

## Trade and COVID-19 Guidance Note

# STREAMLINING TECHNICAL MEASURES ON MEDICAL PRODUCTS TO COMBAT COVID-19<sup>1</sup>

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## KEY MESSAGES

- The urgency of effective responses to the COVID-19 pandemic and the reliance of many low-income countries on imports of medical products, requires new approaches to regulation of these products. The challenge will be particularly acute for the new tests to identify infection, drugs to alleviate symptoms and machines to aid recovery as well as vaccines that are all expected to be developed in the coming months.
- Increased transparency, information sharing and greater cooperation among agencies responsible for the approval and inspection of medical goods around the world can help officials in low-income countries implement their mandate more effectively while maximizing efficient access to these commodities.
- Responsible agencies should focus on implementing technical regulations to protect health and safety, including interception of counterfeit and substandard products, and avoid wasting resources and creating delays by maintaining procedural practices that may be better addressed through alternative risk management strategies or seeking to regulate quality issues, which are best left to the market.
- Where there is a need to rapidly approve, test and inspect new goods or varieties that have not previously been imported, such as new equipment and medicines, the adoption of mutual recognition and/or equivalence can provide effective mechanisms to avoid regulatory delays while maintaining high levels of safety.

Ensuring access to medical products (pharmaceuticals and medical devices) is critical for the response to the COVID-19 pandemic. Beyond measures to [streamline customs procedures](#), it is also important that agencies responsible for the safety of medical goods adopt flexible approaches to licensing, certification, inspection, testing and other measures. This is of particular relevance when well-established trade relations are disrupted by shocks, such as the pandemic, and there is a need to shift to new suppliers and/or different products that may not have been previously imported. For instance, new medical products, including the potential vaccines, will need regulatory approval and effective testing and inspection. This note briefly discusses the key challenges these countries may face, and possible approaches and solutions they can adopt to ensure safety while limiting the delays and costs in accessing essential medical products from abroad. Similar issues related to the access of food products is summarized in Box 1 below.

## LIMITED CAPACITY FOR REGULATION AND CONTROL

**Appropriate technical regulations and effective implementation are critical to ensuring consumer protection, health and safety.** However, capacities for regulation and inspection are often weak in developing countries. The Global Atlas of Medical Devices (World Health Organization, 2017) indicates that of the World Health Organization's (WHO) 194 members, 113 have a legal framework for medical devices. Most of those that do not are in the Middle East and Africa.

## DEFINING A LIST OF CRITICAL PRODUCTS

**Contingency planning, prepared well in advance of a crisis, is a highly effective tool in managing critical trade.** However, in many cases the key commodities required to address a crisis are not known in advance. In the current situation needed critical medical devices, such as ventilators, could not have been anticipated. However, countries can develop contingency plans that include general measures for dealing with crisis. The

<sup>1</sup> Trade and COVID-19 Guidance Notes are prepared by the Global Trade and Regional Integration Unit of the World Bank to provide practical measures governments can implement to mitigate the impact of the COVID-19 virus outbreak. For further information about this note please contact Paul Brenton ([pbrenton@worldbank.org](mailto:pbrenton@worldbank.org)) or Shane Sela ([ssela@worldbank.org](mailto:ssela@worldbank.org)), or Antonio Nucifora (Practice Manager, Global Trade and Regional Integration Unit, [anucifora@worldbank.org](mailto:anucifora@worldbank.org)). A full list of Trade and Covid-19 briefs is available at <https://www.worldbank.org/en/topic/trade/brief/trade-and-covid-19>

World Customs Organization (WCO) (1970) has developed good guidance on preparing for facilitating disaster relief consignments.<sup>2</sup>

**Countries should create a list of medical goods relevant to their particular circumstances to which available domestic capacity for tasks such as regulation and inspection can be prioritized during the COVID-19 emergency.**<sup>3</sup> There would be benefits from a common list across countries, especially for those sharing borders and in a regional agreement or customs union. A common list would facilitate information sharing and the sort of cooperative actions across countries that are discussed below. The WCO and the WHO have created [a list of items needed to combat COVID-19](#) (World Customs Organization, World Trade Organization, 2020). The list is frequently updated as information on the disease and therapies are developed. These include:

- Protective garments: face masks, eye protection, gloves and other personal protective equipment;
- Test kits and diagnostic instruments
- Disinfectants and sterilization products: medical strength alcohol, sanitizers, sterilizing equipment, chemical disinfectants, medical grade chemicals, etc.;
- Oxygen therapy equipment, such as ventilators;
- Other hospital supplies and equipment such as thermometers, stethoscopes, electrocardiographs and ultrasound machines.

**In addition to finished products, countries should also include raw materials and intermediate products required to produce these items locally.** Reagents used in test kits, for example, are chemicals required to extract the deoxyribonucleic acid (DNA) from the patient and various primers and buffers to run the test. These are in high demand as countries seek to increase testing and stem the transmission of the disease.

**Beyond a complete list of finished products, raw materials and intermediate inputs required to produce them, flexibility and dialogue with agencies in other countries on newly developed and new to the market products will be required to quickly identify if new products need to be added to the list.** It is essential to review the classification of new medical products developed for COVID-19 to ensure that appropriate action is taken if they are included under headings that are subject to high tariffs.

**Finally, it would be useful to categorize these key products according to the risk they pose to the health and safety of users including patients and medical practitioners.** This would help to allocate scarce resource within health ministries and standards agencies towards those products that require the highest level of control.

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<sup>2</sup> Guidance developed by the WCO includes: [Recommendation of the customs co-operation council to expedite the forwarding of relief consignments in the event of disasters](#), the [Kyoto Convention, Specific Annex J, Chapter 5, Guidelines on Relief consignments and](#) the WCO (2011) [Resolution of the customs co-operation council on the role of customs in natural disaster relief](#)

<sup>3</sup> A well-defined classification of medical and related products is lacking in WTO agreements and in the Harmonized Commodity Description and Coding System (HS) which is used to monitor and record international trade. The HS system was designed to address tariff classifications and not to separate commodities by purpose or risk. For this reason, HS classifications are not generally useful for monitoring commodities for purposes other than revenues. Many materials used in the production of medical products such as specific chemicals have both medical and non-medical end uses. Some key final products tend to be classified by material inputs rather than end use. For example, protective clothing for health care workers is classified as apparel and according to whether it is made from cotton or other materials. This makes identification of specific commodities needed in a crisis difficult.

**Box 1: Food Trade and COVID 19**

Maintaining global food chains is essential to prevent price spikes and food staple shortages that would disadvantage the poor most of all. Food trade is subject to food safety controls such as inspections, sampling and testing. Often these controls may be applied prior to export and again at or following importation.

Restrictions in movement placed by governments on traders and public officers to prevent the spread of COVID-19 poses a severe challenge to meeting food safety controls and facilitating food trade. In some cases, countries are erecting barriers to the movement of food to prevent disease spread through logistics workers. Several countries have imposed import restrictions on Chinese food on the basis of reducing COVID-19 risks (based on the fact that the disease is presumed to have emerged from a wet-food market). Scientists have stressed, however, that food does not pose a risk for the transmission of the disease. A [joint statement](#) by the heads of the Food and Agriculture Organization (FAO), WHO, and the World Trade Organization (WTO), and two recent op-eds by World Bank Managing Director Mari Pangestu ([here](#) and [here](#)), warn against restricting food trade as a result of the COVID-19 pandemic. The virus does not survive for long outside the human body and the main transmission method is human-to-human contact. Countries should consider the number and magnitude of measures applied through the value chain that are critical in mitigating risks.

As with medical products, the WTO Agreement on the application of sanitary and phytosanitary (SPS) measures provides for countries to consider equivalence when applying controls. Equivalence in the context of the SPS agreement means that where a country demonstrates that an approach to reducing risk (e.g. a treatment, processing, inspection or testing methodology and competency, etc.) meets the importing country's desired level of protection the importing country should accept the proposed approach.

## REGULATING MEDICAL PRODUCTS

**The medical products needed to combat COVID-19 range from high-technology solutions like drugs and ventilators to simple products like protective garments (masks and aprons), hand sanitizers and soap.** There may be limited experience in the regulation of these products and appropriate standards may be absent.

**In this case countries can use international standards which typically capture the state of global knowledge regarding necessary regulation.** Given capacity constraints, low-income countries participate little if at all in international standard setting. Thus, international standards tend to reflect the situation and demands for protection in rich countries and not the particular situation (environment, income, preferences, etc.) in developing countries. Nevertheless, this is unlikely to be important with regard to health and medical products to treat the victims of a global pandemic, where regulatory objectives are likely to be common across countries. Utilizing international standards in this case will reduce the risk of causing unnecessary obstacles to trade.

**When the adoption of international standards would be time consuming or impractical, as in the case in new medical products developed in response to the COVID pandemic, developing countries could rely on other countries' regulatory evaluation, an approach recommended by the WHO.** The WTO's [Agreement on Technical Barriers to Trade \(TBT\)](#) recommends that "*Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.*"

Saudi Arabia's recent regulatory proposal, 'Medical Devices Interim Regulation', exemplifies this approach: *To obtain marketing authorization, medical devices shall comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the United States and the European Union/European Free Trade Area, and additionally with provisions specific to the Kingdom of Saudi Arabia concerning labeling and conditions of supply and/or use.*

**The European Union (EU) is similarly streamlining regulatory measures to accelerate access to COVID-19 medical products.** In March 2020, the European Commission issued a [recommendation](#) aimed at easing access to the EU of personal protective equipment manufactured in accordance with WHO guidelines rather than in strict compliance with EU standards.

**Thus, developing countries do not need to overburden domestic systems or rush prematurely to approve experimental solutions.** They can instead can exploit the safety evaluations of more experienced countries with known infrastructure, robust regulatory frameworks and the resources needed to complete rapid approvals to ensure safe and efficient access to medical products.

**Relying on international standards or accepting the equivalence of regulatory systems in other countries can also simplify the process of conformity assessment including the possibility of recognizing the certificates of conformity from internationally accredited laboratories.**<sup>4</sup> The WTO TBT Agreement also specifies that “*Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.*” The Agreement also states “*Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each others conformity assessment procedures...*”

**Several developed countries have established mutual recognition agreements (MRA) which provide efficiencies that facilitate trade of medical devices and pharmaceuticals.** Similarly, regional free trade agreements include mutual recognition clauses for specific sectors covered by the agreements. The agreements generally focus on transparency, equivalent procedures and cooperation including recognition of good manufacturing practices (GMPs) which ensure that products covered meet both countries standards for safety and quality. Canada for example has signed MRAs with the European Community, Switzerland, Ireland, Lichtenstein, Norway and Australia which include GMPs intended to facilitate trade without reducing safety and quality. The MRA’s are evaluated based on equivalence in legislation and regulatory procedures, GMP standards, oversight, enforcement powers, procedures for alerts or recalls, analytical capacity, etc. Such MRAs allow countries to reduce their reliance on domestic controls such as import testing and validation and rely on export controls ensuring that products entering the marketplace are compliant.

**Regulatory measures including consignment inspection and testing can be a significant revenue stream for government agencies.** Many countries are reluctant to reduce revenues particularly if they directly impact upon the agency’s operating budget. However, maintaining regulatory burdens during the crisis will limit access to novel treatments and critically needed medical devices. In many cases, revenues can be offset by increased efficiencies, improvements in trade volumes and resulting revenues and improved outcomes in crisis management.

**The pandemic has created high demand for medical products and unfortunately, large amounts of substandard products are moving in trade.** This is a particular challenge when medical supplies come from unknown sources or when purchased online (World Customs Organization, 2020). The WCO reports that, amongst others, customs and law enforcement in China, Germany, Indonesia, Uganda, United Kingdom, United States and Vietnam have reported the seizure of counterfeit medical products like facemasks and hand sanitizers. Greater sharing of information among authorities on products and sources of goods that have been identified as counterfeit or substandard can assist in removing such products from circulation by alerting purchasers and customs and health officials.

**Low-income countries can use existing mechanisms, such as equivalence and mutual recognition to access critical medical products and minimize disruption to trade while ensuring safety and probity.** To reform existing regulation to allow for emergency measures and the introduction of principles of good regulatory practice including equivalence and mutual recognition, regulators and practitioners will need access to technical and trade facilitation experts to survey their existing practices and device new solutions. Brazil is an example of a developing country that has very recently notified faster approval procedures to the WTO on 18 and 20 March.<sup>5</sup> Many developing countries may not have the resources and experience of an emerging economy like

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4 The International Laboratory Accreditation Cooperation (ILAC) provides a framework for laboratory accreditation, proficiency testing and accreditation of inspection bodies. The ILAC Mutual Recognition Arrangement (MRA) is a framework that allows national accreditation bodies to be standardized through a peer reviewed process. These bodies can then accredit national testing laboratories, inspection bodies, etc. in accordance with relevant international standards set by ISO. The result is intended to provide confidence that an accredited laboratory regardless of location is performing services in standardized manner. Governments can use the MRA as a component in mutual recognition processes. ILAC maintains a listing of signatory member accreditation bodies.

<sup>5</sup> G/TBT/N/BRA/984 on 20 March 2020, entitled ‘Established extraordinary and temporary criteria and procedure for Good Manufacture Practice Guidelines for market authorization and post-market registration amendments of Active Pharmaceutical Ingredients, medicines and healthcare products due to the international public health emergency of the

Brazil, and may request support from institutions such as the World Bank to design and implement changes quickly.

## REFERENCES

World Customs Organization. (2020). *COVID-19 Urgent Notice; counterfeit medical supplies and introduction of export controls on personal protective equipment*. Brussels: World Customs Organization. Retrieved from [http://www.wcoomd.org/en/media/newsroom/2020/march/covid\\_19-urgent-notice-counterfeit-medical-supplies.aspx](http://www.wcoomd.org/en/media/newsroom/2020/march/covid_19-urgent-notice-counterfeit-medical-supplies.aspx)

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## ANNEX 1: ADDITIONAL RESOURCES

### Trade and COVID-19 Guidance Notes:

[Trade and Covid-19 Brief Page](#)

[Managing Risk and Facilitating Trade in the COVID-19 Pandemic](#)

[Do's and Don'ts of Trade Policy in the Response to COVID-19](#)

[Trade in Critical COVID-19 Products](#)

[Trade Responses to the COVID-19 Crisis in Africa](#)

[Logistics and Freight Services: Policies to Facilitate Trade](#)

[Health Services Trade and the COVID-19 Pandemic](#)

### Other resources:

[Espitia, Rocha, Ruta \(2020\). "Database on COVID-19 trade flows and policies"](#)