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HOW WTO MEMBERS HAVE USED TRADE MEASURES TO EXPEDITE ACCESS TO COVID-19 CRITICAL MEDICAL GOODS AND SERVICES

INFORMATION NOTE1

KEY POINTS:

- The shortages of medical <u>personal protective equipment (PPE)</u> encountered around the world in the early phase of the pandemic have eased, as production and trade have expanded to meet the unparalleled demand spike.
- Initial data for 41 countries suggests that trade in medical goods grew by 38.7 per cent in the first half of 2020. Certain specific products remain subject to periodic shortages, with sourcing a particular challenge for some developing countries.
- Political commitments have been made to keep markets open. The statements made by G20 <u>leaders</u> and <u>trade ministers</u> have been buttressed by some 17 other <u>statements and proposals</u> issued by other WTO members and groups of members.
- Members are sharing information with the WTO about their COVID-19 trade measures as notifications and for inclusion in WTO trade monitoring reports. Transparency is essential to keep markets open, and is an area in which some members are calling for further action.
- Duties, taxes and charges on COVID-19-critical medical goods and other essential supplies have been temporarily removed or deferred by 40 WTO members, including 12 G20 members. These actions help reduce the cost of the goods needed to fight the pandemic, both for the health sector and for the general public. Measures to reduce or eliminate of import tariffs made up around two-thirds of the import trade facilitating measures reported to the WTO.
- Customs procedures and border clearance for COVID-19-critical medical goods have been
 expedited by cutting back <u>red tape</u>. Actions taken by members include establishing priority
 clearance channels, lessening and simplifying documentary requirements and electronic
 processing, and improving border agency cooperation. Expedited <u>transit</u> procedures have also
 helped landlocked countries improve their access to essential supplies.
- Steps have been taken to enhance <u>regulatory approval and cooperation</u> on standards for traded goods, including measures to expedite regulatory assessments, recognizing the results of foreign regulators and allowing remote or electronic conformity assessment procedures.
- Measures related to intellectual property (IP) rights are being used to facilitate innovation in and access to COVID-19-related technologies. Actions include sharing IP to develop treatments and allow the wider use of existing technologies, providing free access to relevant patent databases and COVID-19-specific search facilities, making available reports on COVID-19-related patents, and facilitating the exchange of clinical trial data. By end-July 2020, WTO trade monitoring activities had recorded some 47 COVID-19 related measures regarding trade-related IP rights taken by 24 members.

¹ This document has been prepared under the WTO Secretariat's own responsibility and is without prejudice to the positions of WTO members or to their rights and obligations under the WTO.

- Access to COVID-19-critical medical services has been improved. The international movement of health workers has been facilitated, together with new (temporary) rules on telemedicine.
- Expedited procurement procedures, including limited tendering and expedited payments for contractors, are among the <u>government procurement</u> actions notified by some members.

1. INTRODUCTION

COVID-19 continues to place extraordinary pressure on health systems worldwide. The <u>World Health Organization (WHO)</u> is concerned about further waves of infection. However, the chronic shortages of medical <u>personal protective equipment (PPE)</u> encountered around the world in the early phase of the pandemic have eased as production and trade have expanded to meet the unparalleled demand spike.

Initial data for 41 countries suggests that trade in <u>medical goods</u> expanded by 38.7 per cent in the first half of 2020. Sourcing remains challenging, however, for some developing countries due to periodic shortages of specific products. In this context, this information note surveys the trade measures that WTO members have taken to expedite access to COVID-19-critical medical goods and services and to foster innovation and the development of new treatments and of vaccines, and further actions that could be envisaged.

2. KEEPING MARKETS OPEN

On <u>25 March 2020</u>, then WTO Director-General Roberto Azevêdo called for a global solution to address the challenge brought about by the COVID-19 pandemic. He stated: "No country is self-sufficient, no matter how powerful or advanced it may be. Trade allows for the efficient production and supply of basic goods and services, medical supplies and equipment, food and energy".

On 26 March 2020, G20 leaders issued a <u>statement</u> at an extraordinary summit on COVID-19. In it, they agreed to address international trade disruptions and to keep markets open. On 30 March 2020, <u>G20 trade ministers</u> stated: "We are actively working to ensure the continued flow of vital medical supplies and equipment, critical agricultural products, and other essential goods and services across borders, for supporting the health of our citizens. Consistent with national requirements, we will take immediate necessary measures to facilitate trade in those essential goods".

On 14 May 2020, G20 trade ministers reaffirmed their determination to cooperate to mitigate the impact of COVID-19 on trade, and endorsed the "G20 Actions to Support World Trade and Investment in Response to COVID-19". Collective short-term actions focus on trade regulations, trade facilitation, transparency, logistics networks and support for micro, small and medium-sized enterprises (MSMEs). Long-term actions focus on supporting the multilateral trading system, building resilience and strengthening investment.

A further series of statements and proposals have been made by WTO members. These include statements by the African Group, the Asia-Pacific Economic Cooperation (APEC), the Association of Southeast Asian Nations (ASEAN), the Cairns Group, the Least-Developed Countries Group and the Ottawa Group.² A group of <u>46 members</u> also issued a joint statement in which they committed to "refrain from raising new unjustified barriers to investment or to trade in goods and services". On 25 July 2020, a <u>declaration</u> on "Facilitating the Movement of Essential Goods" was issued by the APEC ministers responsible for trade.

In addition to commitments to keep markets open, these statements include proposals for action on access to medicines and foods and to <u>facilitate</u> the flow of good services and people. They also highlight the importance of <u>MSMEs</u> in the time of COVID-19. Sixty-five WTO members also made statements at the <u>15 May 2020 General Council meeting</u> dedicated to information-sharing and the exchange of views on COVID-19 trade-related measures.

² A compilation of statements and proposals can be found on the <u>WTO website</u>.

3. TRANSPARENCY ABOUT TRADE MEASURES

A key building block of the commitment to keeping markets open is transparency. In addition to the transparency disciplines found throughout the WTO Agreements, the Trade Policy Review Mechanism provides for enhanced multilateral transparency through the consideration of trade monitoring reports submitted by the Director-General. On 29 June 2020, the WTO published a monitoring report covering the G20 member countries. It found that pandemic-related measures to facilitate trade were starting to outpace trade-restrictive measures. As of mid-May 2020, 70 per cent of all COVID-19-related measures were trade-facilitating. On 24 July 2020, the WTO released a monitoring report covering all members. Box 1 below highlights that the same trade-facilitating trend is evident more generally.

Box 1: Trade-facilitating measures on the rise

Overall, WTO members and observers implemented 363 new trade and trade-related measures during the period mid-October 2019 to mid-May 2020, of which 198 were of a trade-facilitating nature and 165 were trade-restrictive. Seventy per cent of these measures (256 in total) were linked to the COVID-19 pandemic. Of these 256 measures, 147 facilitated trade and 109 restricted trade. In the early stages of the pandemic, several of the measures introduced by WTO members and observers restricted the free flow of trade, principally for exports. But, as of mid-May 2020, 57 per cent of all COVID-19-related measures were trade-facilitating. Around 28 per cent of the COVID-19-specific trade restrictions implemented by WTO members and observers had been repealed by mid-May.

Source: Director-General's Report to the Trade Policy Review Body on Trade-Related Developments, mid-October 2019 to mid-May 2020.

4. DUTIES, TAXES AND CHARGES ON COVID-19-CRITICAL MEDICAL GOODS AND OTHER ESSENTIAL SUPPLIES WERE ELIMINATED OR DEFERRED

Tariff reductions or elimination made up around two-thirds of the import trade facilitating measures reported to the Trade Policy Review Body. The remainder included policies such as the simplification of customs procedures (20 per cent) and a reduction of/exemption from other import duties and charges (11 per cent). Certain members and observers (mainly net importers) reduced their tariffs on a variety of goods such as PPE, sanitizers, disinfectants, medical equipment and medicines/drugs. In many cases, tariff reductions were also accompanied by exemptions from value-added tax (VAT), other internal taxes, and other fees and charges.

Moves to temporarily eliminate import tariffs were assisted by the publication in March 2020 of guidance on the customs classification of COVID-19 critical medical supplies by the World Customs Organization (WCO) and the WHO, which was updated on 9 April 2020. This helped governments to identify the goods on which they could eliminate or defer the payment of duties, taxes and charges, and that may require expedited customs procedures.

The WTO's <u>trade monitoring</u> activities highlighted that twelve G2O economies reduced or deferred applied tariffs on a variety of critical COVID-19-related medical goods such as PPE, sanitizers, disinfectants, medical equipment and medicines/drugs.³ In 2019, the simple average of tariffs applied by these twelve countries ranged from 3.2 per cent on medicines to 8.25 per cent for personal protective equipment (PPE). Among the tariffs reduced by these temporary measures was a 16.6 per cent duty on PPE. Six G20 members apply 0 per cent import duties on medicines.

The WTO <u>trade monitoring report</u> published on 10 July 2020 suggests that an additional 28 non-G20 members also took action to eliminate or reduce tariffs and/or VAT across a wide range of products deemed to be essential to combat the COVID-19 pandemic, including pharmaceutical products and medical equipment.⁴ Across the WTO membership as a whole, applied tariff rates average from 2.1

³ Argentina, Australia, Canada, European Union, India, Indonesia, Republic of Korea, Russian Federation, Kingdom of Saudi Arabia, Turkey, United Kingdom and United States.

⁴ Bangladesh, Bolivia, Cameroon, Chad, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Ecuador, El Salvador, Fiji, Lao People's Democratic Republic, Malaysia, Maldives, Mauritius, Nigeria, Norway, Pakistan, Paraguay, Peru, Philippines, Qatar, Saint Kitts and Nevis, Chinese Taipei, Serbia, Ukraine, Uruguay, Viet Nam and Zimbabwe.

per cent on medicines to 11.5 per cent for PPE – with tariff peaks on some products, such as PPE, reaching as high as 27 per cent and 65 per cent on hand soap. A separate <u>information note</u> on trade in medical goods in the context of COVID-19 provides further details.

Five of the members taking import-facilitating measures are least-developed countries, including <u>Bangladesh</u>, which temporarily eliminated most-favoured-nation customs duties, VAT and other taxes applied to the imports of PPE, isopropyl alcohol, disinfectants and COVID-19 test kits.

Most measures were implemented on a temporary basis. At the 15 May 2020 WTO General Council meeting dedicated to information-sharing and exchanges of views on COVID-19 trade-related measures, some members indicated that they were cautious of making permanent any temporary measures they had taken to respond to the pandemic.

Two exceptions are <u>New Zealand</u> and <u>Singapore</u>, which agreed to eliminate tariffs on protective equipment and other products as part of an initiative to ensure supply chain connectivity and remove blockages to trade for a list of essential products including medicines and medical and surgical equipment.

Such actions have not been limited to critical COVID-19-related medical goods. The temporary reduction or elimination of import tariffs could be extended to other or to all essential products, including food products. In the case of India, for example, tariff relief extended not only to medical products, but also to the inputs needed to manufacture these items: India temporarily eliminated import tariffs on artificial respiration or other therapeutic respiration apparatus, PPE, COVID-19 testing kits and inputs for the manufacture of these items subject to certain conditions. In the case of Colombia, tariff relief also encompassed the transport equipment needed to deliver medical supplies and required for sanitation. Colombia not only temporarily eliminated tariffs on the importation of certain medical devices and pharmaceuticals, but also exempted devices for water sanitation and inputs for the aviation sector from tariffs.

In some cases, measures taken were directed at specific groups or made conditional on a particular defined final usage. For example, <u>Canada</u> waived tariffs and sales taxes on goods imported by or on behalf of public health agencies, hospitals and testing sites and first response organizations (e.g. police, fire and local civil defence groups, including medical response teams). Canada <u>also</u> waived tariffs and sales taxes on goods imported by or on behalf of public or private care residences, such as seniors' residences, retirement homes, nursing homes and shelters.

The European Union also exempted from VAT and removed import duties from imported goods needed to combat the effects of the COVID-19 outbreak if these goods were intended for one of the following uses: (i) to be distributed free of charge by bodies and organizations to persons affected by or at particular risk from COVID-19 or involved in combatting the COVID-19 outbreak; (ii) to be made available free of charge to persons affected by or at particular risk from COVID-19 or involved in combatting the COVID-19 outbreak, while remaining the property of the bodies and organizations; and (iii) to be imported for free circulation by or on behalf of state organizations, including state bodies, public bodies and other bodies governed by public law or by or on behalf of organizations approved by the competent authorities in the member states.

In some cases, tariff reductions were also accompanied by cuts in VAT (e.g. measures taken by Argentina, Canada, the European Union, Indonesia, the Russian Federation and the United Kingdom). For example, the <u>Dominican Republic</u> temporarily exempted from VAT imports of ethyl alcohol, and eliminated tariffs on PPE. It <u>also</u> temporarily eliminated import tariffs, VAT and other duties and charges on the importation of certain medical equipment, thermometers and hydrogen peroxide.

In other cases, the payment of tariffs was deferred (e.g. <u>Costa Rica</u>, Saudi Arabia, United States). The United States deferred for 90 days the time to deposit certain estimated duties, taxes, and fees during the national emergency caused by the COVID-19 outbreak. On 4 May 2020, the US International Trade Commission published an <u>investigation</u> into imported goods related to the response to the COVID-19 pandemic.

Two G20 members (Argentina, Brazil) also suspended anti-dumping duties on the importation of <u>syringes</u>, <u>parenteral solutions</u> and <u>tubes for blood collection</u>. Argentina also temporarily exempted certain imports from its statistical fee. India also exempted from the "health cess" (a tax earmarked for a particular purpose) imports of certain medical and surgical instruments and apparatus.

5. BORDER CLEARANCE FOR CRITICAL GOODS HAS BEEN EXPEDITED BY CUTTING RED TAPE

The WTO's trade monitoring work further highlights measures taken to cut <u>red tape</u> at borders to expedite the importation of essential products. Early in the pandemic response, the WTO's Trade Facilitation Assistance Facility conducted a <u>survey</u> that found that improvements in access to trade-related information were the main area in which border measures had become less cumbersome or time-consuming in the context of COVID-19 containment efforts. The survey was published on 6 May 2020 based on replies from 199 respondents.

Transit was another area where the TFAF Survey registered some improvements. Many goods pass through the ports, airport or territory of other legal jurisdictions before reaching their final destinations. Ensuring that goods can transit without unnecessary costs or delays is a basic and essential condition for the smooth circulation of COVID-19-critical medical goods and related humanitarian assistance consignments, particularly for <u>landlocked countries</u>.

Monitoring of trade measures taken by WTO members identifies eight other areas in which measures were taken to speed up or simplify the clearance of goods in response to the COVID-19 pandemic. These measures include:

- Prioritization of customs clearance for COVID-19 goods. Japan simplified import and export
 declaration forms for relief goods and granted more time to complete customs procedures,
 including those for payment of customs duties. <u>Chile</u> established procedures by which
 essential goods could be imported on a preferential basis and with priority over the arrival
 of any other cargo; special treatment was also provided to goods destined for the public
 health network.
- Establishing special procedures to further expedite consignments of medical equipment/pharmaceuticals to authorized operators. Brazil temporarily relaxed administrative procedures on imports of certain used medical machinery and equipment and parts thereof. China implemented nine facilitation measures regarding three categories of agricultural administrative approval (licence renewal, simplification of approval procedures and optimization of approval process). The Dominican Republic took measures aimed at simplifying customs procedures to assist traders, including the elimination of surcharges for late declaration, not including the days under lockdown within the period of time after which goods are declared to have been abandoned. It also extended business hours in the customs posts of Caucedo, Haina and Santo Domingo. Chile established a series of instructions for imports declared by its health authority to be inputs that are critical to the response to the COVID-19 emergency, as well as for donated goods in a state of emergency. Singapore committed to expedite the movement of essential goods through sea and airports.
- Temporary suspension or simplification of import licensing procedures (e.g. permits, authorizations, technical visas, etc.). Examples include the elimination by Argentina and Brazil of non-automatic import licensing for medical equipment and PPE, while Indonesia temporarily eliminated import certification requirements on imports of PPE. Myanmar temporarily eliminated import licence fees on medicines and raw materials used in medicines. Singapore temporarily relaxed certain import licensing requirements by the Health Science Authority of Singapore (HSA) for the importation of hand sanitizers, facemasks, thermometers and protective gear; instead, importers only needed to notify the HSA of their intention to import and to provide information on the brand and quantity of the devices to be imported.
- Accepting the electronic submission of documents for pre-arrival processing. China
 encouraged enterprises to apply for import and export licences in a paperless way and
 simplified the materials required for the paperless application for import and export licences.
- Temporary suspension or simplification of origin requirements. Argentina temporarily authorized the submission of origin certificates in electronic format and eliminated the requirement of a paper copy. As part of the Eurasian Economic Community, the Russian Federation took measures to temporarily simplify country-of-origin confirmation procedures applied to goods imported from developing and least-developed economies. This included the possibility of providing electronic or paper copies of origin certificates.

- Simplification of import and export forms. Japan simplified import and export declaration
 forms for relief goods relating to countermeasures to COVID-19. <u>Chile</u> issued guidelines on
 the non-requirement of certain documents in order to facilitate imports and exports, and the
 non-imposition of fines for modifications to customs documents. The <u>Dominican Republic</u>
 promoted the use of electronic procedures, including those relating to payments and
 submission of certain forms, and instructed its institutions to accept copies of plant and
 animal health certificates.
- Implementation of green lanes under the guidelines for border management measures to protect health and ensure the availability of goods and essential services. In order to preserve the EU-wide operation of supply chains and ensure the functioning of the Single Market for goods, wherever internal border controls exist or have been introduced, the European Union requested member states to designate relevant internal border-crossing points in the trans-European transport network, and additional ones, as "green lane" border crossings. The Commission also issued guidance on customs issues concerning the application of customs provisions relating to decision-making processes, procedures and formalities.
- Establishing special and priority health controls for crews operating <u>land</u>, <u>air</u> and <u>maritime</u> transportation, including shipments in transit. The European Commission's Guidelines on Facilitating Air Cargo Operations during the COVID-19 outbreak are a case in point.

Various international groupings and organizations have put forward suggestions for how COVID-critical goods could be moved more quickly across borders. The APEC <u>Declaration</u> on Facilitating the Movement of Essential Goods declares that each APEC economy, consistent with its obligations under the WTO <u>Agreement on Trade Facilitation</u> (TFA), should expedite and facilitate the flow and transit of essential goods. Actions can be taken to smooth the flow of essential goods in transit, including:

- waiving/reducing fees and charges in respect of transit during the COVID-19 crisis;
- establishing simplified transit procedures, reducing documentation requirements, opening priority lanes, expediting procedures to check the health conditions of drivers, expediting disinfection procedures, reducing/eliminating guarantees, etc.

The <u>WCO</u> website provides useful information on simplified customs procedures, notably in relation to the entry of humanitarian assistance, as well as the list of <u>temporary import support measures</u> on certain categories of critical medical supplies in response to COVID-19. The Trade Facilitation Assistance Facility has also compiled a <u>COVID-19 trade facilitation repository</u> where further guidance from international organizations and other stakeholders can be found.

One recommendation of the G20's Trade and Investment Working Group meeting on 14 May 2020 was that accelerating, to the extent possible, implementation of the WTO TFA – a process many developing and least-developed countries were engaged in when the pandemic hit – would expedite access to critical COVID-19 medical supplies.

The G20 <u>Statement</u> identified several provisions of the TFA as especially critical during the pandemic, such as Article 7.1 (Pre-arrival processing), Article 7.3 (Separation of release from final determination of customs duties, taxes, fees and charges), and Article 7.8 (Expedited shipment). It also recommended speeding up and streamlining customs procedures, in line with the TFA, and encouraged the use of electronic documentation and processes, where possible and practical, including the use of smart applications.

Further trade facilitation measures that could be considered by governments include:

- ensuring that national enquiry points and national trade facilitation committees established pursuant to the <u>TFA</u> are familiar with COVID-19 measures;
- if importers of certain products require authorization, expanding the list of authorized importers;
- in case of a *reasonable* doubt on the declared value of the goods, releasing goods without requiring a guarantee or bond;

- strengthening pre-arrival procedures to allow for the submission of customs documentation at any moment with the goal of clearing the declaration, so that the goods can be immediately released upon arrival;
- providing for post-release verification and audits to control for compliance with the tariff classification, valuation, origin, etc.;
- prioritizing inspection and testing of COVID-19 critical medical goods while keeping the number of such procedures to the minimum needed;
- reducing or eliminating penalties for *bona fide* mistakes concerning importation of the products in the national list;
- reducing and/or eliminating procedures that require the physical presence of operators or the submission of physical documents and, where feasible, allowing for self-certification of some commercial or official documents;
- for countries sharing a common border, cooperating on additional working hours and working time could further facilitate the smooth flow of COVID-19-critical medical goods and related humanitarian assistance consignments. Various obligations are set out in <u>Article V</u> of the General Agreement on Tariffs and Trade and <u>Article 11</u> of the TFA in this regard.

6. STEPS TO ENHANCE REGULATORY COOPERATION ON STANDARDS FOR TRADED GOODS

By late May 2020, about two-thirds of the 152 formal notifications and communications on COVID-19 trade-related measures received from WTO members and observers, including from G20 economies, were related to sanitary and phytosanitary (SPS) and technical barriers to trade (TBT) measures.⁵ Many of these measures aimed to streamline certification procedures and move towards more electronic/digital procedures, including electronic certification, to facilitate access to PPE and other medical equipment.

A series of unilateral or autonomous actions were taken, such as temporary measures to streamline or reduce conformity checks without compromising the protection of health and safety. For example, Thailand announced temporary facilitated registration approval for PPE, medical devices and pharmaceuticals (WTO official documents numbers <u>G/TBT/N/THA/569</u> and <u>G/TBT/N/THA/570</u>), and Switzerland exempted PPE from conformity checks and market authorization requirements (WTO official document number <u>G/TBT/N/CHE/245</u>).

Another action that has been taken to speed up trade is to ease requirements for products to be tested in a designated laboratory/body in the importing country and, instead, to accept test results from internationally accredited laboratories. Accepting assessments by trusted regulators in other countries can save time without diminishing health protection (see, for example, pages 60-61 of the TBT Committee's indicative list of approaches to facilitate acceptance of conformity assessment).

Using information technology (IT) tools for remote conformity assessment is also a practice that has grown during the pandemic. This practice aims to avoid certification delays when inspectors cannot travel to medical goods factories abroad or domestically due to COVID-19-related mobility restrictions. An example is Brazil, which notified to the TBT Committee certain temporary and emergency changes to its conformity assessment procedures to allow for remote inspection (through videoconferencing and data transmission) and verification through documentary analysis, including for good manufacturing practices of pharmaceutical and medical devices (e.g. WTO official documents numbers G/TBT/N/BRA/984 and G/TBT/N/BRA/978). A similar trend exists for SPS measures. A number of WTO members are moving towards electronic processes for SPS certification, including by accepting copies or scanned documents instead of requiring originals, by implementing electronic signatures, or by setting up dedicated websites for the verification of documents.

A further regulatory option some members have adopted is to provide temporary flexibilities with regard to compliance with technical regulations for essential medical goods. In practice, this means temporarily suspending requirements to comply with certain secondary elements of the measure (for instance, rules prescribing the format of labelling), when this does not undermine the core

⁵ See WTO (2020), "Standards, Regulations and COVID-19 - What actions taken by WTO members?".

health and safety protection objectives of the measure. For example, <u>Ukraine</u> has established an exceptional and temporary procedure for processing applications and issuing notices for placing on the market COVID-19-related PPE and medical devices that otherwise would not comply with its technical regulations. <u>Canada</u> is temporarily allowing certain hand sanitizers, disinfectants and PPE to be sold that do not fully meet its labelling or packaging requirements.

Enhancing <u>regulatory cooperation</u> on standards for COVID-19-critical medical goods is a further action considered by governments. Mutual recognition of conformity assessment by regulatory authorities helps to facilitate and accelerate trade in essential medical goods and devices. For instance, some consider that the <u>International Medical Devices Regulators Forum</u> and its <u>Medical Device Single Audit Program</u> could help promote more efficient use of regulator resources for faster approval of innovative devices (see the related <u>discussion</u> at the TBT Committee and the <u>summary</u>).

Other actions taken include using unilateral recognition to expedite granting marketing approval of, and access to, essential medication, such as an eventual COVID-19 vaccine. A regulatory authority could do this, for example, by authorizing the importation and use of a vaccine from trusted suppliers in jurisdictions where the vaccine has already been given regulatory approval. This could speed up the importation and use of essential medications by dispensing with the need for regulatory approval by the national authority of the importing country. One example of this is Canada's "Regulations Amending the Food and Drug Regulations" (notified to the TBT Committee in 2017), which create a new process for allowing the importation and use of medications that have been authorized for sale in the European Union, Switzerland or the United States, but are not yet authorized in Canada. While originally devised for addressing a specific health urgency, Canada's notification indicates that this scheme could also be used "for other urgent public health needs (e.g., pandemics)".

Another way in which some countries have supported economic operators is by providing free or reduced cost access to otherwise paid standards relevant to producing medical goods essential for treating COVID-19. This may help to alleviate a cost barrier to accessing information for compliance, in turn supporting the production and supply of safe and effective medical goods, especially for converted production lines.

Finally, international standards, where they exist or are appropriate, should be used as the basis for domestic standards and regulations, as this helps ease access to essential goods by increasing potential sources of supply.⁷

7. USING INTELLECTUAL PROPERTY RIGHTS AND POLICY TOOLS TO FACILITATE INNOVATION IN AND ACCESS TO COVID-19-RELATED TECHNOLOGIES

Efforts to deal with COVID-19 require access to a wide range of inputs and medical products, ranging from protective equipment to vaccines and treatments that are currently being developed. IP rights – notably patents, know-how and clinical trial data – are a significant factor in facilitating access to existing technologies, and in supporting the creation and dissemination of new technologies.⁸

Research institutions, private firms, non-governmental organizations and governments have applied the IP system in diverse ways to support the development, manufacturing and distribution of such products.

By end-July 2020, WTO trade monitoring activities had recorded some 47 COVID-19-related measures regarding trade-related IP rights taken by 24 members. A number of these measures were aimed at facilitating innovation or access with respect to COVID-19-related health technologies, while others eased certain procedural requirements or deadlines for administrative matters. Some aimed to use flexibilities within the WTO Agreement on Trade-Related Aspects of Intellectual

⁶ See OECD (2020), "No policy maker is an island: the international regulatory co-operation response to the COVID-19 crisis".

⁷ The TBT Agreement contain obligations strongly encouraging WTO members to use international standards as a basis of their standards and regulations. Although the TBT Agreement does not define or contain a list of "relevant international standards", in 2000 the TBT Committee agreed on the following six principles for the development of international standards: (i) transparency; (ii) openness; (iii) impartiality and consensus; (iv) effectiveness and relevance; (v) coherence; and (vi) the development dimension (WTO official document number <u>G/TBT/1/Rev.14</u>, pages 62-64).

⁸ For further information, see the second edition of the joint WHO, WIPO and WTO study "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", section on "An integrated health, trade and IP approach to respond to the COVID-19 pandemic".

Property Rights (TRIPS Agreement) that provide wide latitude for governments to take action to protect public health, covering policies such as compulsory licensing (including for export to countries that lack sufficient pharmaceutical manufacturing capacity) and government use, as well as exceptions to patent rights for research and experimental use, and for obtaining early regulatory approval.

Actions surveyed by WTO trade monitoring reports or compiled by the WTO Secretariat regarding the transparency of IP rights information have included:

- Publishing patent landscape reports, patent analysis and trend reports or reports on technologies in the public domain with respect to COVID-19-related technologies (for example by <u>Argentina</u>, <u>Brazil</u>, <u>Chile</u>, <u>Colombia</u>, <u>Ecuador</u> and <u>Republic of Korea</u>);
- Launching databases specific to COVID-19 patent information, e.g. in China.
- Tailoring database search facilities on COVID-19-related patents, e.g. in Chinese Taipei.
- Releasing the drug approval status and patent information for 52 potential medications for combatting COVID-19, e.g. in <u>Chinese Taipei</u>.

Actions surveyed by WTO trade monitoring reports or compiled by the WTO Secretariat include instances of government decisions in support of voluntary collaboration:

- Publishing lists of patents and published applications relating to COVID-19 available for licensing, e.g. in the <u>United States</u>.
- Making freely available copyright-protected standards with respect to certain health technologies, e.g. in the <u>European Union</u> and <u>Singapore</u>.
- Making copyright-protected software related to a contact-tracing solution for COVID-19 freely available under an open source licence, e.g. in <u>Singapore</u>.

Actions surveyed by WTO monitoring reports or compiled by the WTO Secretariat include measures taken by IP offices such as:

- Expedited patent examination procedures for applications related to technology to prevent or treat COVID-19 (Brazil, United States) and fast-track trademark examination procedures for marks used to identify qualifying medical products and services related to COVID-19, e.g. in the <u>United States</u>.
- Guidance or support for IP offices or trademark registration applications, e.g. in <u>Australia</u>, <u>China</u> and <u>Chinese Taipei</u>.
- IP office measures to ease procedural requirements, deadline or fees, e.g. in Australia, China, European Union, India, Italy, Philippines, the Kingdom of Saudi Arabia, Singapore, Switzerland, Chinese Taipei, Thailand, United Kingdom and the United States).
- E-signature (<u>Thailand</u>) or acceptance of plant patent applications through electronic filing systems (<u>United States</u>).

Also noteworthy are voluntary actions taken by private actors, such as pledges of free global licences to use COVID-19-related IPRs (e.g. the Open COVID Pledge); licences to allow open access to design files and software for ventilators (e.g. Medtronic and the Ventilator Training Alliance); technology pooling initiatives, including through the Medicines Patent Pool; non-enforcement or waivers of patent rights; sharing of IP to develop vaccines; free access to COVID-19-related publications protected by copyright; and initiatives to transfer technology and know-how to make, adapt or use COVID-19-related technologies.

In addition, a number of intergovernmental organizations have taken measures, including in collaboration with member governments. For example, in response to an initiative of Costa Rica, on 29 May 2020 the WHO launched the <u>Solidarity Call to Action</u> and the <u>COVID-19 Technology Access Pool</u>. The Solidarity Call to Action has been endorsed by nearly 40 WHO member states and other

stakeholders. It calls upon governments and other key stakeholders to pool knowledge, IP and data relevant for the development of medicines, vaccines and diagnostics to combat COVID-19.

The World Intellectual Property Organization (WIPO) has undertaken initiatives to enhance support for COVID-19-related innovation efforts by launching a new search facility for its PATENTSCOPE database. The WIPO COVID-19 IP Policy Tracker is tracking information on measures adopted by IP offices in response to the COVID-19 pandemic, such as the extension of deadlines for time limits and fee relief. In addition, the policy tracker provides information on legislative and regulatory measures for access and voluntary actions.

Actions surveyed by WTO monitoring reports, or compiled by the WTO Secretariat with respect to compulsory licensing or government use, include:

- The granting of compulsory or government use licences under Article 31 of the TRIPS
 Agreement to allow the manufacturing or import of patent-protected health technologies
 such as medicines, vaccines and diagnostics needed to combat COVID-19. For example,
 <u>Israel</u> granted a government use licence on 20 March 2020 to import generic
 lopinavir/ritonavir from India.
- The definition of the grounds for compulsory and government use licences. National practice has varied in this area; some members have used these mechanisms in the context of enabling access to necessary health technologies.
- The easing of procedures to grant compulsory or government-use licences. For example, Canada's Act respecting certain measures in response to COVID-19 (Bill C-13 of 24 March), notified to the TRIPS Council on 23 April, empowers the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or a specified person to supply a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern.
- <u>Colombia</u> granted powers to its Ministry of Health and Social Protection on public health interest grounds to make more flexible the procedures and requirements for licensing the production, importation, granting, and sale of vaccines, medicines, and other health technologies used for the diagnosis, prevention, and treatment of COVID-19.
- An amendment to <u>Germany's</u> Act on the Prevention and Control of Infectious Diseases in Humans grants its parliament the competence to determine the existence of an "epidemic situation of national significance". On grounds of public interest or national security, the Federal Ministry for Health is 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 PPE.
- A <u>Hungarian</u> government decree created a compulsory public health licence for the
 exploitation of a medicinal product or active substance protected by patents or
 supplementary protection certificates, as well as medical devices, investigational medicinal
 products and any related processes, equipment or tools within Hungary. The special legal
 order ("State of Danger") was terminated on 18 June 2020.

8. MEASURES TO IMPROVE ACCESS TO COVID-19-CRITICAL MEDICAL SERVICES

Members have also reviewed regulations and cooperated in the area of <u>trade in services</u> so as to facilitate access to COVID-19-relevant medical services. Two areas of particular relevance here are the facilitation of the international movement of health workers and the facilitation of telemedicine.

Several examples of the <u>international mobility of health workers</u> have occurred to alleviate the pressure on national health systems. Given the urgency to cover shortages of health workers, an effort at the national level to ease the movement of health workers can facilitate the supply of such services on short notice (e.g. special visas/permits or the recognition of qualifications). Transparency through dedicated web portals and concerted international efforts also increase efficiency.

Examples of measures registered by WTO trade monitoring activities include:

- In Malta, live-in carers and healthcare professionals whose permits were soon to expire in March 2020 were allowed to seek three-month extensions of their permits.
- In the <u>United Kingdom</u>, visas for doctors, nurses and paramedical personnel that are due to expire before 1 October 2020 are to be automatically extended for one year, free of charge. This also extends to the family members of these personnel.

With COVID-19 putting pressure on health systems, and social distancing measures making inperson consultations on medical issues challenging, there has been an increase in the use of ehealth and, in particular, <u>telemedicine</u>. The use of telemedicine has been increasing in recent years, but suppliers are currently facing regulatory challenges, in particular when it comes to international telemedicine.

Some governments are reviewing laws and regulations to facilitate these types of services on a provisional basis. Examples of measures confirmed in WTO trade monitoring include the following:

- <u>Brazil</u> permitted, on an exceptional and temporary basis, the use of telemedicine for medical services, including medical consultation and digital medicine prescription.
- <u>France</u> approved new measures providing that all persons affected by COVID-19 can benefit from telemedicine services, even if there is no prior relation between the healthcare provider and the patient.
- <u>India's</u> Department of Telecommunications relaxed the guidelines for "Other Service Providers", i.e. companies providing "Applications Services" like tele-banking, telemedicine, tele-education, tele-trading, e-commerce, call centres, network operation centres and other IT-enabled services.
- <u>South Africa's</u> Health Professions Council issued a guidance note on the application of telemedicine during the COVID-19 pandemic, and which facilitates the use of video or phone calls by doctors and therapists to treat patients. Previously, such services were essentially for cases where there was already an established practitioner-patient relationship.
- The <u>United States</u> Federal Communications Commission (FCC) voted to adopt a US\$ 200 million telehealth programme to support healthcare providers responding to the COVID-19 pandemic. The programme aims to help healthcare providers purchase telecommunications, broadband connectivity and devices necessary for providing telehealth services. The FCC also launched a <u>Connected Care Pilot Program</u>. This three-year pilot programme will provide up to US\$ 100 million worth of support from the Universal Service Fund (USF) to help defray health care providers' costs of providing connected care services and to help assess how the USF can be used in the long term to support telehealth.

Telemedicine services are often limited geographically (e.g. the health professional providing the service must be located in the jurisdiction of the patient), but the platforms used may be located elsewhere. Easing "territorial" restrictions on telemedicine, with appropriate regulatory oversight, even on a provisional basis, could help relieve pressure on health systems by allowing some basic services to be provided across borders (e.g. simple functions, radiology diagnosis and second opinions).

Cross-border e-health solutions could also be used to share knowledge and experiences in detecting, monitoring and responding to COVID-19. Governments can also respond to and facilitate the supply of telemedicine services or other remote supplies of health services by taking measures in the telecommunication sector.

• For example, to ensure that effective health-related information can be transmitted to and from rural areas, <u>Kenya</u> fast-tracked the issuance of an operating licence to a company to extend the availability of WiFi to remote locations.

9. ACTIONS TO EXPEDITE GOVERNMENT PROCUREMENT PROCEDURES

Public spending represents a significant share of global spending in the public health sector. The <u>WTO Government Procurement Agreement</u> (GPA), which covers 48 WTO members, is relevant to the public health care sector, including with regard to the procurement of medicines, pharmaceutical

products and health services. The GPA sets binding minimum standards for transparent, fair and open public procurement procedures based on international best practices. The GPA also recognizes that, in times of unforeseeable extreme urgency, it may not be possible to adhere to all such standards.

The GPA notably provides two types of flexibilities to address emergency situations. First, it offers flexibilities on procedural requirements. Parties to the GPA may resort to limited tendering, under which procuring entities may directly contact suppliers of their choice without giving notice of intended procurements and while setting shorter-than-usual deadlines (Article XIII:1(d)). Second, parties to the GPA may even depart from their usual obligations under the GPA and take any government procurement-related measures that are necessary to protect human life or health (Article III:2(b)). Such flexibilities enable procuring entities to enhance the efficiency of the government procurement process and speed up the conduct of government procurement procedures.

Some parties to the GPA have put in place new rules for emergency government procurement activities or have issued guidance to their procuring entities regarding the availability under their domestic legal frameworks of existing flexibilities. The WTO Secretariat has issued a <u>compilation of information</u> provided by GPA parties and observers on their COVID-19 procurement measures. These include:

- <u>Measures</u> taken by Hong Kong, China to earmark funds for global PPE procurement, streamline procedures to settle payments to government contractors, including payment schedules with more frequent payments, and advance payment to facilitate cash flow.
- Guidance issued by the Swiss Federal Procurement Conference to public buyers to illustrate the flexibilities provided by existing procurement legislation in times of urgency regarding ongoing contracts, public procurement procedures, and planned and ongoing procurements.
- <u>Exemptions</u> from the Public Procurement Law of Ukraine aimed at preventing the spread of COVID-19 and the establishment of specific, simplified procurement procedures for a list of supplies, works and services necessary for COVID-19 control.
- The Philippines informed GPA members about expedited procurement procedures that include conditions for the acceptance of expired permits and an increase in the threshold for advance payments.
- The United Kingdom also issued guidance for public authorities on procurement regulations and supplier payment in responding to COVID-19 so as to ensure service continuity.

The GPA encourages parties to use electronic means for government procurement. E-procurement saves time, lowers costs and enhances transparency in emergency situations. Brazil, a GPA observer, Brazil, has notified measures to allow public agencies to purchase items such as facemasks, alcohol gels and digital thermometers through a "virtual warehouse" and to use electronic signatures. Brazil has also updated procurement information on an internet page so as to promote more agile responses. Other steps have been taken to "de-bureaucratize" and increase the negotiating power of Brazil's public administration so as to ensure the provision of services and inject capital into market sectors affected by the pandemic crisis.

The GPA recognizes that not all transparency obligations can realistically be followed in situations of extreme urgency. However, the GPA provides that, even in such situations, entities must publish, no later than 72 days after contracts have been awarded, a notice providing certain information, including a description of the goods or services procured, the name of the successful supplier and the value of the successful tender (Article XVI:2). Moreover, if limited tendering has been used, the description should also include the circumstances justifying such use. Such after-the-fact transparency helps ensure responsible management of public resources and "to conduct covered procurement in a transparent and impartial manner that [...] avoids conflicts of interest; and prevents corrupt practices" (Article IV:4 (b) and (c)).

Some parties to the GPA have used joint government procurement procedures within a regional integration framework in order to increase their bargaining power and purchasing options in the context of the restricted supply of certain COVID-19-critical medical goods and services. For example, the European Commission has launched joint procurements of PPE and medical devices

with member states relating to hand and body protection, facemasks, gloves, goggles, face-shields, surgical masks, overalls, ventilators and testing kits, which would otherwise have to be procured through separate tenders by individual member states.