WORLD TRADE ORGANIZATION

27 April 2020

Page: 1/10

Original: English

THE TREATMENT OF MEDICAL PRODUCTS IN REGIONAL TRADE AGREEMENTS

INFORMATION NOTE[1]

Key points

- The share of exports by the world's top 10 exporters of medical products to their regional trade agreement (RTA) partners ranges from between 27 per cent for China to almost 75 per cent for Italy. The majority of the top 10 traders in such products are EU member states.

- In their RTAs, WTO members had liberalized over 84 per cent of these products by 2020. The share is higher for developed members (99.5 per cent) than for developing (84.3 per cent) and least-developed members (68.4 per cent).

- Developed members surveyed had eliminated tariffs (both most-favoured-nation (MFN) tariffs – i.e. without discrimination between trading partners – and preferential tariffs) in medicines and in their RTAs for medical equipment and personal protective (PP) products (compared to an average MFN rate of 0.2 per cent and 2.4 per cent respectively). Their average preferential rate for medical supplies is 0.5 per cent compared to an average MFN rate of 1.8 per cent.

- In developing and least-developed members, average MFN and preferential rates are higher, especially for medical supplies, medicines and PP products.

- The preferential rates of G20 members are less than half of their average MFN rates in 2020, with greater liberalization in PP products and medical supplies, again suggesting there might be room for further tariff liberalization on an MFN basis.

- In addition to tariffs, there are other provisions in RTAs that may prove either trade-restrictive (such as rules of origin) or trade-facilitating (such as increased transparency and cooperation in the formulation of standards regarding medical products and/or procedures to obtain product registration certificates). Some RTAs also explicitly prohibit the use of export restrictions and taxes and import restrictions, except those permitted under WTO rules.

- The COVID-19 pandemic has also highlighted the need for greater cooperation and efforts to reduce barriers to trade, including through increased mutual recognition agreements (MRAs).

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

1 BACKGROUND

With the current supply shortages of certain medical and sanitary products caused by the COVID-19 pandemic, this information note looks at the manner in which such products are treated in RTAs and the extent to which they are traded between RTA partners.

We follow the methodology identified by the WTO Secretariat. Medical products are defined as six-digit subheadings in the Harmonized System classified under four categories: (i) medical equipment; (ii) medical supplies; (iii) medicines; and (iv) PP products, including hand sanitizers and face masks.[2]

2 RTA TRADE AND TARIFF PREFERENCES

The top 10 exporters of medical products, which account for almost 75 per cent of global exports of these products, are all parties to RTAs. Belgium, France, Germany, Ireland, Italy, the Netherlands and the United Kingdom[3] (all of which are currently party to the EU customs union) are party to 44 RTAs, Switzerland to 31, the United States to 14 and China to 15. Other than Japan, which is a party to 17 RTAs, the world's top 10 importers of these products (accounting for 65 per cent of total imports) are the same.

Charts 1 and 2 break down total trade by these members in terms of exports and imports with their RTA partners and with the rest of the world.[4] Their share of exports of medical products to their RTA partners ranges from between 27.1 per cent for China to almost 77 per cent for the Netherlands. Germany and the United States, which account together for over a quarter of exports of medical products, export 67 per cent and 28 per cent respectively to their RTA partners. The United States, however, exports up to 60 per cent of PP products to its RTA partners. The share of exports of PP products to RTA partners is higher than for the other categories for all the traders except China.

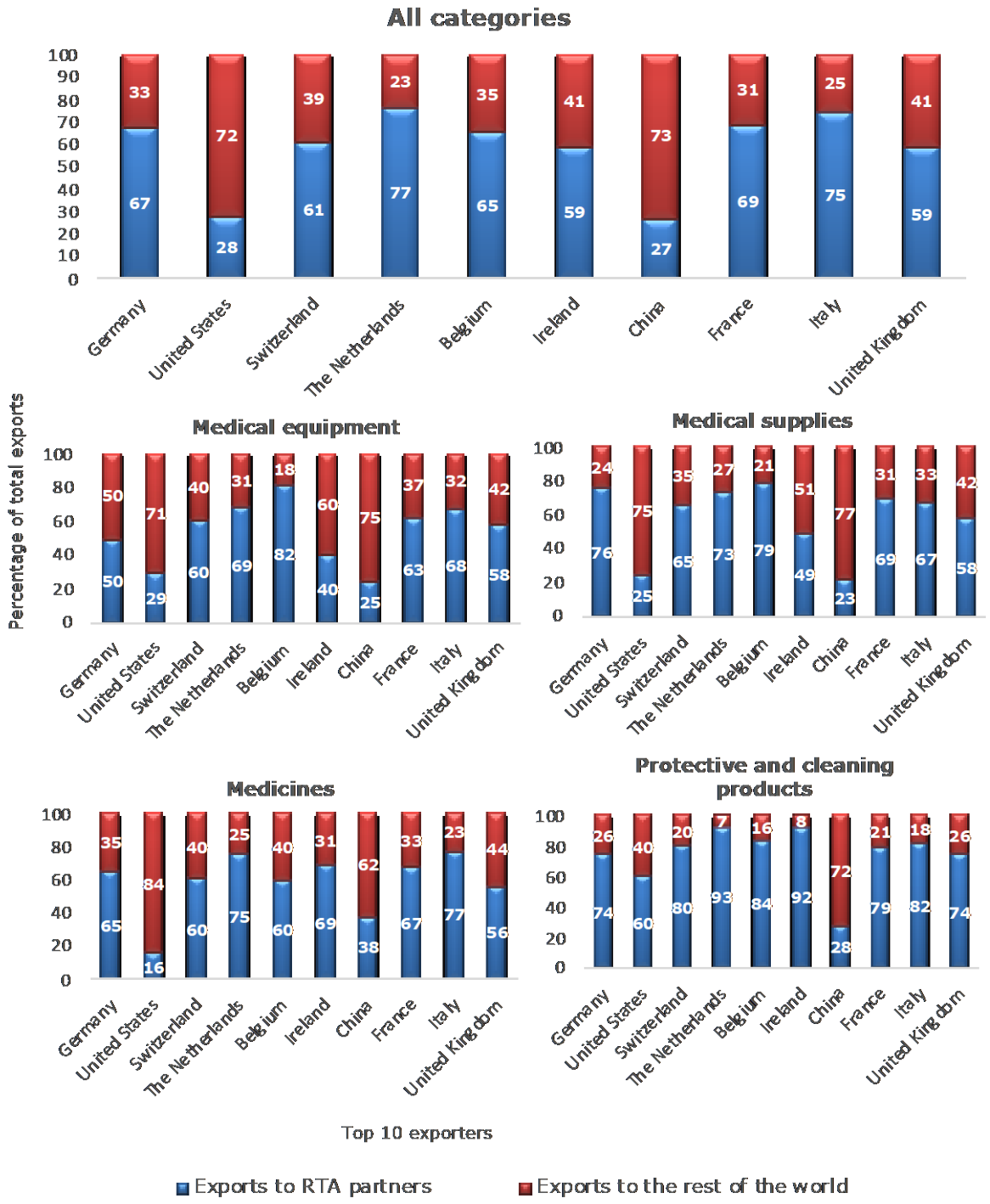
The largest importer of such products, the United States, imports 21 per cent from RTA partners, while the share for the third largest importer, China is lower at 14.3 per cent. The share is significantly higher, 85.9 per cent, for Switzerland which is the tenth-largest importer of medical products. Since the majority of the top ten traders are EU member states, it is not surprising that over half of their total trade in these products is within the European Union.

[2] This product list and categorization have been compiled by the WTO Secretariat, as contained in the Information Note "Trade in Medical Goods in the Context of Tackling COVID-19", available at https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm Calculations of MFN average tariffs include *ad valorem* equivalents for tariffs, including specific duties; for the preferential tariff, only the *ad valorem* part of the tariff has been taken into account and specific duties have been excluded.

[3] While the United Kingdom withdrew from the European Union on 1 February 2020, it remains part of the European Union's customs union for a transitional period up to 31 December 2020.

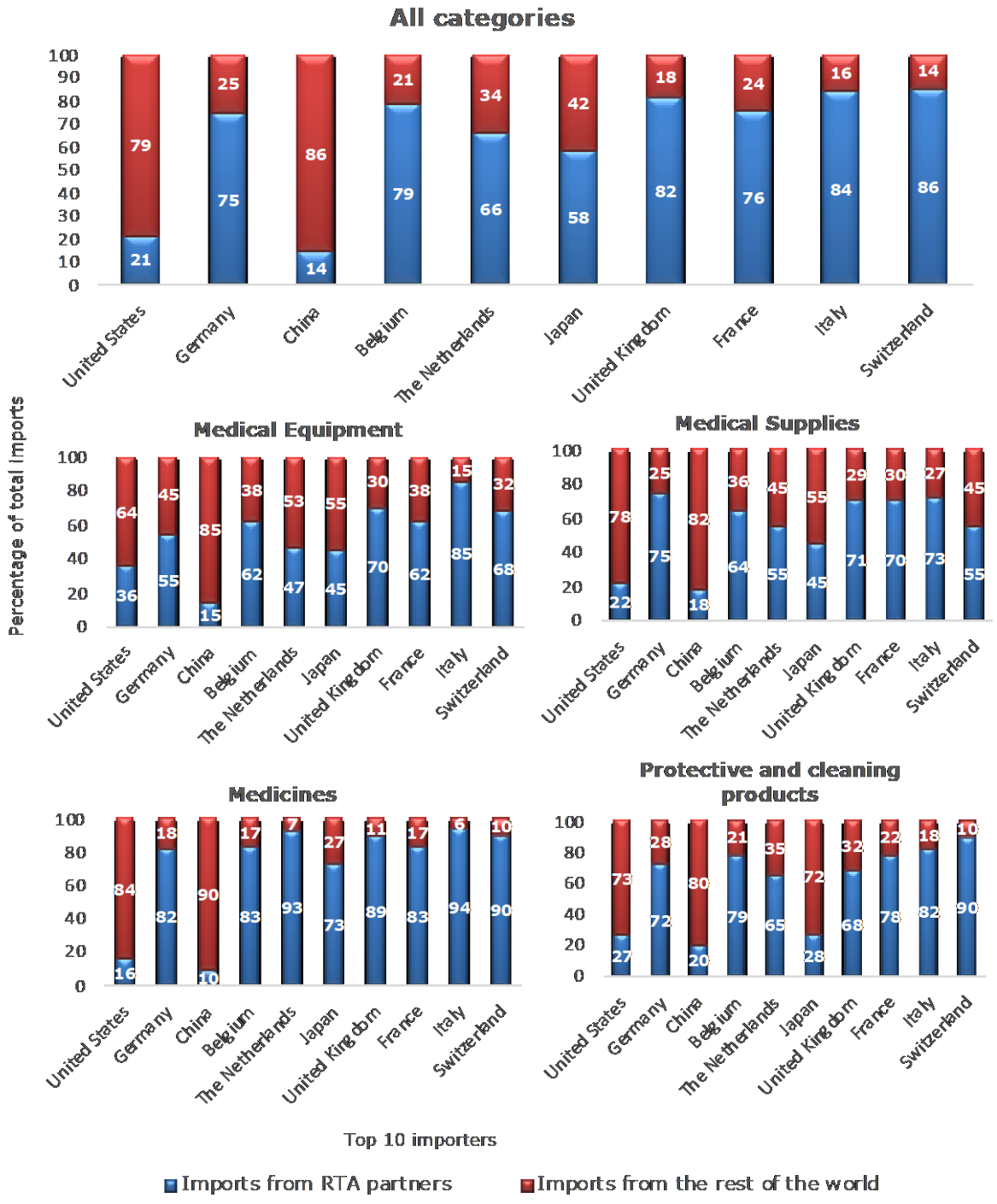
[4] Figures on trade with RTA partners are total trade. However, this does not mean that such trade was carried out under a preferential regime. For example, products may not qualify as originating and thus may not benefit from the preferential tariff, or exporters/imports may decide not to claim for preferential treatment for various reasons.

Chart 1: Top ten exporters: share of exports to RTA partners



Source: WTO Secretariat based on data from the RTA Database and UNSD Comtrade.

Chart 2: Top 10 importers: share of imports from RTA partners



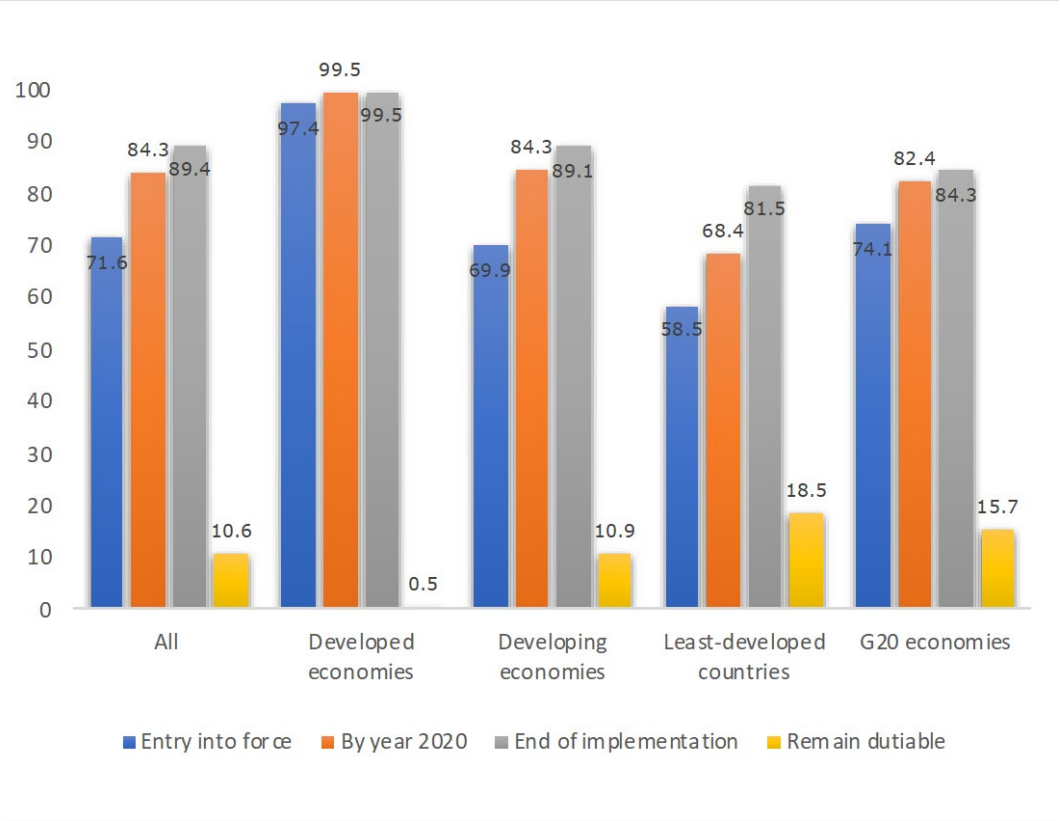
Source: WTO Secretariat based on data from the RTA Database and UNSD Comtrade.

Of the RTAs notified to the WTO, tariff commitments under 174 RTAs (involving 731 bilateral pairs of tariffs) are available and were analyzed.[5] Almost 90 per cent of tariffs on these products are to be liberalized under RTAs by the time they are fully implemented. In 2020, over 84 per cent of tariffs on these products had been liberalized. The rate of liberalization is higher for developed members

[5] The data include RTAs notified to the WTO under Article XXIV of the GATT 1994 as well as paragraph 2c of the Enabling Clause (i.e. 1979 Decision on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries), the latter for the most part covering only a small number of tariff lines. While the MFN rates reflect current applied tariffs, the preferential rates are those that the parties committed to apply in their RTAs. Thus, actual applied preferential rates may be different.

(99.5 per cent in 2020, compared to 84.3 per cent for developing and 68.4 per cent for least-developed countries (LDCs)).[6] Less than 11 per cent of tariffs will remain subject to the MFN rates of duty once all the RTAs currently in force complete the implementation of their liberalization commitments. For developed countries, only 0.5 per cent of tariff lines will remain subject to duties, but the figures are considerably higher for developing economies (almost 11 per cent) and LDCs (almost 19 per cent). The G20 countries have liberalized 82 per cent of their tariff lines in RTAs at present, and almost 16 per cent of tariffs will remain subject to the MFN rate (see Chart 3).

Chart 3: Percentage of tariff lines liberalized in RTAs



Source: WTO RTA Database.

Chart 4 below compares the average MFN and preferential rates for 94 WTO members for which both MFN and preferential rates are available. It should be noted that the average MFN rates for medical products if all WTO members are included (i.e. including those not included in the analysis because of a lack of preferential tariff data) are slightly different, at 4.8 per cent for all categories, 3.4 per cent for medical equipment, 6.2 per cent for medical supplies, 2.1 per cent for medicines, and 11.5 per cent for PP products.

Chart 4 shows that, while the overall applied MFN average is currently at 3.8 per cent for such products, the corresponding preferential average is half that, at 1.6 per cent. The overall rate conceals a range from 0.2 per cent (compared to an MFN average of 0.9 per cent) for developed WTO members to 1.7 per cent (4.3 per cent MFN average) for developing members. For LDCs, the MFN average is 3.3 per cent, compared to a preferential rate of 1.8 per cent. The overall rate (both MFN and preferential) is considerably higher for PP products and medical supplies than for the other two categories of products. For medicines, developed country average MFN and preferential tariffs are set at zero, in line with the WTO Agreement on Pharmaceutical Products. Developed countries eliminate their tariffs in RTAs in medical equipment and PP products (compared to an average MFN rate of 0.2 per cent and 2.4 per cent respectively). Their average preferential rate for medical supplies is 0.5 per cent compared to an average MFN rate of 1.8 per cent. Among developing economies and LDCs, the average MFN and preferential tariffs remain relatively higher, especially

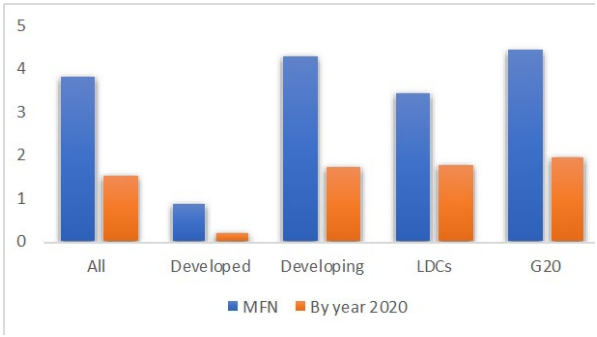
[6] There are currently 47 least-developed countries as defined by the United Nations (https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf); developing countries are as per their status in the WTO.

for medical supplies, medicines and PP products. Developing countries have liberalized their preferential tariffs to a larger extent in medical equipment than in the other categories.

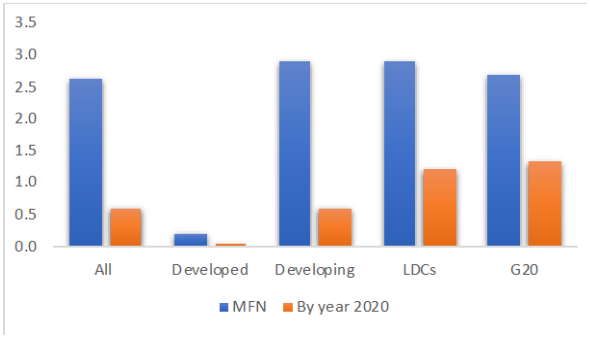
For the G20, the overall average MFN rate is 4.4 per cent, while the preferential average is less than half, at 2 per cent. MFN average tariffs are highest for PP products and medical supplies (7.6 per cent and 6.1 per cent respectively). In comparison, preferential averages are currently 2.1. per cent and 2.8 per cent respectively. For the other two product categories, medical equipment and medicines, the preferential average in 2020 is 1.3 per cent and 1.6 per cent respectively. Thus, in all four categories, G20 members have liberalized tariffs considerably in their RTAs.

Chart 4: Average MFN and preferential rates in RTAs by product groups

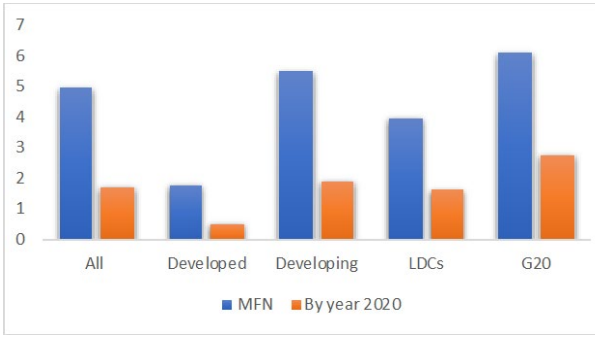
(a) All categories



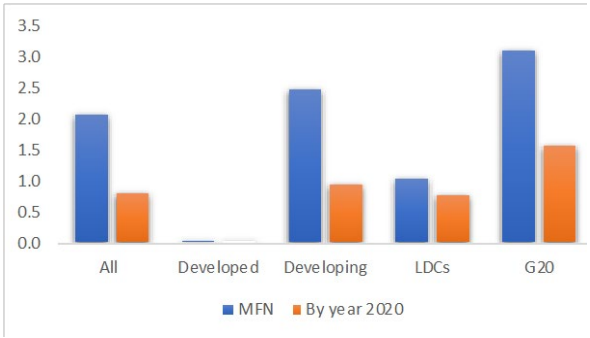
(b) Medical equipment



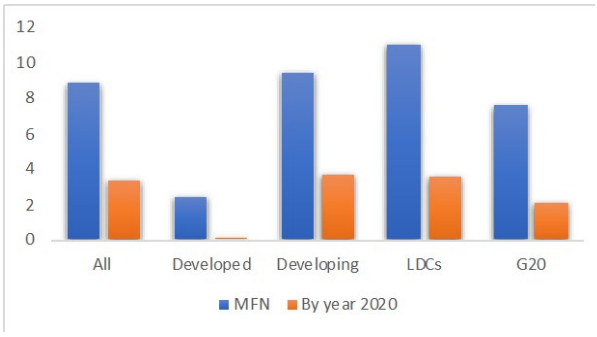
(c) Medical supplies



(d) Medicines



(e) Personal protective products



Note: No data available for the Kingdom of Saudi Arabia (which is excluded from calculations for the G20).

Source: WTO RTA Database and WTO IDB Database.

While tariffs, although reduced in RTAs, remain a barrier to imports, there are other relevant provisions in RTAs, in particular rules of origin. In the case of pharmaceuticals, it is generally recognized that alternative rules of origin facilitate compliance. At a minimum, such alternative rules would grant "originating status" on the basis of either a production process (such as a chemical

reaction rule, or a change in particle size rule), or a change in tariff classification. More generally, the combination of multiple requirements within a single rule, such as an additional regional value content requirement in addition to a change in tariff classification, or a very high regional value content, or not allowing *de minimis* content for non-originating materials, may render the actual use of RTA preferences difficult.

RTAs also have disciplines on exports, with around a third of RTAs explicitly prohibiting the parties from maintaining or placing new taxes or charges on exports except those permitted under Article XI of the GATT, while around half explicitly prohibit export restrictions.[7] Other provisions found in over 90 per cent of RTAs that have been notified to the WTO and that are currently in force permit the parties to use GATT Article XX and GATT Article XXI-type measures to restrict imports for health, safety and security reasons.[8]

3 STANDARDS, REGULATIONS AND CONFORMITY ASSESSMENT

One of the issues determining the import of pharmaceuticals and medical products is the recognition of the exporting country's standards, regulations and conformity assessment procedures by the importing country. A number of RTAs have sector-specific provisions, including on pharmaceuticals and medical devices. Currently, such sector-specific provisions mainly involve WTO members in Asia, Canada, the European Union, the United States, and some countries in Latin America.

All such provisions on technical barriers to trade (TBTs) in RTAs covering pharmaceutical and medical products focus mainly on cooperation, transparency and/or procedures to obtain a product registration certificate.

The EU-Korea Agreement, for example, contains provisions to facilitate access to high-quality pharmaceutical products and medical devices through increased cooperation and transparency on pricing and reimbursement of such products. Each party will consider requests by the other party to accept conformity assessments of that party when performed in accordance with good laboratory and manufacturing practices based on international practice.[9]

In their RTA, the European Union and Singapore agree to enhance cooperation between their respective health authorities, based on international standards and practice. As in the EU-Korea Agreement, they agree on objective, fair, reasonable and non-discriminatory criteria, rules and procedures for listing, pricing or reimbursement of pharmaceutical products. They also agree to be transparent in their measures of general application related to pharmaceutical and medical products, including by making such measures publicly available before they come into force and by giving interested parties an opportunity to comment on the measures.[10]

The RTA between Japan and India aims to increase cooperation on generic medicine to build mutual confidence in the regulatory measures of the parties.[11]

The India-Singapore Agreement, through an exchange of letters, is more specific and establishes a special scheme for registration of generic medicinal products from India provided that they have been evaluated and approved by any one of the regulatory authorities in the United States, the United Kingdom, Australia, the European Union and Canada.[12]

In the plurilateral Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), which is currently in force for seven parties,[13] there are annexes on pharmaceuticals and medical devices that cover the preparation, adoption and application of technical regulations, standards, conformity

[7] Based on a survey of 287 RTAs for which information is available.
[8] Based on a survey of 287 RTAs for which information is available.
[9] Annex 2-D of the EU-Korea Free Trade Agreement (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2011:127:FULL&from=EN).
[10] Free Trade Agreement between the EU and Singapore, Annex 2-C (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2019:294:FULL&from=EN).
[11] Japan-India Comprehensive Economic Partnership Agreement (https://www.mofa.go.jp/region/asia-paci/india/epa201102/pdfs/ijcepa_ba_e.pdf).
[12] India-Singapore Comprehensive Economic Cooperation Agreement (https://www.enterprisesg.gov.sg/-/media/esg/files/non-financial-assistance/for-companies/free-trade-agreements/CECA_India/Legal_Text/Others/Side_letter_for_the_Special_Registration_Scheme_for_Generic_Medicinal_Products).

assessment procedures, marketing authorization and notification procedures for trade. Many of the provisions are, however, of a "best endeavour" nature, such as encouraging collaboration in international and regional initiatives to harmonize and align regulations and regulatory activities, and encouraging the parties to consider regionally developed scientific or technical guidance that is aligned with international efforts. Mandatory provisions include transparency measures, such as the identification and publication of available information by agencies authorized by the parties to regulate these products, and measures related to the granting of marketing authorization. In that respect, the CPTPP prohibits (a) linking the granting of market authorization to the submission sales data or related financial data; (b) the suspension of marketing authorization for products pending any required periodic re-authorization, unless there are significant health or safety concerns; and (c) requiring prior marketing authorization from a regulatory authority in the country of manufacture as a condition for granting marketing authorization in a party.

The CPTPP also requires an appeal or review process in the case of any negative decision on marketing authorization. The parties may restrict recognition of prior marketing authorization only to some parties if there are regulatory resource limitations from another regulatory authority. They will also improve collaboration and transparency in pharmaceutical inspection. In the medical devices annex, the parties agree to classify medical devices based on risk, and to regulate the device in a manner consistent with the classification the party has assigned to it. Finally, both the pharmaceuticals and medical devices annexes extend the coverage of the non-discrimination provisions of the TBT Agreement to a marketing authorization, notification procedure or elements of either that do not fall within the definition of a technical regulation or conformity assessment procedure.[14]

The RTA between Colombia and Mexico includes provisions regarding the administration and issuing of registration certificates. The parties agree on technical cooperation to identify, for example, any requirements to apply good manufacturing practices to produce and approve medicines especially for human use; and the application of good laboratory practices in line with international standards.[15] In the Chile-Peru RTA, the parties specify the time required to obtain registration certificates for pharmaceuticals for both human and veterinary use.[16]

The EU-Canada Agreement (CETA) goes further by including a protocol on mutual recognition regarding good manufacturing practice (GMP) for pharmaceutical products. It aims to strengthen cooperation between the parties to ensure that the covered products meet appropriate quality standards through the mutual recognition of certificates of GMP compliance. The parties agree to make public a list of regulatory authorities they recognize as equivalent, and they shall accept certificates of GMP compliance issued by these authorities. They may also accept certificates of GMP compliance issued by an equivalent regulatory authority of the other party from a manufacturing facility outside the parties under certain conditions. Finally, the parties may also determine the terms and conditions for accepting certificates of GMP compliance for products not included in the Agreement.[17]

To monitor implementation and propose new provisions, a number of committees or sub-committees have been formed to enhance cooperation on a number of issues, including to facilitate authorization

[14] While not yet in force, the United States-Mexico-Canada agreement (USMCA) contains similar provisions. The Medical Devices Sectoral Annex encourages regulatory alignment and harmonization on the basis of the work of the International Medical Devices Regulators Forum (IMDRF), and requires that parties recognize audits conducted under the IMDRF Medical Device Single Audit Program (MDSAP), thereby avoiding duplicative procedures and promoting more effective use of regulator resources (WTO official document number G/TBT/GEN/287, available at https://docs.wto.org/). Under the Pharmaceuticals Annex, the parties aim to improve collaboration on inspections and share related data, as well as establishing common principles for marketing authorization.

[15] Article 14-13 of the Colombia-Mexico Agreement (http://www.sice.oas.org/Trade/go3/text_s.asp#a14-13).

[16] Annex 10.5 of the Agreement lists the timelines: seven and 67 days for Peru for generic and new products and 90 days and 120 days for Chile for generic pharmaceuticals new pharmaceuticals (http://www.sice.oas.org/Trade/CHL_PER_FTA/Annexes/Anx10.5_s.pdf).

[17] Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products (http://data.consilium.europa.eu/doc/document/ST-10973-2016-ADD-8/en/pdf).

by the importing member.[18] In other cases, these functions fall under the more general functions of a committee on technical barriers to trade.

More generally, WTO members have negotiated and signed bilateral MRAs recognizing conformity assessment done by regulatory authorities in other members. Such MRAs can speed up the provision of critical supplies and reduce the cost of conducting inspections of sites in other countries. The European Union, for example, has MRAs with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States.[19] The Trans-Tasman MRA (TTMRA) between Australia and New Zealand is broader and covers all goods produced and services provided in either country regardless of differences in standards.[20]

[18] For example, the Working Group on Pharmaceuticals Products and Medical Devices (EU-Korea); the Working Group on Medical Products (US-Singapore Free Trade Agreement); and the Sub-Committee for Medicines, Pharmaceuticals and Medical Equipment (Colombia-Mexico Free Trade Agreement).

[19] The MRAs apply to human and animal medicine (https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra).

[20] The TTMRA does, however, allow for temporary or permanent exceptions.

List of abbreviations

GMP	good manufacturing practice
LDCs	least-developed countries
MFN	most-favoured nation
MRA	mutual recognition agreement
PP products	personal protective products
RTA	regional trade agreements
TBT	technical barriers to trade