVID-19 vaccines and to enable international cooperation, among other actions.

International Health Regulations (2005) and COVID-19

The IHR (2005) provide an overarching legally binding framework that sets out the rights and obligations of WHO member states in public health emergencies that have the potential to cross borders.[14] Following the outbreak of COVID-19, a review committee was convened by the WHO Director-General to review the performance of the IHR (2005) during the COVID-19 response to understand what did and did not function in its implementation and any shortcomings.[15] In its report[16], the Review Committee provided 40 recommendations to improve the functioning of the IHR (2005) in 10 key areas:

(1) role and function of National IHR Focal Points;
(2) core capacity requirements for preparedness, surveillance and response;
(3) legal preparedness;
(4) national notification and alert system;
(5) risk assessment and information sharing;
(6) COVID-19 Emergency Committee and the determination of a public health emergency of international concern;
(7) travel measures;
(8) digitalization and communication;
(9) collaboration, coordination and financing;
(10) compliance and accountability.

> **The International Health Regulations (2005) provide the legally binding framework in public health emergencies that have the potential to cross borders.**

Independent Panel for Pandemic Preparedness and Response

The Independent Panel for Pandemic Preparedness and Response (IPPPR) was established by the WHO Director-General to provide an impartial, independent and comprehensive review of the international health response to COVID-19. The IPPPR reviewed experiences gained and lessons learned for pandemic preparedness and response in the future. Among the recommendations of the IPPPR in its 2021 report were the establishment

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;
- financing;
- institutional arrangements.

The final instrument is expected to complement other relevant international instruments, including the IHR (2005). In December 2022, member states considered the conceptual zero draft and agreed to start negotiations in February 2023.[29] To support those negotiations, the INB Bureau circulated a zero draft on 1 February 2023. Member states and other stakeholders provided initial comments and drafting suggestions at the fourth and fifth meeting of the INB, held in March and April, respectively. Experts were also invited to provide comments on selected parts of the zero draft in intersessional briefings in March.[30]

Public health and social and economic measures

During a certain period of time, governments have implemented restrictions to economic and social activities in an effort to slow the virus's spread, including through policies of lockdowns, social distancing and restrictions on travel. These restrictions sought to reduce pressure on health systems, allow sufficient time to improve health infrastructure and to develop and distribute diagnostics, vaccines and treatments to effectively respond to the virus. The WHO publishes a regularly updated interim guidance in *Considerations for Implementing and Adjusting Public Health and Social Measures in the Context of COVID-19* to help WHO member states assess the situation at national and sub-national levels by providing key recommendations about the implementation of public health and social measures.[31]

Monitoring variants of concern

Viruses change over time – although most changes have little impact on the viruses' characteristics. However, some changes can affect how easily a virus spreads, the associated disease severity, the efficacy of vaccines and therapeutic medicines, and the effectiveness of diagnostic tools and public health and social measures. The emergence of viral variants triggers renewed calls for global collaboration to slow the spread globally and necessitates the continued monitoring and adaptation of the collective response. Accordingly, the WHO collaborates with national authorities, institutions and researchers routinely to assess the potential danger of new variants.

COVID-19 Weekly Epidemiological Update

The WHO publishes the *COVID-19 Weekly Epidemiological Update* and the *Monthly Operational Update on Health Emergencies*[32], which provide the

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]

> **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.**

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]

Policy challenges posed by the 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]

> **An additional 71 to 100 million people are being pushed into extreme poverty as a result of the pandemic.**

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.

Meeting the demand for health technologies and medical services

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:

- WHO: COVID-19 vaccine tracker and landscape.[46]
- United Nations Children's Fund (UNICEF): COVID-19 Market Dashboard.[47]
- Prickly Research, on behalf of the Third World Network: VAXMAP.[48]
- DukeGlobal Health Innovation Center: Launch and Scale Speedometer.[49]
- Coalition for Epidemic Preparedness Innovations (CEPI): mapping multinational vaccine capacity.[50]
- The New York Times: Coronavirus Vaccine Tracker.[51]

Creating sustainable partnerships

Creating sustainable regional and global partnerships is essential to the development of local production capacity. For example, manufacturers and stakeholders from the Republic of Korea and countries in Africa have held discussions on challenges, potential and opportunities to build mutually beneficial partnerships to improve the capacity of local diagnostics manufacturers in Africa.[52] The African Union has also launched the Partnerships for African Vaccine Manufacturing (PAVM) and the PAVM Framework for Action, which aim at leveraging pan-African and global partnerships to scale up vaccine manufacturing to meet the continent's vaccine needs.[53] Additional initiatives can be found in the section "COVID-19 technologies: international initiatives to support R&D and equitable access".

Creating sustainable regional and global partnerships is essential to the development of local production capacity.

Facilitating the movement of skilled workers

Facilitating the movement of health workers, for example through visas or work permits and programmes for recognition of qualifications, has been considered by certain governments as instrumental to keeping health systems operational.[54] Equally, the international movement of skilled personnel has been identified as a key contribution to the pressing need to expand the transfer and dissemination of critical vaccine technologies. While some states have considered the idea of implementing COVID-19 vaccine passports as a condition of travel, the WHO does not promote the use of vaccine passports as a precondition for travel of entry.[55]

The Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response recommends that a risk-based approach should be promoted in relation to travel measures. The focus should be on protecting health, sharing essential information and specimens and accepting that travel and trade restrictions may be required. The effectiveness of travel measures depends on their timing. However, precautionary measures should still be proportional to the perceived threat, non-discriminatory, continually reviewed in the light of new knowledge and applied in accordance with the

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]

Furthermore, to ensure that essential products remain available at competitive prices, a number of competition authorities across the globe have launched investigations relating to COVID-19 health products, including into price hikes for health products and diagnostic manufacturing information held as a trade secret.[65] In Greece, for example, the Hellenic Competition Commission conducted an investigation into the market for health-care materials following numerous consumer complaints regarding price increases.[66] Based on econometric analysis of the collected data, the interim results indicated that the price increases were consistent with competitive behaviour.[67] Supermarkets and enterprises have been investigated over excessive or "unjust" prices for medical protective equipment, oxygen and sanitary supplies in a number of jurisdictions, including Argentina, Brazil, China, Fiji, Kenya and Nigeria.[68] In a number of cases, breaches of competition laws were found and remedial orders were issued.[69]

Some authorities amended legal rules to tackle pricing abuses more effectively during the pandemic or adjusted their economic analyses to take into account the temporary nature of the crisis. For example, South Africa amended its competition and consumer protection legislation to introduce anti-price-gouging provisions.[70] The Chinese competition authority issued warnings against price increases and guidelines for swift enforcement against increases in the prices of facemasks.[71] Argentina[72] and Morocco[73] have issued decrees setting maximum pricing for surgical masks, hand sanitizers and other products.

Preserving effective international trade

While low- and middle-income countries face particular challenges caused by the global scarcity of key health technologies, the vast majority of countries are net importers of all categories of health technologies, including those needed to address COVID-19.

Medical goods sector

Before the pandemic, trade in the medical goods sector was just 6.4 per cent of total world trade in 2018. During the pandemic, this share increased to 8.3 per cent in 2020. Between 2019 and 2021, imports and exports of medical goods increased by an annual growth rate of 14.4 per cent, reaching US$ 2,654 billion in

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.[79] Countries and international organizations work closely together to facilitate the smooth cross-border flow of vital medical supplies and to avoid unnecessary disruptions to global trade and supply chains.

To support those efforts, the WTO Secretariat has developed a number of practical resources:

- The information note *Developing and Delivering COVID-19 Vaccines Around the World*[80] explores the role trade policy can play to ensure the rapid roll-out of COVID-19 vaccines.
- The updated *Joint Indicative List of Critical COVID-19 Vaccine Inputs (Version 2)*[81] compiles information on the critical inputs for the manufacturing, distributing and administering of COVID-19 vaccines that has been produced by several organizations. The list has been prepared in collaboration with key stakeholders and is a living document open to development through stakeholder input.
- The information note *Improving Trade Data for Products Essential to Fight COVID-19: A Possible Way Forward*[82] describes data problems and how to monitor trade in products essential to combat the COVID-19 pandemic and future health crises.
- The updated *Indicative List of Trade-related Bottlenecks and Trade-facilitating Measures on Critical Products to Combat COVID-19*[83] is a non-exhaustive list facilitating access to granular information on inputs used in vaccine manufacturing, vaccine distribution and approval, therapeutics and pharmaceuticals, diagnostics and medical devices. It is a living document open to development through stakeholder input.
- The information note *Trade in Medical Goods in the Context of Tackling COVID-19: Developments in 2019-2021*[84] presents trade statistics for medical goods for 2021 and comparisons with previous years. It includes data on critical products for administering COVID-19 vaccines, such as rubber gloves, syringes and needles.
- The information note *Covid-19 Vaccine Production and Tariffs on Vaccine Inputs*[85] provides an analysis of the tariffs imposed in the 27 top manufacturing economies identified in July 2021.
- The WTO-IMF COVID-19 Vaccine Trade Tracker[86] database aimed at providing greater transparency on the cross-border flow of COVID-19 vaccines. It provides data on the trade and supply of vaccines by product, country and arrangement type. Updates to the database ended from June 2022 onwards.

In addition to the above resources, activities undertaken at the WTO in close coordination with international partners have examined issues such as what the multilateral trading system can contribute to the COVID-19 response and to achieving vaccine equity, main trade-related challenges to vaccine supply chain and regulatory transparency and how international trade can be leveraged to expand COVID-19 vaccine manufacturing to promote equitable access.[87]

Trade-restrictive and trade-facilitating measures

From the outset of the pandemic, governments have concomitantly implemented both trade-restrictive measures (e.g. restrictions on exports of key products) and trade-facilitating measures to reduce costs and delays (e.g. facilitation and simplification of customs procedures).[88] Some countries have reduced or eliminated tariffs on certain imported health technologies or deferred payment deadlines for the same.[89]

Regulatory conformity checks have been streamlined through international cooperation and standards, as well as through mutual or unilateral recognition of third-country or WHO Emergency Use approvals. As

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 had been repealed, leaving 27 export restrictions and 14 import restrictions in place. Although the number of the pandemic-related trade restrictions still in place has decreased, their trade coverage remains important and is valued at US$ 134.6 billion.[90]

Pandemic-related trade restrictions are valued at US$ 134.6 billion, but are decreasing.

Intellectual property aspects

The global IP system provides an incentive framework in which urgently needed innovation in relation to COVID-19 can be encouraged. It covers the stages from invention to supply of a product or service.[91] The impact of patents on access is complex and an area of particular focus. Other IP rights, including trade secrets, are also being discussed. IP policy and the administration and enforcement of the IP laws aim to balance and accommodate a range of interests in a way that promotes overall public welfare. A wide range of policy options and flexibilities are built into the international IP regime and can be used to promote access to health products and other public health objectives.

Patent examination, disclosure and patent information

The disclosure requirement is considered one of the important rationales of the patent system, as it enables dissemination of information and an increase in the public stocks of knowledge.[92]

WIPO has established a COVID-19 search facility[93] within its global PATENTSCOPE database. The tool offers predefined search strings that support the searching of COVID-related patent information. The European Patent Office[94] and a number of national patent authorities have developed similar tools, as well as databases of COVID-related patents, for example:

- China has launched a freely accessible database for COVID-related patents.
- The Republic of Korea has made available patent information on technology relating to the diagnosis and treatment of COVID-19, including patent analysis and trend reports.
- As part of the PROSUR/PROSUL regional technical cooperation initiative, Argentina, Brazil, Chile, Colombia, Ecuador, Peru and Uruguay have published patent reports on technologies relevant to COVID-19.[95]
- The United States Patent and Trademark Office has created a COVID-19 Prioritized Examination Pilot Program, which fast-tracks examination of COVID-related applications filed by small and micro enterprises.[96]
- The Brazilian National Institute of Industrial Property prioritized the examination of patent applications related to innovations that can be used to fight COVID-19 from 7 April 2020 to 30 June 2021.[97]

The WHO launched the Technology Access Pool (TAP) database[98] in 2023 to provide wide-ranging information on selected COVID-19 therapeutics, diagnostics, vaccines and other health products. This is in response to the call for user-friendly databases in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI).[99] The database provides information on patent and licensing status, clinical trial status, regulatory status, and suppliers of selected COVID-19 health products, as well as other relevant data. It is the first single point of access to such information sourced from all countries and it will be updated regularly.

The MPP provides patent and licensing information in its Medicines Patents and Licences Database (MedsPaL)[100], the COVID-19 Vaccines Patent Database (VaxPal)[101] and the newly-created Long-acting Therapeutics Patents and Licences Database (LAPaL)[102]. On 31 March 2020, with the support of WHO and Unitaid, the MPP temporarily expanded its mandate to cover any health technologies that could contribute to the response to COVID-19.[103]

A WTO Staff Working Paper[104] examines 74 patent families contained in the VaxPal database relating to ten COVID-19 vaccines and vaccine candidates. It finds that most of the related patent applications were filed in the top 25 innovation economies in WIPO's 2021 Global

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 biotechnological R&D on SARS-CoV-2.

Domestic IP laws frequently provide for research exceptions. Where a research exception is available, R&D on patented COVID-related technologies does not constitute patent infringement.[108] In countries where a regulatory review exception exists, a patented invention can be used without the consent of the patent holder for the purposes of developing information to obtain regulatory marketing approval.[109] A number of national patent systems provide options addressing the further development, and repurposing, of existing medicines, including incremental innovation, medical indication claims and limiting evergreening.

Available policy measures include compulsory licences and government-use licences.[110] Legislation has been passed in some countries to ensure that mechanisms for expedient compulsory licensing and government-use licensing are in place if needed in order to facilitate access to COVID-19 therapies.

In Canada, for example, the Patent Act was amended in March 2020 to empower the Commissioner of Patents to authorize use of patented inventions in response to a public health emergency. The amendment expired in September 2020.

In Germany, the Federal Ministry for Health was authorized to order the competent authority to allow the use of patent-protected inventions to ensure the supply of various health technologies, including medicines, diagnostics and personal protection equipment, on the grounds of public interest or national security. This measure expired in April 2021.[111]

In France, Emergency Law No. 2020-290 of 23 March 2020 to combat the COVID-19 epidemic introduced Article L3131-15 into the Public Health Code, which gives extraordinary powers to the French prime minister. It enables the prime minister to order the seizure of all goods and services necessary to fight against sanitary disaster to temporarily control the prices of products and to take any measures necessary to make relevant medicines available to patients. This goes beyond compulsory licensing measures taken by other governments and may also affect other IP rights, such as designs, to ensure the availability of PPE.[112]

In some countries, such as Italy[113] and Hungary[114], these amendments were made permanent.

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 example, by notifying the WTO of the expected needs at an early stage of the procurement of a COVID-19 health technology, a member would open up the widest possible range of suppliers, including through, but not limited to, the System; this would also facilitate groups of members to aggregate demand and benefit from economies of scale and exercise joint leverage to secure access.

In early 2021, the Plurinational State of Bolivia and Antigua and Barbuda notified the TRIPS Council of their respective intentions to use the Special Compulsory Licensing System for the importation of pharmaceutical products, in particular vaccines.[128] On 11 May 2021, the Plurinational State of Bolivia notified the TRIPS Council of its specific needs to import 15 million doses of COVID-19 vaccines.[129] The Canadian pharmaceutical company, Biolyse Pharma, expressed its intention to produce and export a generic version of the Johnson & Johnson vaccine and signed an agreement with the Government of the Plurinational State of Bolivia to manufacture and export COVID-19 vaccines. This was subject to the necessary regulatory approvals and voluntary and compulsory licences through Canada's Access to Medicines Regime (CAMR),[130] the law to implement the System domestically.

CAMR requires medicines to be positively scheduled before being considered for a compulsory licence and links regulatory approval with the System – so that the product intended for export meets the same safety, efficacy and quality standards applicable to drugs destined for Canada's domestic market.[131] Internal discussions as to whether COVID-19 vaccines should be scheduled under CAMR reportedly cover the question of whether Biolyse Pharma has the capacity to manufacture vaccines that meet regulatory standards.[132] In October 2022, a committee report to the House of Commons recommended, among other things, the immediate launch of a public consultation of CAMR as

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

Ministerial Decision on the TRIPS Agreement

The WTO's 12th Ministerial Conference, held in Geneva from 12 to 17 June 2022, adopted the Ministerial Decision on the TRIPS Agreement.[134] The Decision clarifies certain TRIPS flexibilities that enable members to limit the exclusive effect of patent rights, and adopts a single targeted waiver.[135] As elaborated above, the TRIPS Agreement already permits any WTO member to authorize the use of the subject matter of a patent without the patent holder's consent on any grounds.[136]

Under Article 31(f) of the TRIPS Agreement, any use without the patent holder's consent "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." The Decision waives this requirement by allowing the producing member to export any quantity of COVID-19 vaccines to any developing country member of the WTO, either directly or through international humanitarian programmes.[137] This waiver will allow manufacturers to scale up production capacity and support countries with insufficient or no manufacturing capacity. In addition to providing a waiver of Article 31(f), the Decision clarifies, that in the context of producing and supplying COVID-19 vaccines, Members:

(i) may issue government use authorizations through any instrument available in domestic law, including but not limited to legislative acts and compulsory licensing regimes;[138]
(ii) are not required to undertake efforts to obtain right holder consent under Article 31(b) prior to authorizing use of a patent;[139] and
(iii) may take into account the humanitarian and not-for-profit purpose of certain vaccine programmes, as well as existing good practices in national emergencies and pandemics, in determining adequate remuneration for right holders.[140]

Finally, the Decision specifies that the obligation to protect regulatory test data required under Article 39.3 of the TRIPS Agreement does not prevent an eligible member from taking steps for rapidly approving the use of a COVID-19 vaccine.[141]

The Decision also includes transparency and safeguard requirements. To ensure that production is not siphoned to unintended beneficiaries, importing members must undertake all reasonable efforts to prevent the re-exportation of goods imported under the Decision. In exceptional circumstances, however, imported COVID-19 vaccines may be re-exported to another eligible member for humanitarian and not-for-profit purposes.[142]

The Decision is applicable to eligible members, which is defined as all developing country members. Those with manufacturing capacity are encouraged not to avail themselves of this Decision. So far, China is the only member which has committed not to use the Decision.[143] Eligible members may apply the provisions of the Decision until 17 June 2027. The WTO General Council may decide to extend this period taking into consideration the exceptional circumstances of the COVID-19 pandemic.[144]

Importantly, the Decision is without prejudice to the flexibilities that members have under the TRIPS Agreement, including flexibilities affirmed in the Doha Declaration on the TRIPS Agreement and Public Health. This means that developing country members may rely on existing flexibilities provided by the TRIPS Agreement including compulsory or government use licences to facilitate access to affordable medical products. The Decision is an additional option provided to a developing country member, to facilitate the production and supply of COVID-19 vaccines. When the Decision expires, members in need of importing COVID-19 vaccines may notify their needs under Article 31*bis* of the TRIPS Agreement, which will allow the manufacturing member to continue to waive Article 31(f).

As with any other flexibility, the Decision is not self-executing.[145] Although it expands the scope for government action, it does not replace the steps members may have to take at the domestic level to make use of it. The WHO, WIPO and the WTO are available to provide coordinated technical assistance upon request to support the effective implementation of the Decision. Requests may be submitted via the WHO–WIPO–WTO COVID-19 Technical Assistance Platform.[146]

Pre- and post-grant opposition procedures

Pre- and post-grant opposition procedures also play an important role in striking a balance in the IP system.[147] Such measures have traditionally been used more often by commercial competitors. For example, Moderna sought in 2018 to invalidate two US patents on an mRNA delivery system owned by Arbutus Biopharma which Moderna uses for its COVID-19 vaccines. In July 2020, the United States Patents Trial and Appeal Board (PTAB) ruled that portions of one of the patents, US Patent No. 9,364,435 were invalid but otherwise ruled in Arbutus Biopharma's favour – rejecting Moderna's petition that the subject matter was obvious and therefore not patentable.[148] In December 2021, the Court of Appeals affirmed the PTAB rulings.[149]

Civil society organizations have opposed the granting of certain patents on technologies that could be potentially used in a new COVID-19 medicine.[150] For example, in India, the Cancer Patients Aid Association filed a pre-grant opposition to the patent application for molnupiravir on

the basis that the pharmaceutical composition of some claims made in the application cannot be considered novel and inventive.[151] Low Cost Standard Therapeutics filed a post-grant opposition to a patent for remdesivir in India on various grounds including lack of novelty, inventive step and non-patentability of the invention under local laws.[152] Civil society organizations have also called on governments to revoke certain patents in India[153] and South Africa.[154] Some civil society organizations have also submitted requests to government authorities in Chile, Colombia, the Dominican Republic and Peru to issue compulsory licences over Paxlovid.[155]

A balanced copyright system that supports the interests of rights holders and allows access to copyright-protected works can support R&D activities and enable the development of digital solutions to support diagnostics and treatment. Text and data mining exceptions have been used in initial research into COVID-19, including for tracking and predicting its spread, and are being used in the search for treatments.[156]

Software licensing schemes can also support the development of eHealth products and digital processes that may allow easier diagnosis and treatment of COVID-19 patients.[157]

Voluntary actions and initiatives

Many organizations, corporations and other rights holders have undertaken voluntary actions and initiatives during the COVID-19 crisis.[158] Licensing agreements are diverse in their subject matter and cover several steps along the production and supply chain. A breakdown of publicly announced agreements shows that collaboration covers one or more of the following elements: technology transfer, fill-and-finish, distribution and storage.

Transfer of technology and know-how

Governments and the private sector have also undertaken initiatives to transfer technology and know-how to make, adapt or use COVID-related technologies.[159] A concrete example of IP management for a new COVID-19 technology was seen in a vaccine developed at Oxford University in the United Kingdom and licensed to AstraZeneca for manufacture. While the exact contract terms are not public, the company committed to supplying the vaccine globally on a not-for-profit basis and signed an agreement with an Indian-based manufacturer allowing the latter to supply low- and middle-income countries.[160] The company also signed a US$ 750 million agreement with CEPI and Gavi for the manufacture, procurement and distribution of additional doses. Later in 2021, the company signed a licensing agreement with Fiocruz[161] (a public health research institute in Brazil), Siam Bioscience[162] (in Thailand), mAbxience (a biotechnology company in Argentina) and the Mexican foundation Carlos Slim. Publicly available data and information on licensing or other agreements for manufacture and transfer of technology for COVID-19 vaccines and vaccine candidates are available from a number of sources.[163]

Voluntary licensing

Another voluntary licence was concluded between Aspen SA Operations and Janssen Pharmaceuticals. It covers manufacturing and making available an Aspen-branded COVID-19 vaccine throughout Africa, which expands the existing technology transfer and manufacturing agreements between the parties through transactions with designated multilateral organizations and with national governments of member states of the African Union.[164] In August 2022, Aspen also signed a deal with the Serum Institute of India to manufacture and sell four of the Aspen-branded vaccines for Africa.[165] In the absence of orders, Aspen closed its production line.[166]

In May 2020, Gilead signed voluntary licensing agreements with several manufacturers of generic pharmaceuticals in Egypt, India and Pakistan for supply of remdesivir in 127 countries.[167]

MSD announced in April 2021 that it had signed voluntary licensing agreements with five Indian manufacturers of generic pharmaceuticals to expand supply of remdesivir in India and other low- and middle-income countries.[168]

In May 2021, Eli Lilly granted royalty free licences to six manufacturers in India for domestic supply of baricitinib.[169]

In the area of therapeutics, licence agreements focus on newly launched (as opposed to repurposed) treatments. Noteworthy examples include the Pfizer voluntary licences for its oral antiviral nirmatrelvir/ritonavir to the MPP, which was announced shortly after Merck agreed to licence its molnupirarvir to MPP.[170]

In January 2022, the MPP signed sub-licence agreements with 27 manufacturers of generic pharmaceuticals to manufacture the oral COVID-19 antiviral medication molnupirarvir and supply in 105 low-and-middle-income countries.[171] These sub-licences are the result of the voluntary licensing agreement signed by MPP and MSD in October 2021 to facilitate affordable global access for molnupirarvir. As of March 2022, the MPP had granted sub-licences to 36 manufacturers of generic pharmaceuticals for the production of the generic version of Pfizer's oral COVID-19 treatment (nirmatrelvir/ritonavir) for supply in 95 low- and-middle-income countries.[172] In October 2022, the MPP signed a licence agreement with Shionogi for the production and distribution of the investigational antiviral candidate ensitrelvir fumaric acid, pending regulatory approval.[173]

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-how, materials and other technical knowledge relating to its patent rights which may be necessary for Biotech Africa to make full use of the patents and biological material.[175]

In May 2022, the NIH granted worldwide, non-exclusive and transparent licences to C-TAP for the development of eleven innovative therapeutics, early-stage vaccines and diagnostic tools for COVID-19.[176]

C-TAP has continued to engage with other technology holders for a new pipeline of global, non-exclusive licenses. Public research institutions, academia and a private company have offered to share key health technologies with C-TAP. The technologies include two COVID-19 vaccine candidates and a diagnostic tool.

To secure voluntary transfer of additional health technologies, C-TAP has been collaborating with the University of Cape Town, a public research university based in Cape Town, South Africa, and the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), an Institution of National Importance under the Department of Science and Technology in India.

Other observed voluntary actions in support of R&D include the permission to use text and data mining and machine learning technologies and to freely access and reuse COVID-related scientific literature protected by copyright,[177] and the making available of standards protected by copyright.[178] For example, as part of the Open COVID Pledge, a number of private companies and universities are granting free access to patented technologies and protected designs relating to diagnosing, preventing, containing and treating COVID-19.[179]

Despite voluntary actions and initiatives taken by certain stakeholders, there is a strong call from the global health community for urgently needed additional voluntary licences, in particular from the holders of key vaccines, therapeutics or diagnostics to prevent, detect and treat COVID-19 and achieve equitable global access.[180]

There is a strong call from the global health community for urgently needed additional voluntary licences.

Open COVID Pledge

The Open COVID Pledge called on organizations around the world to make their patents and copyrights freely available in the fight against the COVID-19 pandemic.[181] The Pledge was developed by an international group of scientific and legal experts who sought to accelerate the rapid development and deployment of diagnostics, vaccines, therapeutics, medical equipment and software solutions in this urgent public health crisis. From April 2020 through January 2023, more than 30 entities worldwide pledged an estimated half million patents and copyrights to the COVID-19 response.[182] Many of these IP assets remain available for free use today under the Pledge.

Advance purchase agreements

According to an analysis of R&D funding for COVID-19 vaccines conducted by the Global Health Centre of the Graduate Institute of International and Development Studies, advance purchase agreements (APAs)[183] took the lead among all of what can be considered funding sources for COVID-19 vaccines so far, with EU member states and the United States accounting for the majority of the funding (US$ 41.6 billion of the US$ 52 billion tracked).[184] These APAs include, to varying degrees, clauses with implication on vaccines production that are either general in nature, or specifically governing licensing matters. An example of licensing provisions are provisions governing the transfer of technology, and future licensing thereof, such as those granting conditional licences to the purchaser/funder in case of abandonment by the manufacturer/contractor in order to ensure continuity.

Other private sector initiatives

A number of private sector companies have taken other access-oriented actions that include:

(i) publishing scientific data on a free-to-use basis;
(ii) publishing technical specifications of vital equipment (e.g. ventilators);[185]
(iii) sharing knowledge to enable others to manufacture and use such technologies; and
(iv) committing not to enforce IP rights (AbbVie, Moderna).

All these initiatives and measures related to IP set out in the previous sections have different characteristics and could be implemented in different ways. There

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] approved a number of specific activities including the WIPO COVID-19 Response Package aiming to answer to member states' evolving needs with respect to technical assistance in the areas of COVID-19 response, recovery and future pandemic resilience. This includes a special focus on transfer of technology, such as various technology transfer structures in developing countries. It also includes conducting research and commissioning studies on topical issues relating to the COVID-19 pandemic and pandemic preparedness. WIPO is also making available tools, materials and data in support of member states and other international organizations and initiatives. These activities such as providing granular patent landscaping for critical health technologies and materials on IP policies, such as guidelines on the disclosure requirement.

The study *The Determinants of COVID-19 Vaccine Development Success*,[187] commissioned by WIPO, finds that development progress for COVID-19 vaccines is predicated on decades of research characterizing SARS-related viruses, existing scientific tools, development collaborations worldwide and across governments, multilateral agencies and private firms. Many of these collaborations are multi-party. They include, but are not limited to, knowledge that is IP protected by one or more parties. Private firms are willing to invest in COVID-19 therapeutic development. This was especially true given the daunting scientific and manufacturing challenges and the significant risks and uncertainty they faced.

The diversity of vaccine candidates in development was highly unusual and suggested both a willingness of innovators to think creatively and a willingness of funders to fund across vaccine platforms. This had important implications for the success of COVID-19 vaccines and the industry in the future to address unmet needs. The study also stated that the funding committed to support vaccine development by both private firms and funders was significant in magnitude and unusual in its support for manufacturing at risk. This also presented some challenges for future planning, including:

- how best to keep manufacturing running without suffering quality deficits;
- how best to democratize access to manufacturing technology, and allow capacity to meet local demands; and
- how best to fund sustained manufacturing capacity to meet the next emergent epidemic or pandemic.

In 2023, WIPO commissioned a study about the role and impact of licensing trends during COVID-19 on innovation and access, which examines the development, manufacture and dissemination of 12 distinct health products with a focus on trends and approaches related to the underlying the licensing agreements related to these products.[188]

WHO initiatives

C-TAP is preparing a study on strategies to incentivize sharing of technology and knowledge by technology holders. The study is based, in part, on responses to a questionnaire addressed to WHO member states to identify legislation, regulations, guidelines and procedures that can be amended or introduced to encourage sharing of technology. The report also analyses possible measures including technology buy-outs and inclusion of access and innovation terms in funding agreements, to promote participation of technology holders in C-TAP. In addition, C-TAP is undertaking a study on access provisions in funding agreements for R&D of medical products. The study focuses on specific contractual terms and conditions and associated policies related to the funding of R&D, clinical trials, and the manufacturing of medical products, particularly those needed to respond to international public health crises.

The WHO, together with Unitaid and with the support of Medicines Law & Policy, has published a briefing document for countries on pathways to access affordable COVID-19 treatments.[189] The briefing document explains some of the legal instruments that WHO member states are allowed to use to promote public health and access to key therapeutics, in the framework of their multilateral trade obligations and rights, and according to their national legislation and level of development, and it contains:

- background information and resources on the therapeutics landscape and WHO recommendations;
- an overview of the Medicines Patent Pool licences for oral antivirals and the implications for country access;
- C-TAP;
- other licences relevant to COVID-19 therapeutics; and
- guidance on the use of TRIPS flexibilities.

COVID-19 technologies: international initiatives to support R&D and equitable access

Since the start of the COVID-19 pandemic, myriad public and private actors have launched collaborative global efforts to develop treatments, vaccines and diagnostics, with the aim of guaranteeing equitable access to those technologies. Many such efforts strive to simultaneously address R&D and access needs simultaneously. Collaborative efforts include substantial investments in product development partnerships[190] to support the non-commercial development of a vaccine and large multi-stakeholder R&D initiatives.[191]

WHO initiatives

The WHO report *2019 Novel Coronavirus (2019-nCoV): Strategic Preparedness and Response Plan*[192] includes actions to coordinate international R&D efforts such as using the R&D Blueprint Global Coordination Mechanism[193] and convening of expert consultations that have resulted in the Coordinated Global Research Roadmap.[194] The *COVID-19 Strategic Preparedness and Response Plan 2021* builds on achievements and lessons learned from 2020 with strategic actions that aim to address new challenges such as new viral variants.[195]

The WHO R&D Blueprint and COVID-19 highlights the importance of a collaborative approach, stating that "virus materials, clinical samples and associated data should be rapidly shared for immediate public health purposes and that fair and equitable access to any medical products or innovations that are developed using the materials must be part of such sharing."[196] Genetic sequences of viral samples have been shared openly worldwide. Timely sharing of epidemiological and other data is also crucial.[197]

> **Genetic sequences of viral samples have been shared openly worldwide.**

The WHO provides information about the global response such as R&D landscapes, regulatory approval status and manufacturing and distribution of vaccines, diagnostics and therapeutics.[198]

WHO forums

To further contribute to international R&D efforts, WHO has hosted three forums of world experts on research and innovation during the COVID-19 pandemic to help shape the global research agenda for COVID-19. Held in February 2022, the most recent was the 3rd COVID-19 Global Research and Innovation Forum[199], which highlighted the need to:

- produce a global evidence base and world-class data for better outcomes;
- build global trust for global research;
- put equitable access at the centre of research; and
- strengthen global research capability and invest in pandemic preparedness in the long term.

Solidarity I

To ensure efficiency in testing potential treatments, the WHO launched Solidarity I, an international clinical trial platform for COVID-19 treatments, which enrols patients in one single randomized trial to facilitate the rapid worldwide comparison of unproven treatments.[200] Since the end of 2020, the Solidarity Trial has recruited over 15,000 patients in 500 hospitals globally. The Solidarity Trial examined the effectiveness of repurposed drugs (remdesivir, hydroxychloroquine, lopinavir/ritonavir, interferon) for the treatment of COVID-19. In line with the Policy Statement on Data Sharing by the WHO in the Context of Public Health Emergencies, interim results from the trial were published in October 2020 and found that all four treatments had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay for patients having been hospitalized.[201]

Solidarity PLUS

The WHO is also leading a global collaboration that promotes the implementation of serological surveys on SARS-CoV-2, Solidarity II.[202] The global platform allows governments and academic collaborators to carry out seroepidemiological, risk factor and severity studies. In August 2021, WHO launched Solidarity PLUS Trial, an international randomized trial of additional three treatments (artesunate, imatinib, infliximab) for COVID-19 in hospitalized patients.[203] Through the trial, the WHO has facilitated access to thousands of treatment courses for the trial through donations from a number of manufacturers.[204] In late 2021, the WHO launched the Solidarity Trial Vaccines (STV) as a large, international, randomized clinical trial for evaluation of the efficacy and safety of several candidate COVID-19 vaccines and facilitate regulatory and deployment decisions through ACT-A and the COVAX facility (the vaccines pillar of ACT-A).[205]

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.[208]

COVID-19 Vaccine Delivery Partnership

In January 2022, the WHO partnered with UNICEF and Gavi to create the COVID-19 Vaccine Delivery Partnership to expedite vaccine delivery in 34 countries that were at or below 10 per cent full vaccination coverage to progress towards national and global targets.[209] This initiative prioritizes full vaccination and boosters for high-priority populations such as older adults, health-care workers and persons with co-morbidities. To support the work of the therapeutics pillar of ACT-A, the WHO and the Global Fund are developing allocation strategies to ensure access to critical COVID-19 therapeutics.[210] The allocation strategies are based on the principles of equity, transparency, and ethics.

COVID-19 Therapeutics Dashboard

The COVID-19 Therapeutics Dashboard[211] was created to provide information about countries' responses to the ACT-A Therapeutics Allocation process. It includes information on expressions of interest received through the Partners Platform,[212] allocation and acceptance amount of COVID-19 therapeutic products made available through the initiative, and its funding source.

Solidarity Call to Action and COVID-19 Technology Access Pool (C-TAP)

In response to an initiative of the Government of Costa Rica, the WHO on 29 May 2020 launched the Solidarity Call to Action and C-TAP.[213] The Call has been endorsed by 45 other member states as well as international organizations and other stakeholders.[214] It states:

"The COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies. This initiative sets out an alternative, in line with WHO's efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity."[215]

Key elements of the Solidarity Call to Action include:

- public disclosure of gene sequences and data;
- timely publication of all clinical trial results;
- encouragement of governments and R&D funders to include clauses in funding agreements with pharmaceutical companies and other innovators concerning equitable distribution, affordability and transparency, including the publication of trial data;
- use of global non-exclusive licensing for relevant health technologies, including through licensing to the MPP;[216]
- promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity, including through joining the Open Covid Pledge and the United Nations Tech Access Partnership.

To operationalize the Solidarity Call to Action, the WHO and partners launched C-TAP to facilitate timely, equitable and affordable access of COVID-19 health products. C-TAP, working through its implementing partners – MPP, the Open COVID Pledge and the United Nations Technology Bank – provides a global one-stop-shop for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their IP, knowledge and data, with quality assured manufacturers through public health-driven voluntary, non-exclusive and transparent licences. By promoting licensing of IP and know-how through pooling and voluntary agreements, developers of COVID-19 health products can facilitate production through multiple manufacturers that currently have untapped capacity.

COVAX Manufacturing Task Force

The WHO and partners established the COVAX Manufacturing Task Force as a proposed pathway to increasing supply and ensuring regional health security.[217] The Task Force aimed to increase immediate supply (three to six months) for existing vaccines, ensure vaccines coming onto market can be produced at maximum scale

and not constrained by existing contracts, and enable low- and middle-income countries to acquire COVID-19 vaccine production technology and to establish sustainable outbreak response capacity for regional health security.

As part of the task force, the WHO established in April 2021 a COVID-19 mRNA vaccine technology transfer hub in South Africa to scale up global manufacturing.[218] On 4 February 2022, Afrigen, one of the companies taking part in the WHO mRNA hub, announced the development of the first mRNA COVID-19 vaccine using publicly available technical data about Moderna's vaccine technology, which had announced earlier that it will not enforce its IP rights in this regard.[219] Afrigen expects to start clinical trials of the vaccine in 2023.[220]

Messenger RNA hub

In February 2022, the WHO announced that Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia will be the first countries on the African continent to receive the technology needed to produce mRNA vaccines through the mRNA hub.[221] As of August 2022, the list of recipients has been expanded to include Argentina, Bangladesh, Brazil, India, Indonesia, Pakistan, Serbia, Ukraine and Viet Nam.[222]

Training hubs

On 23 February 2022, the WHO led the establishment of a global biomanufacturing training hub in the Republic of Korea to serve all low- and middle-income countries wishing to produce biologicals, such as vaccines, insulin, monoclonal antibodies and cancer treatments.[223] The facility will provide technical and hands-on training on operational and good manufacturing practice requirements and is set to complement the trainings delivered by the mRNA vaccine technology transfer hub in South Africa.

In 2021, WHO established the BioHub system to facilitate sharing of biological materials with epidemic or pandemic potential by WHO member states for effective surveillance and timely development of medical response products such as diagnostics, therapeutics or vaccines.[224]

WTO initiatives

In close collaboration with international partners, WTO activities included a technical symposium on vaccine supply chain and regulatory transparency,[225] and a webinar on regulatory cooperation during the COVID-19 pandemic[226] in 2021. These activities examined how to strengthen transparency in the regulatory approval process and how to increase regulatory cooperation. These events explored the main challenges to vaccine supply chain and regulatory transparency in the context of COVID-19, and discussed cooperation towards finding practical solutions to scale up the global COVID-19 response and address gaps in the global production and distribution of vaccines, diagnostics and other medical technologies.

In February 2022, WTO hosted a technical workshop on COVID-19 vaccines R&D, manufacturing and distribution[227] to support the ongoing discussions and to improve knowledge on the practical aspects of vaccine R&D, manufacturing and distribution.

A WTO Secretariat information note also provides an overview of discussions in the Committee on Technical Barriers to Trade (TBT) relating to COVID-19[228] and covers:

- COVID-related TBT notifications;
- discussions of COVID-19 in specific trade concerns in the TBT Committee;
- members' exchange of experiences;
- relevant work of the WTO Secretariat; and
- inputs from WTO observers on COVID-related matters in the TBT Committee.

Government investment

European Commission

The need for rapid development of new technologies has spurred unprecedented government investment in R&D.[229] Launched by the European Commission in May 2020, Coronavirus Global Response pledging events reached a total of €15.9 billion by the end of June 2020 to fund collaborative development and universal deployment of, and access to, diagnostics, treatments and vaccines against coronavirus.[230] The European Commission has also instituted a temporary framework to allow state aid to go to COVID-related R&D if beneficiaries commit to grant non-exclusive licences under non-discriminatory market conditions to third parties in the European Economic Area.[231]

United States

A report from the Kaiser Family Foundation[232] on the United States finds:

> "Congress has enacted six emergency supplemental funding bills to address the COVID-19 pandemic as of June 23, 2022, which collectively provide approximately $ 19.03 billion for the global response, including for health and humanitarian efforts. Of this amount, $ 10.54 billion (55%) was either directly appropriated to or is managed by the U.S. Agency for International Development (USAID). […] The remainder was appropriated to the State Department and the Centers for Disease Control and Prevention (CDC).[2]

"[2] CDC has posted broad information on how it plans to spend $1.55 billion of the emergency funding; see CDC, 'CDC's

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 $31.9 billion of public funds directly into the development, production and procurement of mRNA COVID-19 vaccines.[233] While the vast majority of this investment was made during the pandemic, according to the study, at least US$ 337 million were invested in mRNA related science before the pandemic erupted.

Other initiatives

Coalition for Epidemic Preparedness Innovations

CEPI, a PDP created in the wake of the 2014 Ebola virus outbreak by philanthropies and a number of governments, has initiated a US$ 3.5 billion action plan aimed at, among others, funding late-stage clinical trials of promising COVID-19 vaccine candidates that can offer doses to COVAX, and build on vaccine technologies validated in the COVID-19 response to develop clinical proof of concept for broadly protective SARS-COV-2 vaccines and broadly protective beta-coronavirus vaccines.[234]

CEPI requires producers to provide equitable access to any vaccine developed through its funding. It further requires product developers to be willing to undertake technology transfer to enable production by a global network of manufacturers.[235] It is playing a key role in the work of COVAX.

World Bank

In June 2021, the World Bank announced that it had expanded its COVID-19 vaccine financing from an initial US$ 12 billion to US$ 20 billion over a period of 18 months.[236]

Multi-stakeholder engagement

It has become increasingly evident that collaborative multi-stakeholder engagement is key to resolving issues of vaccine scarcity and equitable access. Numerous multi-stakeholder initiatives are under way to help identify the challenges and practical steps needed to help scale up manufacturing capacity for and facilitate equitable distribution of COVID-19 vaccines. Since 2021, these multi-stakeholder initiatives have included:

- The January 2021 call to action issued by the WHO for vaccine equity and working together in solidarity to accelerate the equitable rollout of vaccines in every country, starting with health workers and those at highest risk for COVID-19.[237]
- The April 2021 World Bank event "COVID-19: Vaccines for Developing Countries".[238]
- A series of high-level consultations by the Multilateral Leaders Task Force, co-led by the heads of the IMF, the World Bank Group, the WHO and the WTO, with other stakeholders, such as UNICEF, Gavi, and the heads of leading vaccine manufacturing companies.[239] These consultations were aimed at increasing access to COVID-related vaccines and other critical medical countermeasures in low- and lower-middle-income countries.[240]
- The April 2021 Economic and Social Council event "A Vaccine for All", focusing on scaling up manufacturing and financing.[241]
- The WHO–WTO High Level Dialogue on Expanding COVID-19 vaccine manufacture to promote equitable access in July 2021.[242]
- A series of practical capacity-building workshops held by the WHO, WIPO and the WTO under the trilateral framework to enhance the flow of updated information on current developments in the pandemic and responses to achieve equitable access to COVID-19 health technologies. The first workshop on innovation in, and access to, COVID-19 technologies, intellectual property licensing, technology transfer, and the sharing of know-how and clinical trial information was held in September 2021.[243] In February 2022, a second workshop was held on accessing and using information resources for the pandemic response.[244] In October 2022, the third workshop was on innovation and access to diagnostics for COVID-19 and beyond.[245]
- The COVID-19 Technical Assistance Platform website was created by the WHO, WIPO and the WTO as a one-stop-shop for the three organizations to make available their expertise in public health, IP and trade matters in a coordinated and systematic manner to help members address the COVID-19 pandemic.[246]

Regulatory responses

Regulatory assessment and approval of health technologies are essential in every health system to ensure product quality, safety and efficacy. As of January 2023, the WHO has recommended a number of treatments for patients with varying levels of severity of COVID-19.[247] The treatments include molnupiravir, baricitinib and nirmatrelvir/ritonavir. Clinical trials are ongoing for new treatments as well as for repurposed medicines.[248] "Compassionate use" of medicines (i.e. their clinical use before approval) occurs in specific cases.[249]

WHO Emergency Use Listing

The WHO Emergency Use Listing (EUL) procedure aims to streamline the process by which new or unlicensed products can be used during public health emergencies. The EUL provides a time-limited listing for unlicensed products in an emergency context when limited data are available and when products are not yet ready to apply for WHO prequalification.[250] In this context, products are still undergoing development and are not yet licensed. The WHO assesses the quality, safety and efficacy of the data generated during development and conduct a risk–benefit assessment to determine use outside of clinical trials. Certain eligibility criteria apply to EUL for COVID-19 products, including:

- whether the disease may cause an outbreak, epidemic or pandemic;
- whether there are any products available capable of eradicating or preventing the disease;
- whether products are manufactured in compliance with good manufacturing practices;
- whether the applicant undertakes to complete the development of the product and apply for prequalification once it is licensed.

The list assists interested United Nations procurement agencies and member states in determining the acceptability of specific products, based on an essential set of available quality, safety and efficacy and performance data. For Brazil's health regulatory authority ANVISA, the EUL has served as the basis for the exemption of market and emergency use authorization and the procedure for the import and monitoring of vaccines acquired by the Ministry of Health within the scope of the COVAX Facility for the tackling the COVID-19 pandemic.[251]

The EUL is currently open to candidate *in vitro* diagnostics to detect SARS-CoV-2, including for assays for the detection of SARS-CoV-2 nucleic acid, immunoassays for the detection of SARS-CoV-2 specific antibodies and rapid diagnostic tests for the detection of SARS-CoV-2 antigens.[252]

The up-to-date status of COVID-19 vaccines within WHO EUL/PQ evaluation process is available on the WHO website,[253] together with a list of companies which produce COVID-19 vaccines with EUL.[254]

Ensuring transparency

Transparency and the availability of up-to-date information on measures taken by governments are of critical importance and cut across both legal and policy areas addressed in the Trilateral Study.[255]

> **Transparency and the availability of up-to-date information on measures taken by governments are of critical importance.**

International Health Regulations (2005)

The IHR (2005) include a broad notification requirement, which aims at detecting, early on, all public health events that could have serious and international consequences, and preventing or containing them at source through an adapted response before they spread across borders.[256] Notifiable events must be reported to the WHO immediately (i.e. within 24 hours after the assessment of public health information relating to the event). As well as submitting information about health measures taken in addition to those recommended by the WHO, Article 6 of the IHR (2005) states:

"2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern."

Transparency in COVID-19 R&D

Transparency in COVID-19 R&D and access initiatives is also an essential principle in the WHO Solidarity Call to Action which, for example, promotes the inclusion of specific provisions in COVID-19 funding agreements with regard to accessibility to and affordability of resulting COVID-related health products through global non-exclusive voluntary licensing, transparency and, when necessary, other commitments to expand access by sharing, for example, other IP rights, know-how and data.

Transparent and timely sharing of information, data and other elements at all levels has been identified as a guiding principle to effectively prevent, prepare and

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 way forward

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 provides a platform for WTO members to work together to diversify vaccine manufacturing capacities. It facilitates and streamlines vaccine exports. As the Decision is not self-executing, measures at domestic and regional levels are required to allow for its effective implementation and use. The Decision also requests members to decide on whether to extend its scope to cover the production and supply of COVID-19 diagnostics and therapeutics no later than 17 December 2022. On 6 December 2022, the co-sponsors of the original waiver proposal submitted a proposal to extend the Decision *mutatis mutandis* for the production and supply of COVID-19 therapeutics and diagnostics[269]. However, as agreement could not be reached, the General Council at its meeting on 19-20 December extended the deadline following a recommendation submitted by the TRIPS Council[270] and substantive considerations are due to continue in the TRIPS Council in 2023 while the item will also stay on the agenda of the General Council.[271]

Negotiations at the WHO for an international instrument on pandemic prevention, preparedness and response began in February 2023.[272] The negotiations are based on the zero draft prepared by the INB Bureau, and it is expected that a final draft of the instrument will be ready for consideration by the 77th World Health Assembly in 2024. Other complementary efforts, such as discussions on proposed amendments to the IHR (2005),[273] are ongoing to strengthen the global response to communicable diseases and pandemic threats. In addition, the President of the United Nations General Assembly, in collaboration with the WHO, will convene a high-level meeting on pandemic prevention, preparedness and response on 20 September 2023 to mobilize political momentum, including through the integration of a multi-sectoral approach towards pandemic prevention, preparedness and response.[274] The high-level meeting is expected to approve an action-oriented political declaration on, inter alia, mobilizing political will at the national, regional and international levels for pandemic prevention, preparedness and response.

Endnotes

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64 See *Trade Therapy: Deepening Cooperation to Strengthen Pandemic Defenses*, 2022, available at https://www.wto.org/english/res_e/publications_e/trade_therapy2022_e.htm.

65 Competition investigations were initiated to the extent they raised concerns within competition law. To address excessive pricing, some authorities have as well applied either existing consumer protection laws against exploitative pricing or misleading advertising or price-gouging laws that apply in times of crisis.

66 See https://www.epant.gr/en/enimerosi/press-releases/item/840-press-release-investigation-in-healthcare-materials.html.

67 See https://www.epant.gr/en/enimerosi/press-releases/item/959-press-release-in-depth-investigation-in-healthcare-materials-during-the-coronavirus-health-crisis.html.

68 See http://english.scio.gov.cn/pressroom/2020-02/28/content_75754311_0.htm and https://www.allenovery.com/global/-/media/allenovery/2_documents/news_and_insights/publications/2020/06/covid-19_antitrust_tracker.pdf.

69 See https://www.fijivillage.com/news/-Nine-more-traders-charged-by-FCCC-45xrf8 and https://cak.go.ke/sites/default/files/2020-03/CAK%20Remedial%20Order%20to%20Cleanshelf%20Supermarkets.pdf.

70 See 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.

71 See *Exploitative Pricing in the Time of COVID-19*, 26 May 2020, available at https://www.oecd.org/daf/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf.

72 *Global Competition Measures in Response to COVID-19*, September 2020, available at https://www.lexmundi.com/media/stigrpdq/global-competition-measures-report.pdf.

73 See https://www.allenovery.com/global/-/media/allenovery/2_documents/news_and_insights/publications/2020/06/covid-19_antitrust_tracker.pdf.

74 *Trade in Medical Goods in the Context of Tackling COVID-19: Developments in 2019-21*, 19 July 2022, available at https://www.wto.org/english/tratop_e/covid19_e/med_goods_2019_21_e.pdf.

75 See WTO Blog Trade in medical goods stabilises after peaking during pandemic, 23 May 2023, available at https://www.wto.org/english/blogs_e/data_blog_e/blog_dta_23may23_e.htm

76 As set out, for instance, in the Rome Declaration of 21 May 2021, available at https://global-health-summit.europa.eu/rome-declaration_en.

77 See https://www.wto.org/english/news_e/news20_e/dgra_30mar20_e.pdf and *G20 Trade and Investment Ministerial Meeting*, WTO document WT/GC/221, 29 September 2020.

78 See https://www.wto.org/english/news_e/news20_e/igo_14apr20_e.htm and https://www.wto.org/english/news_e/news20_e/igo_06apr20_e.htm.

79 A compilation of WTO members proposals and statements on COVID-19 and world trade is available at https://www.wto.org/english/tratop_e/covid19_e/proposals_e.htm.

80 Available at https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf.

81 Available at https://www.wto.org/english/tratop_e/covid19_e/vaccine_inputs_report_jun22_e.pdf.

82 Available at https://www.wto.org/english/tratop_e/covid19_e/trade_data_report_e.pdf.

83 Available at https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf.

84 Available at https://www.wto.org/english/tratop_e/covid19_e/med_goods_2019_21_e.pdf.

85 Available at https://www.wto.org/english/tratop_e/covid19_e/vaccine_production_report_e.pdf.

86 See https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm. Information has stopped been collected and data have not been updated since 31 May 2022.

87 See https://www.wto.org/english/news_e/news21_e/covid_16sep21_e.htm, https://www.wto.org/english/news_e/news21_e/igo_30oct21_e.htm and https://www.wto.org/english/news_e/news21_e/dgno_26nov21_e.htm.

88 See the Trilateral Study, chapter IV section D.1(b) Trade policy for health-related products. For a regularly updated list of trade and trade-related measures taken in the context of the COVID-19 crisis, see https://www.wto.org/english/tratop_e/covid19_e/trade_related_goods_measure_e.htm.

89 See the Trilateral Study, chapter IV, section D.1(b) Trade policy for health-related products.

90 See the WTO Trade Monitoring Report, December 2022, available at https://tmdb.wto.org/en/reports.

91 For more information on IP systems, see the Trilateral Study, chapters II (section B.1), III (section D) and IV (section C). The role of the IP system for innovation and access to COVID-19 health technologies and action taken by governments and the private sector are set out in the WTO Secretariat information note *The TRIPS Agreement and COVID-19*, available at https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf. WIPO support measures to assist member states in addressing the COVID-19 pandemic, as well as laying the foundations for post-COVID economic recovery efforts comprise five main areas: policy and legislative assistance; technical assistance and capacity building; innovation support and technology transfer; IP dispute resolution; and knowledge resources. Information on the package is available at https://www.wipo.int/covid-19/en.

92 See the Trilateral Study, chapter II sections B.1(b)(iii) and (viii)–(xi).

93 Available at https://patentscope.wipo.int/search/en/covid19.jsf.

94 See https://www.epo.org/news-events/in-focus/fighting-coronavirus.html.

95 See https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

96 See https://www.uspto.gov/initiatives/covid-19-prioritized-examination-pilot.

97 See *Ordinance No. 149/2020 of 7 April 2020, amending resolution 239/19*, which regulates the priority procedure for patent application processes.

98 Available at https://c-tap.essensys.ro.

99 See *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*: resolutions WHA61.21, 24 May 2008, available at https://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf; and WHA62.16, 22 May 2009, available at https://apps.who.int/gb/ebwha/pdf_files/WHA62-REC1/WHA62_REC1-en.pdf.

100 Available at https://www.medspal.org/?page=1.

101 Available at https://www.vaxpal.org/?page=1.

102 Available at https://lapal.medicinespatentpool.org.

103 See https://medicinespatentpool.org/what-we-do/disease-areas#pills-COVID-19.

104 Available at https://www.wto.org/english/res_e/reser_e/ersd202201_e.pdf.

105 Available at https://www.wipo.int/pressroom/en/articles/2022/article_0003.html.

106 Available at https://www.wipo.int/meetings/en/details.jsp?meeting_id=76628

107 See the Trilateral Study, chapters II (section B.1(b)(vii) Exceptions and limitations to patent rights) and IV (sections C.1 Determinants of access prior to patent grant, and C.3 Post-grant determinants of access).

108 See the Trilateral Study, chapter III, sections D.5(a) Research exception and (b) Research tools.

109 See the Trilateral Study, chapter IV, section C.3(a)(i) Regulatory review exception.

110 See the Trilateral Study, chapter IV, section C.3(a)(ii) Compulsory licensing and government use.

111 https://www.bgbl.de/xaver/bgbl/start.xav#__bgbl__%2F%2F*%5B%40attr_id%3D%27bgbl120s0587.pdf%27%5D__1676035392145

112 See https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/ipo-operations; http://www.senat.fr/cra/s20200319/s20200319.pdf and https://www.iam-media.com/article/the-key-covid-19-compulsory-licensing-developments-so-far.

113 See https://www.ipinitalia.com/licensing/compulsory-licensing-amendment-approved-by-italian-parliament-for-health-emergencies.

114 See https://www.lexology.com/library/detail.aspx?g=0e2f0d4a-e4a3-4dec-9868-a6f02edd9cce.

115 See https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf and https://www.wipo.int/ip-development/en/agenda/flexibilities/details.jsp?id=9205.

116 See https://www.law.cornell.edu/uscode/text/28/1498.

117 See https://www.acquisition.gov/far/52.227-1.

118 See https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf.

119 See https://law.justia.com/cases/federal/district-courts/delaware/dedce/1:2022cv00252/78146/64.

120 See https://spicyip.com/wp-content/uploads/2021/04/Rakesh_Malhotra_vs_GNCTD__Order_20_4.pdf and https://spicyip.com/2021/04/compulsory-license-for-covid-drugs-on-the-table-says-delhi-high-court.html.

121 See https://main.sci.gov.in/supremecourt/2021/11001/11001_2021_35_301_27825_Judgement_30-Apr-2021.pdf.

122 See https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_224_1_EN_ACT_part1_v11.pdf.

123 Article 31*bis* of the amended TRIPS Agreement; see the Trilateral Study, chapter IV, section C.3(a)(iii) The Special Compulsory Licensing System: an additional flexibility aimed at enhancing access to medicines, and annex III.

124 See the TRIPS Council Report, *Annual Review of the Special Compulsory Licensing System*, WTO document IP/C/86, 11 November 2020.

125 See in particular the statement by South Africa in WTO document IP/C/86, para. 43. See also: *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Responses to Questions, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe*, WTO document IP/C/W/672, 15 January 2021, paras 3, 4, 21, 76, 112 and 114; *Response to Questions on Intellectual Property Experienced by Members in Relation to COVID-19 in Document IP/C/W/671, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe*, WTO document IP/C/W/673, paras 4, 47 and 48.

126 See: footnote 3 to the Annex to Article 31*bis* of the amended TRIPS Agreement; https://www.politico.eu/wp-content/uploads/2020/06/Van-Brempt-2.pdf; and https://www.keionline.org/wp-content/uploads/KEI-WTO-Letter-DrNgozi-1March2021.pdf.

127 Available at https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

128 See *Notification under the Amended TRIPS Agreement*, WTO documents IP/N/8/BOL/1 and IP/N/8/ATG/1, 19 February and 17 May 2021.

129 See *Notification under the Amended TRIPS Agreement*, WTO document IP/N/9/BOL/1, 11 May 2021.

130 See https://www.keionline.org/wp-content/uploads/Bolyse-Bolivia-Spanish.pdf.

131 See: the Food and Drugs Act, RSC 1985, c. F-27, s. 37.2; and the Food and Drug Regulations, CRC, c. 870, C.07.004.

132 See https://ici.radio-canada.ca/nouvelle/1798935/bolivie-vaccins-covid-19-canada-biolyse-pharma-ontario.

133 See https://www.ourcommons.ca/DocumentViewer/en/44-1/FAAE/report-5.

134 *Ministerial Decision on the TRIPS Agreement*, WTO document WT/L/1141, 22 June 2022.

135 In the run-up to the Ministerial Decision, WTO members had first considered a proposal for a waiver of certain provisions of the TRIPS Agreement as a response to the COVID-19 pandemic in 2020 (*Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa*, WTO document IP/C/W/669, 2 October 2020), as well as other texts targeting IP aspects of the production and trade in pandemic-related vaccines, medicines and other health technologies (*Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, Communication from the European Union to the Council for TRIPS*, WTO document IP/C/W/681, 18 June 2021; *Communication from the Chairperson*, WTO document IP/C/W/688, 3 May 2022).

136 As confirmed by the Doha Declaration; see *Declaration on the TRIPS Agreement and Public Health*, WTO document WT/MIN(01)/DEC/2, 20 November 2001, para. 5(b).

137 See WTO document WT/L/1141, para. 3(b). Developing country members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to make use of the targeted waiver provided for in the Decision (WTO document WT/MIN(22)/30 WT/L/1141, footnote 1 to para. 1). As of the date of the Decision, China was the only WTO member that has made such a commitment. The TRIPS Council publishes a record of such binding commitments in *Record in Accordance with Footnote 1 of the Ministerial Decision on the TRIPS Agreement of 17 June 2022 (WT/L/1141),* WTO document IP/C/W/690, 22 June 2022.

138 WTO document WT/L/1141, para. 2

139 WTO document WT/L/1141, para. 3(a). The Doha Declaration clarified that members have the right to determine what constitutes a national emergency or other circumstances of extreme urgency and noted an understanding that public health crises can constitute a national emergency or circumstance of extreme urgency (see WTO document WT/MIN(01)/DEC/2, para. 5(c)).

140 WTO document WT/L/1141, para. 3(d) and footnote 4.

141 *Ibid*., para. 4.

142 *Ibid*., para. 3(c) and footnote 3.

143 WTO document IP/C/W/690.

144 WTO document WT/L/1141, para. 6.

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 WTO Members in Response to the COVID-19 Pandemic", *WTO Staff Working Paper ERSD-2020-12*, 21 October 2020, available at https://www.wto.org/english/res_e/reser_e/ersd202012_e.pdf.

154 See https://msfaccess.org/south-africa-must-urgently-revoke-patents-key-covid-19-treatments-and-vaccines.

155 See https://msfaccess.org/south-africa-must-urgently-revoke-patents-key-covid-19-treatments-and-vaccines, https://www.corporacioninnovarte.org/ong-innovarte-junto-con-colegio-de-quimicos-farmaceuticos-y-bioquimicos-de-chile-solicitaron-a-ministro-de-salud-y-presidente-de-la-republica-que-se-permita-fabricar-y-o-importar-genericos-de-med, https://www.statnews.com/pharmalot/2022/04/05/covid19-colombia-pfizer-paxlovid-patents, https://aisperu.org.pe/organizaciones-de-la-sociedad-civil-solicitan-el-uso-gubernamental-de-paxlovid-para-tratar-el-covid-19 and https://www.healthgap.org/press/109-civil-society-organizations-call-on-dominican-republic-president-luis-abinader-to-support-compulsory-license-to-expand-access-and-break-pfizers-monopoly-over-lifesaving-covid-19-treatment.

156 See: the Trilateral Study, chapter II, section B.1(e)(ii) Exceptions and limitations – text and data mining; and *The TRIPS Agreement and COVID-19*, available at https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

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

158 For an overview of voluntary action taken, see: *The TRIPS Agreement and COVID-19*, available at https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf; and the WIPO COVID-19 Policy Tracker on voluntary actions, available at https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/voluntary-actions-text.

159 See the Trilateral Study, chapter IV, section A.10 Manufacturing and technology transfer.

160 See: https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html; and the Trilateral Study, chapter IV, section C.3(c) Socially responsible licensing policies and management of IP developed at public institutions.

161 See https://agencia.fiocruz.br/sites/agencia.fiocruz.br/files/u34/contrato_etec.pdf.

162 See https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Thai-king-owned-biotech-starts-production-of-AstraZeneca-vaccine.

163 See https://www.unicef.org/supply/covid-19-vaccine-market-dashboard, https://www.keionline.org/covid-contracts, https://www.knowledgeportalia.org/covid-19, https://globalhealthgrades.org and https://ghiaa.org/about-ghiaa.

164 See https://www.aspenpharma.com/aspen-concludes-agreement-to-manufacture-and-make-available-an-aspen-branded-covid-19-vaccine-aspenovax-throughout-africa.

165 See https://www.reuters.com/business/healthcare-pharmaceuticals/safricas-aspen-indias-serum-institute-sign-vaccines-deal-africa-2022-08-31.

166 See https://healthpolicy-watch.news/important-lessons-from-the-african-vaccine-producer-that-never-sold-a-single-dose.

167 See https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir?_sm_au_=iVV3rM63ZjssVkHrvMFckK0232C0F and https://www.statnews.com/pharmalot/2020/05/12/gilead-generics-remdesivir-covid19-coronavirus-licenses.

168 See https://www.msd.com/news/amid-humanitarian-crisis-in-india-msd-announces-voluntary-licensing-agreements-with-five-indian-generics-manufacturers-to-accelerate-and-expand-global-access-to-molnupiravir-an-investigational-oral.

169 See https://www.pharmaceutical-technology.com/analysis/lillys-indian-drugmakers-baricitinib-covid-19.

170 See https://medicinespatentpool.org/licence-post/pf-07321332 and https://www.washingtonpost.com/world/2021/10/27/merck-license-ip.

171 https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir

172 See https://medicinespatentpool.org/news-publications-post/update-ukrainian-company-darnitsa-signs-sublicence-agreement-with-mpp-bringing-to-36-the-number-of-generic-manufacturers-to-produce-generic-versions-of-pfizers-oral-covid-19-treatment.

173 See https://medicinespatentpool.org/news-publications-post/shionogi-and-the-medicines-patent-pool-mpp-sign-licence-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-increase-access-in-low-and-middle-income-countries.

174 See https://www.who.int/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology.

175 See https://medicinespatentpool.org/licence-post/elisa-antibody-technology.

176 See https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses.

177 See https://wellcome.ac.uk/press-release/publishers-make-coronavirus-covid-19-content-freely-available-and-reusable.

178 For the European Union, see https://ec.europa.eu/commission/presscorner/detail/en/ip_20_502; for Singapore, see https://www.enterprisesg.gov.sg.

179 See https://opencovidpledge.org/.

180 See https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-who--wipo--wto-joint-technical-symposium-on-the-covid-19-pandemic--response--preparedness--resilience---16-december-2022.

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182 See https://opencovidpledge.org/pledgor-licenses.

183 For general information, see the Trilateral Study, advance market commitments and advance purchase commitments: Chapter III, section C.5(d).

184 See https://www.knowledgeportalia.org/covid-19-vaccine-r-d-funding.

185 See https://news.medtronic.com/2020-03-30-Medtronic-Shares-Ventilation-Design-Specifications-to-Accelerate-Efforts-to-Increase-Global-Ventilator-Production and https://www.medtronic.com/content/dam/medtronic-com/global/Corporate/covid19/documents/permissive-license-open-ventilator.pdf.

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188 The publication is forthcoming.

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192 Available at https://www.who.int/publications/i/item/strategic-preparedness-and-response-plan-for-the-new-coronavirus.

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194 See https://www.who.int/teams/blueprint/covid-19.

195 Available at https://www.who.int/publications/i/item/WHO-WHE-2021.02.

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198 Some resources can be found at https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines and https://www.who.int/news/item/15-01-2021-information-and-resources-on-covid-19-r-d.

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

Second update, May 2023

Extract from *Promoting Access to Medical Technologies and Innovation* (Second Edition)

The coronavirus disease 2019 (COVID-19) pandemic constitutes an extraordinary global public health crisis. It has created a pressing need for intensified global cooperation. The pandemic has from its outset raised issues at the crossroads of public health policy, trade policy and the framework for and management of innovation, including those relating to intellectual property rights.

The second edition of the joint WHO, WIPO and WTO publication "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", published in 2020, included a special insert mapping the challenges posed by the COVID-19 pandemic in relation to the integrated health, trade and IP policy framework set out in the study. This update revises the information contained in the last version launched in October 2021 in the light of more recent developments as of 17 May 2023.

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