UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT
UNCTAD

IMPROVING ACCESS TO MEDICAL PRODUCTS THROUGH TRADE: WHAT CAN REGIONAL TRADE AGREEMENTS DO IN TIMES OF CRISIS?

UNITED NATIONS
Geneva, 2021

United Nations publication issued by the United Nations Conference on Trade and Development.

UNCTAD/DITC/TNCD/2020/4

eISBN: 978-92-1-005635-9

ACKNOWLEDGEMENTS

This paper was originally prepared Chi Le Ngo, Divya Prabhakar, Mingcong Li and Seul Lee as a contribution to the Policy Hackathon on Model Provisions for Trade in Times of Crisis and Pandemic in Regional and other Trade Agreements organized by the Economic and Social Commission for Asia and the Pacific (ESCAP) as part of a United Nations Initiative, in collaboration with ARTNeT, World Trade Organization (WTO), CUTS International and other organizations from civil society, academia and the private sector. The study was revised under the supervision of Miho Shirotori, Head of Trade Negotiations and Commercial Diplomacy Branch, Division on International Trade and Commodities of the United Nations Conference on Trade and Development (UNCTAD).

The authors would like to thank Mia Mikic, Director of Trade Investment and Innovation Division (TIID), UN ESCAP, Yann Duval, Chief of Trade Policy and Facilitation Section, TIID, UN ESCAP, and the UN Policy Hackathon support team for their tremendous support, including Mathilde Liger and Runqiu Du. Invaluable comments also come from Paul Baker, Simon J. Evenett, and Taisuke Ito, panellists attending UNCTAD Trade Policy Dialogue: Towards model RTA provisions for trade in essential supplies in times of crisis.

The cover design and desktop publishing were done by Laura Moresino-Borini and Belén Camarasa.

ABBREVIATIONS AND ACRONYMS

CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
ESCAP	Economic and Social Commission for Asia and the Pacific
GHTF	Global Harmonization Task Force
GLPs	Good Laboratory Practices
GMPs	Good Manufacturing Practices
GPRs	good regulatory practices
ICH	Human Use
IEC	International Electrotechnical Commission
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
IMDRF	Medical Device Regulators Forum
FTA	Free Trade Agreement
MDSAP	Medical Device Single Audit Program
MRAs	Mutual Recognition Agreements
OIE	World Organization for Animal Health
OECD	Organisation for Economic Co-operation and Development
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PPE	personal protective equipment
RTA	regional trade agreement
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
WHO	World Health Organization
WTO	World Trade Organization
UNCTAD	United Nations Conference on Trade and Development

CONTENTS

Appendices

CONTENTS

Boxes

Figures

Tables

EXECUTIVE SUMMARY

The criticality of maintaining trade flows of essential medical products and protective equipment during the COVID-19 pandemic cannot be emphasized more. The speed and the scale of the pandemic made it necessary to keep trade channels of such products open and eliminate traditional hurdles to trade to minimise all unnecessary costs and delays. The sense of urgency, and the reliance of many countries on imports for medical goods, highlight a need to simplify and streamline customs procedures and technical regulations.

The way the pandemic unfolded has exposed some loopholes in the capacity of the current trading system. Building an international trade environment that can respond to such threats effectively and efficiently is the first step towards better response, and regional trade agreements (RTAs) are a good potential platform to accomplish this. Specifically, provisions on regulatory cooperation in RTAs can aid countries to quickly respond to medical emergencies by simplifying unnecessary burdens posed by technical regulations. Enhancing "regulatory cooperation" through simple efforts such as increasing transparency and enhancing consultations among cross-border regulatory agencies, as well as more complex undertakings such as mutual recognition and harmonization of standards and conformity assessment procedures – can enable countries to trade better during emergency situations.

Based on a review of 107 RTAs and an examination of country efforts to reduce regulatory divergence in order to facilitate trade in medical goods during the pandemic, this study attempts to advance the discussion on the need for emergency provisions in RTAs, culminating into a proposal for model RTA provisions. All proposals are built upon the various strengths as well as shortcomings of existing RTAs and regulatory cooperation measures adopted by countries during COVID-19.

The text of most RTAs reviewed indicates the will of Parties to pursue regulatory cooperation through different approaches. For instance, two-thirds of the technical barriers to trade chapters of RTAs promote mutual recognition of standards and/or conformity assessment procedures. In terms of equivalence of standards, it is mentioned in around half of the RTAs reviewed for chapters addressing sanitary and phytosanitary measures and technical barriers to trade, while equivalence of conformity assessment is much less prevalent in RTAs. Harmonization of requirements for technical barriers to trade is another topic covered by around one-third of RTAs, while more than half of the RTAs refer to international, regional, or other Member(s)' standards as a benchmark for their own standards. There is however a need to solidify the commitment which is still vague and weak in most RTAs' text and bring in (i) specific provisions which explicitly regulate the regulatory cooperation in medical goods and (ii) emergency provisions on mutual recognition, equivalence, and harmonization of standards and conformity assessment during crisis.

Following the RTA analysis, the assessment of efforts by nine economies (Brazil, Canada, European Union, Kenya, Kuwait, Namibia, Switzerland, Uganda, and the United States) to reduce regulatory divergence shows that countries pursued equivalence and harmonization of standards and conformity assessment procedures with their trading partners to facilitate trade of specific medical goods. While there is little evidence to show whether these measures had any impact, one cannot overlook that these well-intended, well planned, and timely measures were a commendable attempt to prevent regulatory barriers from becoming bottlenecks to trade. Equivalence of standards and conformity assessment was applied temporarily along with other complementary measures. Yet, it is worth noticing that countries acted unilaterally instead of seeking cooperation from their trade partners. Countries did not pursue mutual recognition. Existing mutual recognition arrangements would have contributed to addressing the problem in part.

The findings from RTAs and country case studies point towards the need to incorporate specific, temporary, or emergency provisions into RTAs that can facilitate regulatory cooperation and ensure that trade in medical goods flows unhindered during crises. Such ready-to-apply regulations and action plans would reduce uncertainty during the already difficult times.

The key to solid emergency provisions in RTAs is to base them on predefined "criteria". The recommendations of this study makes some proposals to this end, for example: to clearly define a situation of "public health emergency" or a "shortage" of essential goods; to classify, at a tariff line level, "essential" goods that could be critical during an emergency; to agree to temporarily adopt international standards as a basis for regulatory cooperation; to treat as equivalent standards of jurisdictions with similar regulatory frameworks, among others. Specifying a start and an end date of such temporary measures would help provide more legitimacy to the provisions.

Further from these criteria, the study offers some "model provisions" that can be a starting point for RTA negotiators to build upon. The objective of enlisting these model provisions is to establish a formal basis for advancing regulatory cooperation in a quick and smooth fashion, while making good use of available mechanisms and possibilities.

Model regional trade agreements provisions

Model provision 1	During [the emergency situation], Parties would consider a request to recognize the results of conformity assessment procedures conducted by bodies in the other Party's territory.
Model provision 2	Parties [shall] undertake to agree on a common list of [standards and conformity assessment procedures] for a specified list of critical medical products that can be applicable during [an emergency situation], based on [one-another's standards/standards of member countries to some specified association/ international standards].
Model provision 3	During [the emergency situation], [agreeing] Parties [shall] treat as equivalent/recognize [standards and conformity assessments procedures] of another Party to the agreement if the latter [has similar regulatory system/is recognized or treated as equivalent by other countries with similar regulatory systems/is a member of a specified association or international organizations] for [medical] products included in a pre-defined list of critical products for [XX days/a number of days considered suitable and necessary at that point in time, provided the following conditions are satisfied […].
Model provision 4	During [the emergency situation], if a Party recognizes [standards and/or conformity assessment procedures] of [other Parties/member countries to an association/international organizations], in addition to those specified in the common list, the Party [shall] notify other Parties of its decision within [XX number of days] of such recognition.
Model provision 5	[Upon the development of emergency situations], Parties [shall] review [standards and/or conformity assessment procedures] within a period of [XX days] from the day when the emergency situation is first established.
Model provision 6	During [the emergency situation], Parties shall establish [emergency registration/licensing/certification scheme] for the other Parties provided their products have been evaluated and approved by anyone of the regulatory authorities in [Any advanced country: specify a list of countries, *e.g.*: the United States, the United Kingdom, Australia, the European Union and Canada].

1. Introduction: Regional trade agreements as a tool for strengthening regulatory cooperation during medical emergencies

As COVID-19 spread rapidly across the globe, the world witnessed an unprecedented spike in the demand for medical products to support prevention, diagnosis, and treatment of the virus such as medicines, medical supplies, and personal protective equipment (PPE). Governments were under extreme pressure to ensure adequate supply of essential medical products in the domestic market. At the same time, reduced international flows of essential products became a cause of concern worldwide.

International trade has been a key factor influencing global supplies during the pandemic. Exports of COVID-19 medical products from China, the European Union, and the United States rose from about US$ 25 to 45 billion per month, between January and May 2020. Yet only a tiny fraction of the additional production of these goods reached the middle and low-income countries (UNCTAD, 2020a). Such crises, wherein ensuring domestic supplies of essential goods is critical to protecting public health and safety, often prompt countries to take temporary, sometimes drastic emergency trade-related measures. As of October 2020, nearly 390 such measures, ranging from export-control measures to import-facilitation ones, had been adopted by countries in response to the pandemic. Measures as extreme as export bans can be counterproductive and possibly nullify the effect of import facilitating measures and disrupt global supply chains, depriving the most vulnerable countries of essential products.

Situations like this call for countries to cooperate to seek for new and innovative approaches to deal with trade measures and regulations. Increased “regulatory cooperation” among countries can be a solution. Trade in medical products is subject to a myriad of technical regulations and standards. Imported goods often need to undergo multiple inspections for verification of conformity with the destination country’s standards and regulatory requirements. To comply with such requirements, exporters need to obtain several permits and certifications in both destination and home country. All this prolongs the time required for completing cross-border trade. Further, divergence in regulations and standards across countries exacerbates the problem. Increased transparency, information sharing, and cooperation among national agencies responsible for approval and inspection becomes the key for smoother flows of medical products (World Bank, 2020).

Within the context of trade in medical products during the COVID-19 pandemic, this study provides an assessment of how such regulatory cooperation can be achieved, particularly through RTAs.

A. Regulatory cooperation: Objectives and approaches

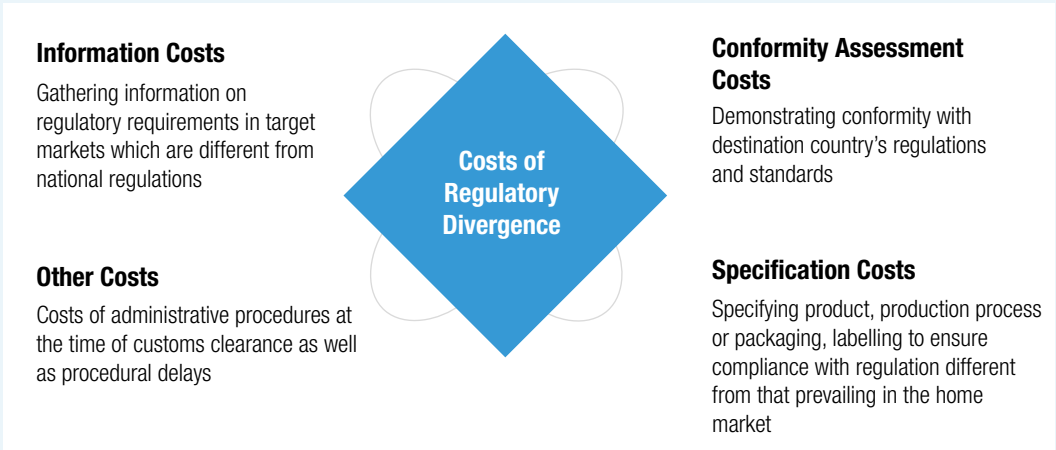
Divergence in regulatory measures across countries can raise unnecessary costs for businesses and citizens (Kauffmann and Malyshev, 2015). When exporters have to comply with regulations in destination markets that are different from those in their home markets, they would have to collect information on regulations in destination markets and to verify compliance of their products to such regulatory requirements. Sometimes, firms may have to get products tested for the second time using a method of testing adopted by the importing country, even when the same product characteristics has been tested in the country where the product was produced. Divergence in regulations can thus slow down trade. It has been suggested that regulatory cooperation could reduce trade costs by over 25 per cent (UNCTAD, 2018).

Regulatory cooperation among countries can reduce trade costs particularly through shortening the lengthy process of conformity assessment without undermining the policy objective, i.e. protecting health, safety, and the environment. Thus, regulatory cooperation can help countries find ways and means to minimise negative impact of national regulatory measures on trade, particularly in times of emergencies (Lejárraga, 2014).

Approaches to reduce regulatory divergence can be unilateral, bilateral/regional, or multilateral. A unilateral approach could mean that a country adopts applicable international standards or converges its regulations/standards to those of its trading partners without any request for reciprocity. Adoption of international standards in national frameworks can help promote regulatory convergence globally. Countries may also make a unilateral effort towards systematic use of regulatory impact assessments, stakeholder engagement, promotion of transparency to help lower information costs. The adoption of good regulatory practices (GRPs) can enhance the quality of the regulatory framework and can support greater exchange among regulators based on a better understanding of the impacts of regulatory measures.

A **bilateral/regional** approach is undertaken not by one country but by a group of countries, mostly under reciprocal conditions. It can help streamline the administrative processes. An example exists in RTAs,

Figure 1. Costs of regulatory divergence



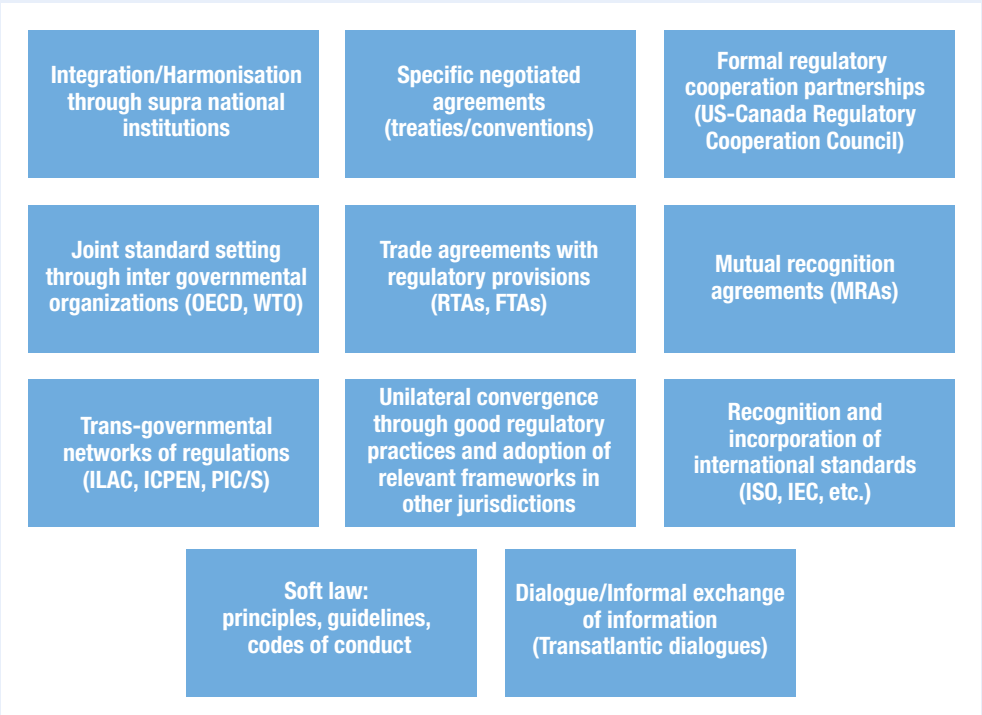
Source: Organisation for Economic Co-operation and Development (OECD), 2017.

through provisions promoting convergence to international standards, mutual recognition, harmonization or transparency, and information exchange. As a **multilateral** approach, the World Trade Organization (WTO) offers a multilateral transparency and notification system through monitoring the implementation of relevant WTO Agreements, such as the Agreement on Sanitary and Phytosanitary (SPS) Measures and the Agreement on Technical Barriers to Trade (TBT). Such agreements, which address technical regulations, standards, and conformity assessment procedures between members, provide a platform for countries to learn about each other's regulatory systems and to collaborate to eliminate unnecessary duplications that are trade-restrictive (Lejárraga, 2014).

The proliferation of "deep" RTAs, *i.e.* those that encourage regulatory cooperation among Parties, has been a noteworthy development in recent years. Today, many RTAs go beyond traditional issues such as tariffs and cover a wider range of issues that are not covered under the WTO Agreements, such as competition policy and e-commerce. With respect to essential commodities, regulatory cooperation in an RTA can help ensure that the need to comply with regulations and standards does not become an impediment to trade during emergency and crisis situations (The E15 Initiative, 2017).

Regulatory cooperation can refer to multiple actions, such as enhancing better information exchange, creation of a joint committee to implement the SPS/TBT chapters, aligning with international standards, treating other Parties' standards as equivalent, among others. (Figure 2). RTAs can become a tool to enhance regulatory cooperation in times of medical emergencies by including specific provisions to be applied in specific situations. Such provisions in RTA allow Parties to be clear on types of temporary changes in the agreed trade rules in times of crisis, which would increase predictability at a time of uncertainty.

Figure 2. A Continuum of approaches to international regulatory cooperation



Source: OECD, 2013.

B. Structure and methodology

Against the above background, this study proposes a number of "provisions" that can be incorporated into RTAs to better respond to the challenges that medical emergencies such as the COVID-19 pandemic present to trade flows of essential goods. This is done through a two-pronged approach covering the following:

I. **Assessment of existing RTAs** to identify provisions embedded in existing RTAs that can help enhance cooperation on technical regulations among trading partners; and

II. **Assessment of country practices adopted during the pandemic** to identify some innovative approaches that helped countries ease the burden of regulations during COVID-19.

Chapter II breaks down the concept of regulatory cooperation into three concrete approaches, which are: (i) mutual recognition, (ii) equivalence, and (iii) harmonization. Each approach is explained in detail with theoretical underpinnings.

Chapter III provides an in-depth analysis of 107 selected RTAs to identify provisions on mutual recognition, equivalence, and harmonization within the SPS measures and TBT chapters in each RTA. This chapter also assesses whether specific provisions for regulatory cooperation exist for medical products and if any temporary provisions have been established for emergency situations. Beyond mapping such provisions, the analysis develops a scoring system to assess how concrete and binding these provisions are. Provisions that have scored high based on the scoring system have been highlighted.

Chapter IV then examines nine country cases whereby governments pursued regulatory cooperation to ease trade flows during the pandemic. These cases were selected after reviewing measures adopted by various countries in country notifications to WTO, media presses, and government websites among others. It is found that the countries took steps towards equivalence and harmonization with other countries' or international standards and/or conformity assessment procedures. These measures targeted specific medical goods. Most country measures were temporary in nature and often complemented with other measures.

The first prong above reveals that while existing RTAs have several "generic" provisions on regulatory cooperation, there is a conspicuous absence of provisions to deal with medical emergencies. The second prong of the approach is to conduct country case studies to fill this gap. The country case studies provide a basis to understand key actions that countries prefer to use, which can demonstrate as a starting point to negotiate RTAs and make regulatory cooperation more suitable to emergency situations.

A review of the RTAs indicates several gaps as far as regulatory cooperation is concerned. RTAs tend to lack temporary provisions or those targeting medical goods. As such, they can be inadequate in facilitating trade during emergency situations. The country cases provide a good reference point to fill these gaps and provide some cues to strengthen RTAs for emergency situations. In view of this, Chapter V presents a summary of recommendations for RTAs, consisting of general recommendations and a set of model RTA provisions, that can fill existing gaps.

II.

Key pillars of "regulatory cooperation"

There are many approaches towards regulatory cooperation as presented in Chapter I.B. This study draws attention to three approaches, which have been found most commonly in RTAs: (i) Mutual recognition, (ii) Equivalence, and (iii) Harmonization (Figure 3). These three approaches will serve as the foundation for the RTA analysis in Chapter III, in terms of how strongly regulatory cooperation has been promoted, and country case studies in Chapter IV to investigate what measures have been adopted to make regulatory cooperation more suitable during crisis situations.

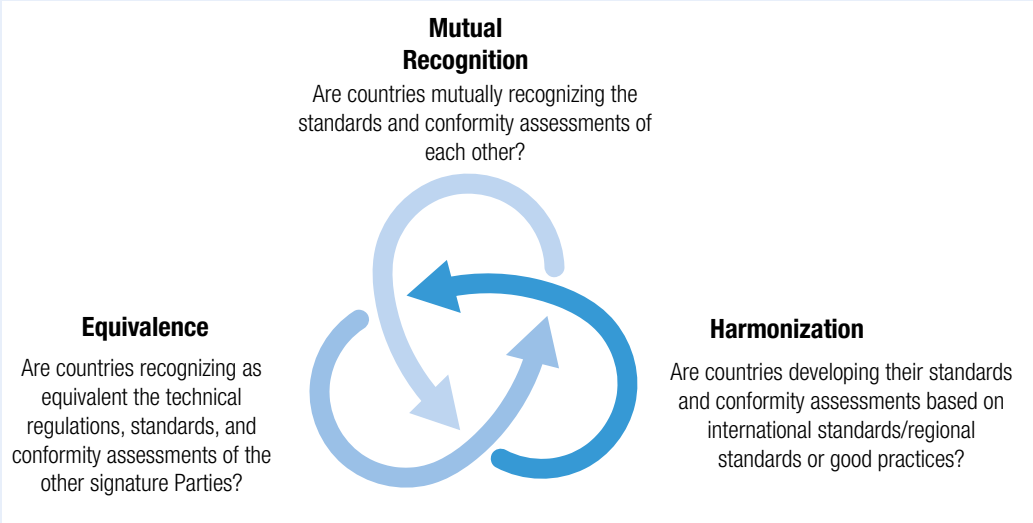
A. Mutual recognition

The concept of mutual recognition refers to a scenario where two or more Parties mutually accept each other's standards, regulations, or conformity assessment procedures or their results. Per Article 2.3 and 2.4 of the WTO TBT Agreement, this implies that products produced under regulations/regulatory systems of exporting countries enjoy market access even in the importing country where different regulations/ regulatory systems exist.

Mutual recognition has been promoted under the TBT Agreement for technical regulations, standards, and conformity assessment, whereas in the SPS Agreement, mutual recognition has not been mentioned explicitly for either standards or conformity assessments. One potential reason behind it could be that TBT measures largely address manufactured products or production methods where geographical or environmental surroundings of a country do not matter much, and standards for product quality could be common across countries. Whereas for SPS measures, which is largely affecting agricultural, fishery, and forestry products, the quality of such products may be dependent on country specificity.

That being said, standards adopted by one country may not be easily recognized as having the same impact as measures existing in the importing countries. Mutual recognition can be applied to both standards and

Figure 3. Three approaches for regulatory cooperation in regional trade agreements



Source: Authors' own elaboration.

procedures for conformity assessment (*e.g.* inspection, certification, test results, etc.). Mutual recognition of standards means a country that is a signature Party accept other Parties' products as meeting the same quality requirements as its own, whereas mutual recognition of conformity assessment is about two or more signature Parties accepting each other's verification procedures as equivalent to ensure that duplicate inspection, testing, and other procedures when entering into the importing country can be avoided.

These two aspects are not identical. Ideally, mutual recognition of standards and conformity assessment should be pursued simultaneously. If standards are mutually recognized, but there is a lack of convergence between conformity assessment systems then burdens to trade can persist as products cannot freely enter the market of importing countries since the testing, inspection and other control procedures of the exporting countries are not recognized.

Mutual recognition of conformity assessment would help trading partners reduce the costs associated with multiple testing, inspection, and other procedures at the destination markets. For some time-sensitive products, such as medical and pharmaceutical products during the COVID-19 period, the time delays associated with product inspection, testing, and certification at the importing country can heavily impact the general public in times of crisis.

Generally, mutual recognition of conformity assessments is considered a less ambitious approach than mutual recognition of standards or regulations and is also more commonly used than the latter.

B. Equivalence

The concept of **equivalence** is based on the fact that regulatory goals such as meeting health and food safety quality, may be fulfilled by the use of different kinds of measures. Products shall be accepted as long as they fill relevant regulatory objectives, even though actual regulatory measures in place are

different. For this kind of provision, the importing country recognizes the equivalence of the objectives and/or conformity assessment in the exporting country for a certain product even though the standard and conformity assessments applied on that product are not exactly the same for importing and exporting countries (Veggel & Elvestad, 2004).

Once equivalence is established, the signature Parties can then mutually recognize each other's systems. Mutual recognition is the outcome of an evaluation process in which one or more Parties agree that goods traded in one country may be freely traded in another country that is also a Party to the agreement (Veggel & Elvestad, 2004).

Equivalence has been mentioned in both the WTO SPS and the TBT Agreement. Under Article 4.1 of the SPS Agreement, it is defined as the 'level of protection deemed appropriate' by the members to protect human, animal, or plant life or health within its territory. In the TBT Agreement, equivalence applies separately to technical regulations and conformity assessment procedures. Article 6.1 of the WTO TBT Agreement specifies equivalence of conformity assessment procedures as accepting that different procedures for compliance checks can achieve the same level of conformity assurance. That is, it is possible to accept the results of conformity assessment procedures of other Parties as equivalent even if the underlying technical regulation is not equivalent. Since TBT measures are more diverse, they can be adopted to a broader range of objectives than in the SPS case (Schroder, 2011).

The main difference between the concept of equivalence and mutual recognition under the TBT Agreement is that equivalence refers to "unilateral" acceptance/recognition of technical regulations, standards, or conformity assessment of the other Party, whereas mutual recognition refers to "two-way" equivalence of each other's technical regulations, standards or conformity assessment.

C. Harmonization

Harmonization is another useful tool for regulatory cooperation, which is promoted in both the WTO SPS (Article 3) and the TBT Agreement (Article 2.4-2.6) to reduce the burden to trade. Under both Agreements, Parties are encouraged to harmonise their national regulations with relevant international standards when such standards exist. International standards can be especially useful in RTAs where countries look for common ground on standards.

Harmonization can be accomplished at different levels. At one level, national standards bodies can harmonize national standards with standards issued by international standardizing bodies such as Codex Alimentarius, International Plant Protection Convention (IPPC), World Organization for Animal Health (OIE), International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), or regional standardization bodies such as the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), etc. At the other level, harmonization can also be achieved by one country adopting or aligning its standards with another country or region, or two countries working to harmonize their respective standards with each other.

For SPS measures, Article 3 of the WTO SPS Agreement encourages harmonization based on international standards as much as possible. It recognizes the standards, guidelines, and recommendations developed explicitly by the Codex Alimentarius, OIE, and IPPC for international standards. Although the use of international standards is voluntary in nature, they provide the basis for harmonization of SPS measures unless Parties can provide 'scientific justification' based on 'risk assessment', in that case, they can then introduce a different measure with a higher level of SPS protection.

In terms of TBT measures, Articles 2.4 and 5.4 the TBT Agreement requires members to use relevant international standards, guides, or recommendations, as a basis for their national standards, technical regulations, conformity assessment procedures, except when such international standards are 'ineffective or inappropriate' to achieve their legitimate goals. Unlike the SPS Agreement, the TBT Agreement does not contain a definition of international standards nor recognized international standardizing bodies.

Full harmonization with international standards may be difficult to achieve in reality particularly for countries that lack infrastructure or technical capacity. Hence, the WTO Agreements recommends that the deviation of national standards from international standards is 'not significant' and that countries can use national standards if they reach the 'same objectives'. Nevertheless, having standards and conformity assessments harmonized can in theory remove the cost of adapting to multiple trading conditions and regulations requirements.

III.

How do regional trade agreements encourage regulatory cooperation?

This chapter provides an in-depth analysis of 107 selected RTAs to identify provisions on mutual recognition, equivalence, and harmonization within the SPS measures and TBT chapters in each RTA. To examine the extent to which existing RTAs provide for regulatory cooperation, in general, and in crisis situations, the study adopts the following approach:

(i) Mapping of provisions related to **mutual recognition**, **equivalence**, and **harmonization** of technical regulations, standards, and conformity assessments in SPS and TBT chapters of 107 RTAs.[1] A scoring system is developed, to gauge how binding the provisions are.

(ii) An investigation of temporary provisions for regulatory cooperation during emergency and crisis situations.

(iii) Identification of provisions targeting medical products in specific.[2]

Since this study aims at facilitating the trade of medical products during crisis situations, both SPS and TBT measures could be applicable. Therefore, all three approaches – mutual recognition, equivalence, and harmonization provisions under the SPS and TBT chapters of RTAs respectively will be studied to identify the level of commitment of such provisions.

The scoring system

The scoring system is based on the level of commitment of the RTA provisions, which is related to the level of enforceability of the said agreement text. Based on the methodology put forth by the United Nations Conference on Trade and Development (UNCTAD) (UNCTAD, 2020b), this study examines the enforceability of the RTA provisions on mutual recognition, equivalence, and harmonization, respectively. It is important to note that this study does not apply the methodology of the above-mentioned study in full, *i.e.* does not scrutinize all types of enforceability at a very detailed level not makes clear distinctions on enforcement right, enforcement obligation, recommendation, provisions with weak enforceability, and

unenforceable provisions.[3] Rather the study takes a more generalized approach where it groups different types of enforceability and creates a scoring system from a scale of 0 to 4 to rate the level of commitment of Parties to the agreement in promoting regulatory cooperation through mutual recognition, equivalence, and harmonization.

The level of commitment is defined as follows:

- **Score 0** indicates there is no commitment or provisions in RTA text on regulatory cooperation in terms of mutual recognition, equivalence, and harmonization;
- **Score 1-2** indicates a commitment from level low to high, where it encompasses provisions that are either considered as unenforceable or serve as recommendations;
- **Score 3** indicates that an RTA contains a stronger commitment level where the provisions are considered as having either weak enforceability or have an enforceable obligation; and
- **Score 4** indicates that an RTA contains the strongest commitment level, where the provision not only shows enforceable obligation but also provides a detailed implementation schema.

Detailed criteria to define the level of commitment of RTA provisions on mutual recognition and/or equivalence provisions on standards and conformity assessments is presented in Appendix 1 and that towards harmonization with international/regional standards or country good practices is listed in Appendix 2.

The scoring system was developed only for the purpose of this study. It does not intend to provide any legal interpretation of the provisions. Neither does it discuss whether the languages used in the agreement text will have a legal effect under international law and in the context of a dispute. The scoring system was elaborated simply for identifying RTA provisions that constitute a strong commitment or a good practice to ease regulatory burden in times of crisis. Since the analysis is based on the review of the legal text of the RTAs, limitations exist in assessing the actual implementation of the relevant provisions. Furthermore, the analysis does not take into account separate Mutual Recognition Agreements (MRAs) or any other stand-alone agreements unless they are part of the RTAs mentioned in the agreement texts.

The main findings from the review of RTAs in terms of mutual recognition, equivalence, and harmonization are summarised below. The reviews had a specific focus on the level of commitment for technical regulations, standards, and conformity assessments; the existence of temporary mutual recognition, equivalence or harmonization provisions or emergency provisions; and the existence of provisions on regulatory cooperation specific to medical goods. RTAs with provisions that have scored highly which could serve as model provisions are presented in Appendix 3.

A. Mutual recognition of technical regulations, standards, and conformity assessments

For the total 107 RTAs studied, 71 per cent (76 RTAs) have mutual recognition provision on conformity assessments under the TBT chapter (see Figure 4). Out of those, 17 per cent (18 RTAs) mention mutual recognition of conformity assessments along with mutual recognition on technical regulations and/or standards (see Figure 5). There are no RTAs that mention mutual recognition of technical regulations and/or standards alone without mentioning conformity assessments at the same time.

In total, around 46 per cent (64 RTAs) score relatively high (i.e. grade 3 and 4) with regards to the commitment level of mutual recognition of conformity assessment. These agreements often stipulate that Parties shall *"encourage their conformity assessment bodies/accreditation bodies to promote mutual acceptance of conformity assessment results"* or they should also recognize conformity assessment bodies outside their country as *"no less favorable than those in its own territory"*.[4] Only a few RTAs (around 6 per cent) go beyond this commitment level by specifying detailed strategies or implementation schema of accepting conformity assessment results or procedures.[5] A couple of RTAs such as the Japan–Thailand Free Trade Agreement (FTA) (2007) have a horizontal chapter on mutual recognition with detailed commitments

Figure 4. Level of Commitment for mutual recognition provision on conformity assessments under the Technical Barriers to Trade chapter

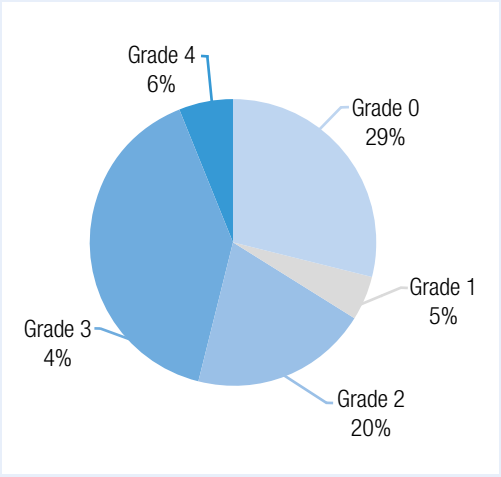
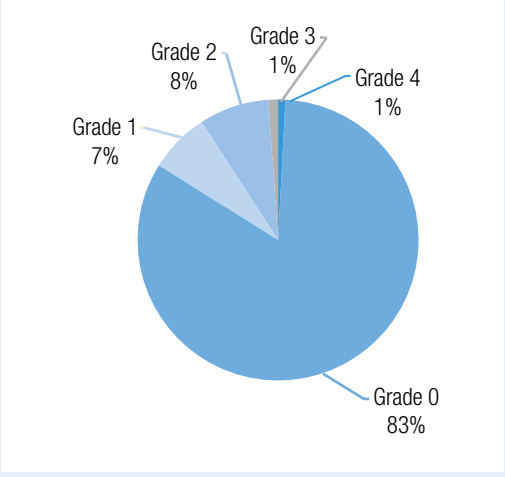


Figure 5. Level of commitment for mutual recognition provision on technical regulation and/or standards under the Technical Barriers to Trade chapter



Source: Authors' estimates.

where Parties accept results of conformity assessment procedures conducted by registered/accredited conformity assessment bodies.[6]

Regional trade agreements promoting both mutual recognition of standards and conformity assessments are mainly concluded by countries with similar development statuses including the European Union, Australia, Singapore, and Japan (***i.e.*** the European Union–Canada RTA (2017), the European Union–Singapore RTA (2019), the European Union–Japan (2019), etc.).

Among these agreements, the New Zealand–Singapore RTA (2001) is ranked the highest (grade 4), where it does not only exhibit a high level of commitment through the "wording" of the text but also puts forth an implementation scheme (see Box 1). Furthermore, the agreement covers mutual recognition of conformity assessment results for a wide range of sectors including electrical products, telecommunications equipment, and food products.

Another agreement, the Singapore–Australia (2003) FTA also agrees on mutual recognition of conformity assessment results for food products and further makes reference to the Sectoral Annex on Medical Devices, where it stipulates the requirements for the preparation, adoption, and application of technical regulations, standards, conformity assessment procedures of medical devices between signature Parties.[7]

In terms of the SPS chapter, mutual recognition on either standards and/or conformity assessments is not mentioned explicitly, probably because the nature of mutual recognition relates more to the objective of TBT than SPS (Trivedi et al., 2019). However, the implication is just as relevant for SPS measures as for TBT measures. The agreements checked do mention mutual understanding of each other's rules and regulatory processes, which is more related to the concept of equivalence presented in part B of this Chapter *"Equivalence of technical regulations, standards, and conformity assessments"*.

Based on the results of the analysis, it can be observed that mutual recognition of conformity assessment is more prevalent than mutual recognition of standards. The RTAs reviewed in this study suggest that it is easier to establish mutual recognition of conformity assessment than for standards.

Box 1. A high-score example: Mutual recognition of standards and conformity assessment under the Technical Barriers to Trade chapter of the Singapore-New Zealand Regional Trade Agreement (2001)

Article 40 – Mutual recognition of equivalence of mandatory requirements (Grade 4)

Applicability

2 Under this Article, mutual recognition shall affect certain laws relating to the products of the Party where the products are intended for supply. Such laws may, unless otherwise provided in the Product Chapters, include: a) requirements relating to production, composition, quality or performance of a product; b) requirements that a product satisfy certain standards relating to presentation such as packaging, labelling, date or age stamping; and c) requirements that products be inspected, passed or similarly dealt with.

Article 41 – Mutual recognition of conformity assessment (Grade 4)

General Obligations

2 Each Party recognises that the conformity assessment bodies designated by the other Party in accordance with this Article are competent to undertake the conformity assessment activities necessary to demonstrate compliance with its mandatory requirements.

3 New Zealand shall accept the results of conformity assessment activities to demonstrate conformity of products and/or manufacturers with its mandatory requirements when the conformity assessment activities are undertaken by conformity assessment bodies designated by Singapore's designating authorities in accordance with this Article.

4 Singapore shall accept the results of conformity assessment activities to demonstrate conformity of products and/or manufacturers with its mandatory requirements when the conformity assessment activities are undertaken by conformity assessment bodies designated by New Zealand's designating authorities in accordance with this Article.

5 This Article shall not require mutual acceptance of the mandatory requirements of each Party, or mutual recognition of the equivalence of such mandatory requirements. The Parties shall, however, give consideration to increasing the degree of harmonisation or equivalence of their mandatory requirements, where appropriate and where consistent with good regulatory practice. Where both Parties agree that the mandatory requirements are harmonised or established as equivalent, the results of conformity assessment that demonstrate compliance with the exporting Party's mandatory requirements shall be accepted as demonstrating compliance with the importing 33 Party's mandatory requirements without the need for further conformity assessment by the importing Party to demonstrate compliance with its own mandatory requirements.

[.....]

(New Zealand-Singapore RTA, 2001, Article 40)

B. Equivalence of technical regulations, standards, and conformity assessments

Out of the 107 RTAs reviewed, 41 per cent (45 RTAs) include an Equivalence Provision under the SPS chapter (Figure 6) for standards, conformity assessments, or both. Most RTAs with an Equivalence Provision fall under grade 3 where the RTA text indicates a rather strong level of commitment by using wordings such as "shall" or "will" in the provision's text.

High grades for the level of commitment of Equivalence Provision under the SPS Chapter mainly come from RTAs concluded by the European Union, New Zealand, Australia, and China (*i.e.* Australia–China RTA, the European Union–Georgia RTA, etc.).[8] Box 2 presents a sample Equivalence Provision that has a higher commitment level.

Figure 6. Level of commitment for equivalence provision under the Sanitary and Phytosanitary chapter

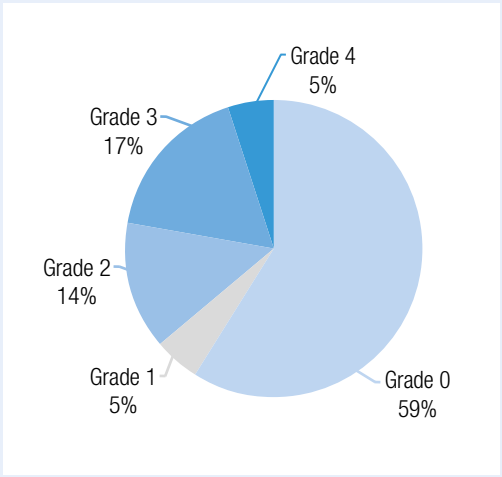
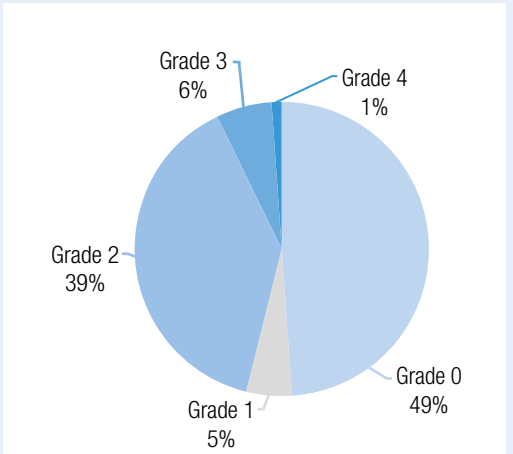


Figure 7. Level of commitment for equivalence of technical regulations and/or standards under the Technical Barriers to Trade chapter



Source: Authors' estimates.

Equivalence provisions have its advantages in that it 'tolerates' regulatory diversity and permits different rules among members. In times of crisis, this type of provision will avoid duplication of conformity assessment procedures (*i.e.* testing, inspection, etc.) and will eventually save time and resources for both importing and exporting countries for critical and time-sensitive products. However, it is also important for Parties to keep in mind that "equivalence" does not mean "exactly the same" of policy measures (which would then go against the nature of this policy tool) but demonstrates an *"appropriate level of protection"*.

Out of 107 RTAs checked, 51 per cent (55 RTAs) contain provisions on equivalence for the TBT chapter, *i.e.* those that encourage acceptance of other members' technical regulations and standards as equivalent (see Figure 7). The majority of these RTAs received a grade 2, where the text mentions that Parties of the RTAs *"shall give positive consideration* to accepting as equivalent *technical regulations and/or standards of the other Party"*, even though they are different from their own, provided that they *"adequately fulfill the objectives of its own regulations"*.

Among the RTAs with a provision on equivalence for standards and technical regulations, only 15 per cent (8 RTAs) received high grades (3 and 4). These provisions are mainly concluded by the European Union (*i.e.* the European Union–Japan (2019), the European Union–Canada (2017), the European Union–Georgia (2014), the European Union–Ukraine (2014), etc.), where it specifies not only the recommendation for adopting technical regulations/or standards as equivalence when the Parties of the agreement *"have the same objectives and product coverages"* but also promotes transparency, in the case that Parties do not recognize technical regulation or standards as equivalent, *"shall explain reasons for its decision"*. Such requirements are either common for countries with similar development statuses such as the European Union, Canada, Japan, and the United States, or it could be common for developing countries to consider as equivalent more developed countries standards or technical regulations (*i.e.* United States–Panama (2012), Canada–Columbia (2011), the Republic of Korea–Vietnam (2015), etc.).

Box 2. A high-score example: Equivalence provision under the Sanitary and Phytosanitary chapter of the European Union–Canada Regional Trade Agreement (2017)

Article 5.6 – Equivalence (Grade 4)

The importing Party **shall accept** the SPS measure of the exporting Party as equivalent to its own if the exporting Party objectively demonstrates to the importing Party that its measure achieves the importing Party's appropriate level of SPS protection.

2. Annex 5-D sets out principles and guidelines to determine, recognise, and maintain equivalence.

3. Annex 5-E sets out:

the area for which the importing Party recognises that an SPS measure of the exporting Party is equivalent to its own; and

the area for which the importing Party recognises that the fulfilment of the specified special condition, combined with the exporting Party's SPS measure, achieves the importing Party's appropriate level of SPS protection.

(The European Union-Canada RTA, 2017, Article 5.6)

In these two groups (with a grade of 3 and 4), 4 RTAs mention explicitly mutual recognition, approximation, alignment, and equivalence of technical regulation and standards and/or conformity assessment for medical devices and pharmaceutical products.[9] The New Zealand–Taiwan Province of China RTA (2013) suggests bringing forth further implementing arrangements for principles and procedures of technical regulations and conformity assessment for products including medical goods. The European Union–Canada Comprehensive Economic and Trade Agreement (2017) establishes a protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products.

In addition to more stringent commitments on equivalence for technical regulations, these agreements also refer to or suggest the establishment of separate/stand-alone MRAs between the signature Parties to facilitate trade.[10]

The RTA with the highest-ranked equivalence provision is the Australia–Singapore RTA (2003) which, aside from using higher commitment 'language/wording' such as *'shall'*, provides a Sectoral Annex with detailed procedures for implementing mandatory requirements and accepting conformity assessment results especially for food products (see Box 3).

In comparison to equivalence on technical regulations and standards, RTAs with provisions covering equivalence of conformity assessment are much less prevalent. Only 28 per cent (30 RTAs) out of 107 have mentioned this aspect. Such RTAs are normally concluded by New Zealand, Australia, the European Union, the Eurasia Economic Union, the United States, and Singapore.

For the case of Singapore's agreements with New Zealand (2001), Australia (2003), and India (2005), the Parties commit to accepting as equivalence the results of conformity assessment and approval procedures that are conducted by registered/designated conformity assessment bodies of the exporting party. In practice, this means when both Parties agree that their technical requirements or standards are considered as equivalent (or harmonized), the results of the conformity assessment which demonstrate compliance with the exporting country's requirement or standards will be accepted as compliant with the importing country's requirements or standards as well without the need of for conducting further conformity assessment by the importing country.

In theory, the equivalence of technical regulations and conformity assessments differs from mutual recognition of technical regulations and conformity assessments, as equivalence requires that Parties fulfill the same objectives whereas mutual recognition may not require that the requirements are "equivalent".

Box 3. A high-score example: Equivalence of technical regulations/standards under the Technical Barriers to Trade chapter of the Australia–Singapore Regional Trade agreement (2003)

Article 5 – Equivalence of mandatory requirements (Grade 4)

[….]

2. A Party shall accept the equivalence of the mandatory requirements, and/or the results of conformity assessment and approval procedures, of the other Party in accordance with the respective Sectoral Annex.

3. For the purposes of Article 5.2, a Sectoral Annex shall provide the following details:

(a) the procedures for determining and implementing the equivalence of each Party's mandatory requirements; and/or

(b) the procedures for accepting the results of the conformity assessment and approval procedures; and

(c) the regulatory authorities designated by each Party.

(Australia–Singapore, RTA, 2003, Article 5)

Nevertheless, in practice, Parties often will not mutually recognize each other's regulations and standards if they do not guarantee the same level of protection and outcome (Veggel & Elvestad, 2004).

C. Harmonization/or referencing to international standards/regional standards or national standards

In light of the RTAs reviewed, countries have adopted either unilateral, bilateral, or multilateral approaches in addressing regulatory divergence. Specifically, in terms of harmonization, these approaches can be distinguished by reference to international standards/conformity assessments or foreign country (including regional) standards/conformity assessments. RTA Parties often recommend or request their national standards bodies to follow, align, adopt or recognize as equivalent 1) international standards issued by international standardizing bodies such as Codex Alimentarius, IPPC and OIE for SPS measures and ISO, IEC, etc. for TBT measures, or; 2) foreign standards issued either by regional standardization bodies such as CEN and CENELEC or individual countries with advanced regulatory systems (i.e. the United States, Japan, the Republic of Korea, etc.).

Fifty-five (or 52 per cent) of all RTAs studied contain references to international standards, regional standards, or other members' standards in the SPS chapter (see Figure 8). In this context, many RTAs also try to specify what is meant by international standards (i.e. Codex, OIE, IPPC).

Although approximation, alignment, and harmonization of standards in the SPS chapter are promoted in over 50 per cent of RTAs checked, the RTAs do allow a margin of discretion, where it states that Parties are encouraged to harmonize with international standards whenever possible, and in a situation where national standards deviate from international standards, rational scientific evidence shall be provided to justify the use of *"a level of protection higher than that which would be achieved by measures based on an international standard, guideline or recommendation."* Box 4 provides an example of a highly scored RTA signed by India–Malaysia (2001).

As for the TBT Chapter, 65 per cent (70 RTAs) recommend adopting international standards/regional standards and/or harmonization of standards at different levels (international, regional, or national) for rules and conformity assessments. The majority of RTAs in this group recommend the adoption of international standards in comparison to regional or national standards. These agreements often refer to the WTO TBT Agreement where it recommends that Parties *"shall ensure that international standards, guides, and recommendations are likely to become the basis for technical regulations and conformity assessment procedures"*.

Figure 8. Harmonization or referencing to international/regional or national standards under the Sanitary and Phytosnitary chapter

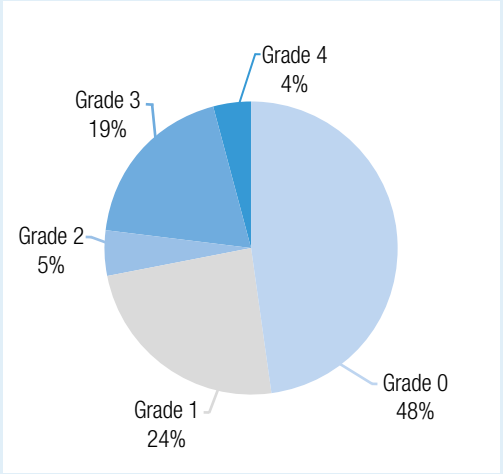
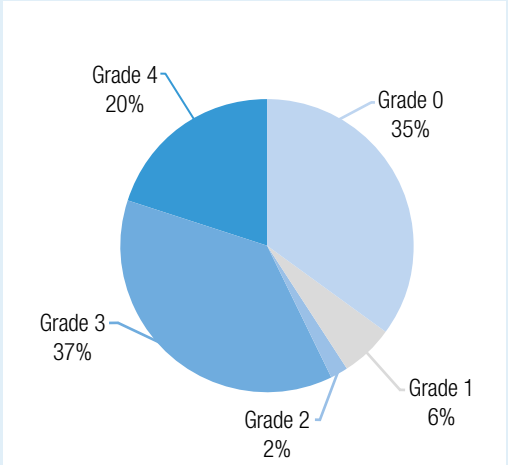


Figure 9. Harmonization or referencing to international/regional or national standards under the Technical Barriers to Trade chapter



Source: Authors' estimates.

For the above mentioned 70 RTAs, about 37 per cent of examined RTAs use languages that reaffirm Parties' relatively strong commitment (grade 3) towards the adoption of international standards/regional standards, by clearly indicating "Parties shall" or "Parties will" (see Figure 9). Around 20 per cent (21 RTAs) exhibit the highest level of commitment (grade 4), where the provision states that international standards/regional standards shall be adopted unless there are *"substantial reasons based on scientific or technical information why such international standards, practices or guidelines should be ineffective or inappropriate for the fulfilment of legitimate objectives pursued."* This is the case for instance for most agreements signed by the European Union, China, New Zealand, and Singapore.[11]

Box 4. A high score-example: Harmonization of international standards under the Sanitary and Phytosanitary chapter of the India–Malaysia Regional Trade Agreement (2011)

Article 6.5 – International standards and harmonization (Grade 4)

1. Each Party shall use international standards, guidelines or recommendations as the basis for its SPS measures, in order to harmonize them.

2. Notwithstanding paragraph 1, the Parties may adopt SPS measures that offer a level of protection higher than that which would be achieved by measures based on an international standard, guideline or recommendation, if there is scientific justification. Provided that, in the event a Party adopts a level of protection different from that which would be achieved by measures based on an international standard, guideline or recommendation, it shall, when requested, provide the other Party within thirty working days of such request and explanation of its scientific justification, except confidential data for the reasons for such higher standards.

(India–Malaysia RTA, 2011, Article 6.5)

In comparison to making references to international or regional standards, RTAs that call for harmonization are much less prominent. Out of the 107 RTAs, only 25 per cent (27 RTAs) mention specifically harmonization for TBT objectives, where the type and level of commitment notably differ. Most RTAs promote equivalence of technical regulations and standards, and/or mutual recognition of results of conformity assessment. The European Union is the main Party that favours its trading partner to harmonize their regulations, standards, and accreditation processes to the European Union system. This approach has been promoted in RTAs signed by the European Union with neighbouring countries in the region, or with developing countries where the technical development gap is large. The agreements signed by the European Union with Serbia (2013), Georgia (2014), Ukraine (2014), Republic of Moldova (2014), Ghana (2016), Armenia (2018) mention respectively, that the signature Party *"shall take measures necessary to gradually achieve approximation"* with the European Union's technical regulations and conformity assessment for certain product sectors (often covers the majority sectors such as electronic and electric equipment, machinery, and medical devices). In addition, these agreements further state that the other Party shall use *best endeavours* to ensure that their national standards progressively transposes to European standards.

Compared to equivalence and mutual recognition for regulatory cooperation, harmonization on standards and conformity assessment could be more difficult to achieve, as this means countries implement exactly the same measures on the same regulatory goals. Nevertheless, harmonization would not require any prior in-depth examination of each other's regulatory measures, which is not the case for mutual recognition. If harmonization is encouraged as an approach for regulatory cooperation, the importance of technical assistance to Parties with less technical and institutional capacity cannot be emphasized enough.

For example, for the above-mentioned agreements signed by the European Union and neighbouring countries, although harmonising with the European standards would provide a positive push for promoting exports to the European Union, the cost of harmonisation might be high and it would be difficult for developing-country partners to technically meet with European standards if they lack the capacity in doing so. In reality, the European Union offers both financial and technical assistance to its neighbouring countries to help them progressively transpose the corpus of European standards as national standards. This could, in turn, increase the benefits from the harmonization of standards and conformity assessments between countries.[12]

D. Other findings

1. Regulatory cooperation specific to medical goods

With respect to medical and pharmaceutical products, 17 RTAs mention explicitly either in the RTA text or Annexes about regulatory cooperation in this area.[13] Harmonization of regulatory requirements and activities of medical products through collaboration with international and/or regional initiatives have been promoted by the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (2018), the Eurasian Economic Union (EAEU) Treaty (2015), and the Australia–Singapore FTA (2003). The European Union–Georgia Association Agreement (2014) puts forth that Georgia shall approximate its technical regulations, standards, and conformity assessment in various sectors including medical devices and pharmaceutical products to the European Union standards and technical regulations.

The Canada–the Republic of Korea FTA (2015), the European Union–the Republic of Korea FTA (2011), and the European Union–Singapore FTA (2019) have gone one step further of committing Parties to base their technical regulations and standards for medical products on international standards, practices, and guidelines developed by the World Health Organization (WHO), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Global Harmonization Task Force (GHTF), the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and the Organisation for Economic Co-operation and Development (OECD) (including those related to Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)), useless they can provide scientific evidence that such standards, guidelines, and practices are *'ineffective or inappropriate'* for the fulfillment of legitimate objectives.

In terms of mutual recognition of standards or results of conformity assessment for medical goods, 5 RTAs commit at different levels to strengthen/promote mutual recognition of standards and to give considerations in accepting conformity assessment results of the other Party.[14]

The remaining 10 RTAs[15] also mention other aspects of regulatory cooperation that include committing to establish a working group for medical products to ensure transparency in regulatory procedures for medical goods; facilitate information exchange aiming at building mutual confidence in each other's regulatory measures, and; establish special schemes for registration of generic medical products.[16]

Full list of exemplary medical products specific provisions can be found in Appendix 4.

2. Temporary provisions/clauses on mutual recognition, equivalence, and harmonization in times of crisis

None of the RTAs studied contain temporary or emergency provisions on mutual recognition, equivalence, and harmonization on either standards or conformity assessments to ease regulatory burden during crisis situations.

There is, however, a provision titled the Emergency Provision under the SPS chapter. This provision allows Parties to the agreement to apply emergency SPS measures when urgent problems of health protection arise or threaten to arise. In fact, 17 out of 107 RTAs (around 16 per cent) feature such a provision, most mentioning that the signature party *"may, without previous notification, take measures necessary to protect human, animal or plant life or health"* and the importing Party *"shall consider the most suitable and proportionate solution in order to avoid unnecessary disruptions to trade for consignments in transport between the Parties"*. It is also common for such provisions to encourage members of the agreement to take into account interests from the public and from other Parties of the RTAs, as well as scientific evidence when determining their responses to the emergency. Terms such as *'allow Parties to submit comments'*, *'engage in technical consultation'*, *'only adopt measures based on scientific evidence or; in case of insufficient scientific evidence; on available pertinent information such as from relevant international organizations'*, *'consider consignments in transport between the two Parties at the time of adoption of the emergency measure to avoid unnecessary disruption to trade'*, *'take risk assessment'*, *'consider options for the facilitation of the implementation of the replacement of the measures'* are often mentioned in the provision text (see Box 5).

This provision by nature does not promote regulatory cooperation. Rather it provides justification for countries in more preventive measures in times of crisis to protect human, animal, and plant life and health. Nevertheless, the provision does not intend to increase the burden to trade either, as it further specifies that countries adopting emergency measures should promptly inform the other Parties to the agreement, and to hold consultations to discuss the reason behind it as well as providing *scientific evidence* to avoid disruption in trade.

Box 5. An example: Emergency provision under the Sanitary and Phytosanitary

Article 7.14 - Emergency Measures

1. If a Party adopts an emergency measure that is necessary for the protection of human, animal or plant life or health, the Party shall promptly notify the other Parties of that measure through the primary representative and the relevant contact point referred to in Article 7.6 (Competent Authorities and Contact Points). The Party that adopts the emergency measure shall take into consideration any information provided by other Parties in response to the notification.

2. If a Party adopts an emergency measure, it shall review the scientific basis of that measure within six months and make available the results of the review to any Party on request. If the emergency measure is maintained after the review, because the reason for its adoption remains, the Party should review the measure periodically.

(Comprehensive and Progressive Agreement for Trans-Pacific Partnership, 2018, Article 7.14)

IV.

Case studies of regulatory cooperation during COVID-19

This chapter identifies and assesses nine cases (Brazil, Canada, Kenya, Kuwait, European Union, Namibia, Switzerland, Uganda, and United States) whereby governments took measures for regulatory cooperation in terms of mutual recognition, equivalence, and harmonization with an aim to ease regulatory burden and facilitate trade in medical products during the pandemic. These cases were selected after reviewing WTO SPS and TBT notifications, media presses and government websites. The country cases serve as a base for finding a gap between existing RTAs and countries' actual practices. Also, the findings from country cases strengthen the recommendations in chapter V.

1. Countries resorted to equivalence and harmonization. No countries established new mutual recognition.

Brazil, Canada, the European Union, Kenya, Switzerland and the United States accepted standards or conformity assessment of other countries as equivalent to their own. First, the countries declared emergency pursuant to a national act addressing public health such as the Public Health Service Act in the United States. Then, the countries either invoked an emergency system that is already embedded in the domestic law such as the Food, Drug, and Cosmetic Act in the United States, or enacted or revised domestic regulations such as National Health Surveillance Agency's Resolution in Brazil. Under the emergency system, or pursuant to such domestic regulations, equivalence was introduced to relax import requirements.

Kuwait, Namibia, and Uganda harmonized their standards with foreign countries or international organizations. Where there was a need for adequate standards or conformity assessments to ensure the safety and quality of the medical products of concern, the countries adopted those of foreign countries or international organizations, rather than developing their own.

No country used mutual recognition as an emergency practice. However, mutual recognition provisions and agreements that have existed before the COVID-19 outbreak could have contributed to facilitate trade in medical goods. For example, the European Union has established MRAs concerning conformity

assessments with seven countries and Canada with two individual countries and two country groups. However, considering that the medical products necessary to cope with COVID-19 are more in number than those generally covered by the MRAs, the contribution of existing MRAs may not have been all-sufficient.

2. Countries used standards and conformity assessments of foreign countries or international organizations as a reference.

When undertaking regulatory cooperation, countries referred to standards or conformity assessments made by foreign countries or international organizations. For example, COVID-19 Rapid Test Kits approved or registered in South Africa, Australia, Brazil, Canada, the European Union, Japan, or the United States can be imported to Kenya under the Emergency and Compassionate Use Authorization. Also, Brazil took a measure to accept the Quality Management System of Medical Device Single Audit Program (MDSAP) or ISO as the replacement for its health agency's GMP Certification. The following categories of reference sources were commonly used:

a) Countries with an advanced regulatory system in the world such as the European Union, the United States, etc.;

b) Countries with advanced regulatory systems in a region such as Mexico, South Africa, etc.;

c) Countries that are members of an association such as International Medical Device Regulators Forum (IMDRF), MDSAP, PIC/S, etc.; and

d) International organizations such as IEC, ISO, World Health Organization (WHO), etc.[17]

3. Equivalence was applied temporarily, while harmonization was not.

Among the nine cases, all equivalence measures were imposed with an end date, while those for harmonization did not have any such indication. Countries define the end date differently, ranging from listing only a condition such as 'until the termination of declaration of emergency' in the United States to specifying the period or date such as '180 days' in Brazil or 'September 13' in Switzerland.

4. Countries used a targeted measure for regulatory cooperation of specific goods.

All the countries imposed equivalence or harmonization targeting specific medical goods. Countries defined the goods subject to a measure with tariff line codes or product descriptions. For example, Canada described drugs subject to exceptional importation and sale and made a list specifying medicinal ingredients, dosage, country of origin, etc.

5. Countries accompanied their measures for equivalence with complementary measures.

To ensure that equivalence or harmonization measures do not result in product quality being compromised, countries made use of complementary measures. For example, instead of accepting a certificate of foreign countries as equivalent to its own, the importing country such as the United States undertook market surveillance and monitoring.

6. Countries took equivalence or harmonization with respect to either standards or conformity assessments, or both.

Products, parts, raw materials, or suppliers at any stage of a product life cycle can be subject to standards or conformity assessment as can be seen in product specification, performance standards, GMP certification, and pre-market registration. It is not easy to distinguish standards and conformity assessment in real examples because regulations do not make clear and explicit distinctions. It happens often that a regulation is named only as 'standards' although it refers to both standards and conformity assessment procedures. For example, six 'standards' adopted by Kuwait concerned both standards such as the use of labelling symbols and conformity assessments such as test methods.

Detailed studies of individual cases are provided in Appendix 8 of this study.

V.

Recommendations for Model regional trade agreements provisions – A menu of possible provisions

A review of RTAs for existing provisions on regulatory cooperation, in general and in emergency situations, coupled with the assessment of country cases during COVID-19 carries important lessons. First, there are gaps between the existing regulatory cooperation provisions in RTAs and what countries actually did during the pandemic. Country cases make for a good reference point in overcoming the shortcomings of existing RTAs. Second, there are other learnings that country cases impart both through their strengths and their weaknesses. Joining all dots, and considering all these strengths and weaknesses, this chapter makes recommendations on how RTAs can pave the way for strengthening regulatory cooperation during medical emergencies.

Assessment of existing RTAs and country cases indicates that RTAs may prove inadequate in addressing public health crises in the following two ways.

- There are no emergency provisions found in RTAs. Countries, on the other hand, define emergency situations and criteria in their national laws to enable them to enact emergency provisions when the need arises. Many countries made use of these laws, declared an emergency, and adopted measures to ease regulatory requirements during a crisis. During the COVID-19 pandemic, it has been witnessed that countries defined the end date of their measures by *e.g.* listing a condition (such as 'until the termination of the declaration of emergency') or specifying the period or date (such as '180 days' or 'September 13'). This – a need to include more temporary provisions which can be invoked under specific clearly-defined "situations" – can be an important takeaway for RTA negotiators.
- Only a small number of provisions targeting medical products have made way into RTAs. Such RTAs normally involve major medical products suppliers such as Canada, the European Union, India, the Republic of Korea, Singapore, and the United States. In other cases, countries have undertaken measures for equivalence and harmonization targeting medical products clearly defined at tariff line

levels and product description. Again, country practices carry an important lesson - i.e. a need to design more concrete and committed regulatory cooperation of medical goods.

A deep dive in-country cases also bring to light two interesting findings which can again feed into RTAs.

- Countries often made **use of complementary measures** when adopting equivalence or harmonization. This was done to ensure that product quality was not compromised as a result of regulatory cooperation. For example, when countries used emergency authorization to accept a certificate of a foreign country as equivalent to its own, they also added additional requirements such as market surveillance and monitoring. Such caveats can ensure that regulatory cooperation helps achieve fruitful outcomes.
- Countries adopted a **unilateral approach** to reduce regulatory divergence, deciding to either adopt international or other countries' standards or simplify their own while ensuring that product quality standards are not compromised. However, a multilateral, regional or bilateral approach would be more efficient in the long term in addressing global health crises. This highlights the need for and the potential of RTAs to be a starting point to encourage countries to consider the benefit of regulatory cooperation. With other Parties to an RTA, which already share an interest in deeper economic integration, it may be easier to come up with coordinated measures to achieve mutual recognition, equivalence or harmonization, than doing so with a country which has less shared interest.

The COVID-19 pandemic has brought to light the criticality of maintaining trade flows of medical supplies during emergencies and the need to avoid unnecessary and counterproductive measures such as export restrictions. RTAs could provide a promising platform for achieving this goal. Yet, in keeping with the above findings, there is a need to negotiate more solid provisions to enhance regulatory cooperation during medical emergencies. Country practices can serve as a useful guideline, with mostly its strengths but also its shortcomings. A set of model provisions for RTAs based on the assessment can be an incredibly useful starting point.

Against the above, this chapter proposes a set of "model" RTA provisions that may serve as a useful starting point to negotiate RTAs, and thus fill existing gaps. This chapter first provides a list of general recommendations that trade negotiators can follow. It then suggests six "Model Provisions" that can be negotiated and incorporated in an RTA.

A. General recommendations for regional trade agreements provisions

The study recommends the following nine general recommendations that negotiators of an RTA may follow:

- Define the criteria for determining a situation of public health emergency.
- Clearly establish a need for regulatory cooperation in situations of "shortage", the existence of "unprecedented demand", etc.
- Clearly define a list of products (at Harmonized System (HS) 6-digit level) to be considered for easing regulatory burden.
- Temporarily adopt international standards as a basis for regulatory cooperation.
- Encourage developing country partner relying on developed country partner's conformity assessment procedures.
- Treat as equivalent standards of jurisdictions with similar regulatory frameworks and eliminating additional inspections AND Recognize foreign country's standards when the product has been evaluated using methods similar to those used by national bodies.

- Forego requirements for labels/marks when there is adequate evidence to believe that the product can ensure an adequate level of health and safety.
- Simplify the import of products manufactured by a foreign entity that carries one or more approval of one's national conformity assessment body for any other product.
- Specify the end date.

The options based on useful country practices adopted during the pandemic that correspond to each of the above recommendations are summarised in Table 1.

Table 1. Emergency provisions based on country practices

Recommendation	Cues for regional trade agreements provisions
Define the criteria for determining a situation of public health emergency	**The United States Emergency Use Authorization:** *"Public health emergencies, or situations where a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a chemical, biological, radiological and nuclear agent or agents, or a disease or condition that may be attributable to such agent(s)"*
Clearly establish a need for regulatory cooperation in situations of "shortage", the existence of "unprecedented demand", etc.	**Canada Interim Orders:** Where manufacturers and importers of products under questions *"notify the Minister of Health about shortages of those medical devices within five days of becoming aware of a shortage in progress or of an anticipated shortage"*
Clearly define a list of products (at HS 6 digit level) to be considered for easing regulatory burden	**The United States Emergency Use Authorization**: In such emergency situations, *"a List of Medical Devices for Exceptional Importation and Sale known as 'designated medical devices' will be made available"*
Temporarily adopt international standards as a basis for regulatory cooperation	**Brazil National Health Surveillance Agency (ANVISA) Resolutions:** *"For situations in which the manufacturing company does not have the Certification of Good Manufacturing Practices issued by ANVISA, the Medical Device Single Audit Program (MDSAP) or ISO Quality Management System Certification will be exceptionally replaced".*
Encourage developing country partner relying on developed country partner's conformity assessment procedures	**Brazil ANVISA Resolutions:** *"directly accept certification of ventilators and other medical devices under MDSAP and novel medical devices and PPE not regulated in Brazil but that are authorized in jurisdictions of other members of the International Medical Devices Regulators Forum (IMDRF), an international forum on future directions in medical device regulatory harmonization."* *"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 labelling and conditions of supply and/or use "* Note: MDSAP is an international quality management systems evaluation program for medical device manufacturers that market their products in Australia, Brazil, Canada, Japan, and/or the United States.
Treat as equivalent standards of jurisdictions with similar regulatory frameworks and eliminating additional inspections. and Recognize foreign country's standards when the product has been evaluated using methods similar to those used by national bodies	**The United States Emergency Use Authorization:** *"allow the use of non-NIOSH approved FFRs from specific countries "where the devices are evaluated using methods similar to those used by NIOSH and are expected to provide adequate protection for healthcare personnel". These countries and regions included Australia, Brazil, Europe, Japan, Republic of the Republic of Korea, and Mexico."*

Table 1. Emergency provisions based on country practices *(Cont.)*

Recommendation	Cues for regional trade agreements provisions
Forego requirements for labels/marks when there is adequate evidence to believe that the product can ensure adequate level of health and safety	**The European Union Commission Recommendation (EU) 2020/403:** "Where market surveillance authorities find that PPE or medical devices ensure an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC or Regulation (EU) 2017/745, even though the conformity assessment procedures, including the affixing of CE marking have not been fully finalised according to the harmonised rules, they may authorise the making available of these products on the Union market for a limited period of time and while the necessary procedures are being carried out." **Canada Interim Orders:** Certain drugs and medical devices that meet prerequisites can be listed upon application as eligible for exceptional importation and sale for a limited period of time, even though they may not fully meet regulatory requirements to be imported and sold in Canada such as bilingual labelling.
Simplify import of products manufactured by a foreign entity that carries one or more approval of one's national conformity assessment body for any other product	**The United States Emergency Use Authorization:** *"Disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals, have been verified by FDA for FFRs and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country"*
Specify the end date	**Brazil ANVISA Resolutions:** *"This Resolution is valid for 180 (one hundred and eighty) days."*

B. Model regional trade agreements provisions

This section presents a streamlined version of all recommendations in the form of "model provisions" that can serve as a basis for negotiating RTAs.

Model provisions

Example 1. *During [the emergency situation], Parties would consider a request to recognize the results of conformity assessment procedures conducted by bodies in the other Party's territory.*

> Such a provision will provide a solid basis for Parties to formally approach the other party seeking flexibility on conformity assessment procedures. By including such a mechanism in an RTA, the process will become smoother and quicker and more importantly, have more legitimacy.

Example 2. *Parties [shall] undertake to agree on a common list of [standards and conformity assessment procedures] for a specified list of critical medical products that can be applicable during [an emergency situation], based on [one-another's standards/standards of member countries to some specified association/international standards].*

> Pre-defined criteria within an RTA will make the process of regulatory cooperation quick and smooth by ensuring that no time is wasted on negotiations and deliberations during an emergency when time is of utmost essence. This will also ensure that countries have a reliable set of agreed-upon basis to ensure trade flows without the need to resort to extreme measures such as export bans.

Example 3. *During [the emergency situation], [agreeing] Parties [shall] treat as equivalent/recognize [standards and conformity assessments procedures] of another Party to the agreement if the latter [has similar regulatory system/is recognized or treated as equivalent by other countries with similar regulatory systems/is a member of a specified association or international organizations] for [medical] products included in a pre-defined list of critical products for [XX days/a number of days considered suitable and necessary at that point in time, provided the following conditions are satisfied […].*

Countries that are members of a specific international association, such as an international medical body, share a common understanding and appreciation of relevant international laws. They also tend to have similar goals. Yet, their regulations can be different due to their respective national legal systems. Likewise, countries with otherwise similar regulatory systems can have some distinctive import regulations which the other country may not have, without necessarily ensuring a better product quality *vis-a-vis* the other country. While a permanent harmonization of regulations in such cases can take significant time, the inclusion of such a provision in an RTA will at least help them trade on a temporary basis.

Example 4. *During [the emergency situation], if a Party recognizes [standards and/or conformity assessment procedures] of [other Parties/member countries to an association/international organizations], in addition to those specified in the common list, the Party [shall] notify other Parties of its decision within [XX number of days] of such recognition.*

In times of crisis, the importance of ensuring transparency in regulatory measures cannot be over emphasized. For example, during emergencies, when countries might need to adopt new legal measures on a daily basis, it is important for all countries to be made aware of each other's actions on a timely basis so that they can assess how it impacts them. Transparency is the key to coordinated action.

Example 5. *[Upon the development of emergency situations], Parties [shall] review [standards and/or conformity assessment procedures] within a period of [XX days] from the day when the emergency is first established.*

When a medical emergency arises, quick action is required to make sure that access to essential medical products is not hampered, and the health of the population is not compromised. It is also important to ensure that countries do not impose unnecessary restrictions on trade. With governments already reeling under pressure to ensure necessary economic and medical support to its citizens, it may take time to act on negotiations with trading partners. Such a provision ensures that the process can be expedited, by providing for a reasonable time frame for countries to review their standards and procedures.

Example 6. *During [the emergency situation], Parties shall establish [emergency registration/licensing/certification scheme] for the other Parties provided their products have been evaluated and approved by anyone of the regulatory authorities in [Any advanced country: specify a list of countries, e.g., the United States, the United Kingdom, Australia, the European Union, and Canada].*

Advanced countries like Australia or the European Union tend to have higher product standards. As such, their standards can be taken as a benchmark at the time of emergencies to avoid unnecessary bottlenecks that may arise if an exporting country has to show compliance with the standards of each country it exports to. In such cases, if a country has already exported to an advanced country, other lesser advanced importing countries could be open to allowing imports from it based on simple, basic checks and procedures. This will save time while also ensuring quality.

C. Conclusion

The need for strengthening regulatory cooperation is stronger now than ever as the COVID-19 pandemic has revealed loopholes in the current trading system and the lack of provisions and mechanisms to strengthen regulatory cooperation in times of crisis. The pandemic saw many countries adopt unilateral measures aimed at simplifying or eliminating unnecessary or burdensome technical regulations. While this was a useful approach, it required additional investment in already difficult times. Witnessing this, a need to better prepare to deal with crises and the demand-supply gaps they create has arisen.

The current bilateral and/or regional trading framework in the form of RTAs does provide a basis for this. However, what needs to be built-into the RTAs of the future are emergency clauses or provisions so that coordinated action can be encouraged during crises. Steps taken by countries already provide cues in this direction. At the same time, such temporary approaches are less burdensome for Parties *vis-à-vis* more complete and holistic forms of regulatory cooperation.

This study has attempted to propose such emergency provisions based on the country practices in times of crisis to form key pillars of these recommendations. To further strengthen these proposals, a study of the actual benefits of these country practices during COVID-19 would add value. Ascertaining the extent to which these measures contributed to the availability of medical goods, specifically in middle and low-income countries will help test whether efforts to reduce regulatory divergence were effective at all, and which ones stood out. Further, it will also be useful to assess how regulatory cooperation provisions embedded in existing RTAs were, if at all, useful during the pandemic; and if not, what factors prevented their application.

ENDNOTES

1 The analysis is based on an assessment of 107 RTAs that have entered into force after 2010. RTAs of Latin American countries are excluded from the study due to language reasons.

2 In addition to the RTAs entered into force after 2010 which form a basis for the study, other major RTAs from before 2010 which include regulatory cooperation provisions targeting medical products are also identified. Such RTAs include: Canada–Peru (2009), Australia–Chile (2009), Association of Southeast Asian Nations (ASEAN) Trade in Goods Agreement (ATIGA) (2009), New Zealand–China (2008), ASEAN–Japan AJCEP (2008), Japan–Thailand FTA (2007), ASEAN–China (2007), the Republic of Korea–Singapore (2006), United States–Morocco (2006), New Zealand–Thailand (2005), Australia–Thailand (2005), Australia–United States (2005), India–Singapore (2005), United States–Singapore (2004), European Free Trade Association (EFTA) States–Chile FTA (2004), China–Hong Kong CEPA (2003), Australia–Singapore (2003), New Zealand–Singapore (2001). These RTAs either have specific provisions mentioning medical products or have rather comprehensive provisions promoting regulatory cooperation through one or more approaches.

3 Enforceability has been categorized as Enforceable right (Er), Enforceable obligation (Eo), Recommendation (R), Weak Enforceability (WE), Unenforceable (UE) by UNCTAD (UNCTAD, 2020b).

4 The majority of the agreements also incorporate the TBT Agreement on mutual recognition and conformity assessment into their text, reaffirming the rights and obligation of members.

5 These RTAs include the New Zealand–Singapore RTA (2001), India–Singapore RTA (2005), European Union–Canada RTA (2017), New Zealand–Thailand RTA (2005), the Republic of Korea–Singapore RTA (2006), Japan–Thailand FTA (2007), and The ASEAN–Australia–New Zealand Free Trade Area (1993).

6 Chapter 6 Mutual Recognition, Japan–Thailand FTA (2007).

7 Annex 5: Technical Regulations and Sanitary and Phytosanitary Measures, 5-E: Sectoral Annex on Medical Devices, Singapore–Australia FTA (2003).

8 This include: the European Union–Japan (2019), Hong Kong, China–Georgia (2019), China–Georgia (2018), the European Union–Canada (2017), the European Union–SADC (2016), Australia–China (2015), the European Union–Georgia (2014), the European Union–Republic of Moldova (2014), the European Union–Ukraine (2014), New Zealand–Taiwan Province of China (2013), New Zealand–Malaysia (2010), Peru–China (2010), Australia–Thailand (2005), Australia–Singapore (2003), China–Hong Kong CEPA (2003), New Zealand–Singapore CEP(2001).

9 These agreements are namely, New Zealand–Taiwan Province of China RTA (2013), the European Union–Canada Comprehensive Economic and Trade Agreement (CETA) (2017), Australia–Singapore FTA (2003), and the European Union–Georgia RTA (2014).

10 Only a few RTAs incorporate MRAs in its Annexes, most MRAs are stand-alone.

11 Agreements include: Hong Kong, China–Australia (2020), the European Union–Singapore (2019), Eurasian Economic Union (EAEU)–the Islamic Republic of Iran (2019), Hong Kong, China–Georgia (2019), Chile–Indonesia (2019), the European Union–Japan (2019), China–Georgia (2018), Turkey–Singapore (2017), China–the Republic of Korea (2015), Australia–China (2015), Hong Kong, China–Chile (2014), Iceland–China (2014), the European Union–the Republic of Korea (2011), Hong Kong, China–New Zealand (2011), China–Costa Rica (2011), New Zealand–Malaysia (2010), ASEAN–Australia–New Zealand (2010), ASEAN Trade in Goods Agreement (ATIGA) (2009).

12 For instance, the European Union's Technical Assistance and Information Exchange (TAIEX) action programme 2018-2020 under the European Neighbourhood-wide measures to be financed from the general budget of the European Union.

13 The European Union–Singapore (2019), Comprehensive and Progressive Agreement for Trans-Pacific Partnership (2018), China–Georgia (2018), the European Union–Canada (2017), EAEU Treaty (2015), Canada–the Republic of Korea (2015), the European Union–Georgia (2014), New Zealand–Taiwan Province of China (2013), the Republic of Korea–Turkey (2013), the Republic of Korea–United States (2012), the European Union–the Republic of Korea (2011), India–Japan (2011), India–Singapore (2005), Australia–United States (2005), United States–Singapore (2004), Australia–Singapore (2003), and New Zealand–Singapore (2001).

14 These include; New Zealand–Taiwan Province of China (2013), the Republic of Korea–Turkey (2013), the Republic of Korea–United States (2012), the European Union–Canada (2017), and India–Singapore (2005).

15 These include; China–Georgia (2018), the European Union–Canada (2017), New Zealand–Taiwan Province of China (2013), the Republic of Korea–Turkey (2013), the Republic of Korea–United States (2012), India–Japan (2011), India–Singapore (2005), Australia–United States (2005), United States–Singapore (2004), and New Zealand–Singapore CEP (2001).

16 These commitment text come from India–Singapore (2005), United States–Singapore (2004), Australia–United States (2005), and India–Japan (2011).

ENDNOTES

17 These four groups may overlap. For example, IMDRF has ten member countries including Australia which is also a member of MDSAP and PIC/S, as well as being a regional and world champion with an advanced regulatory system. Moreover, international organizations may refer to a country's standards, or vice versa – champions may adopt international standards.

18 A full list of EUAs is available at the website. Center for Devices and Radiological Health. (n.d.). Coronavirus Disease 2019 (COVID-19) EUA. from https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices.

19 Exhibit 1 of the Act is available at the website. Center for Devices and Radiological Health. Personal Protective Equipment EUAs. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas.

20 The list of authorized products for import can be accessed in the Appendix of the following link https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas.

21 PIC/S is an informal cooperative arrangement between Regulatory Authorities in the field of GMP of medicinal products. MDSAP is an international quality management systems evaluation program for medical device manufacturers that market their products in Australia, Brazil, Canada, Japan, and/or the United States.

22 10 member countries as of July, 2020 of the International Medical Device Regulators Forum (IMDRF) are Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, Singapore, the Republic of Korea, and the United States. Additional information about the IMDRF can be accessed at http://www.imdrf.org/about/about.asp

REFERENCES

BBC News (2020). Coronavirus: Countries reject Chinese-made equipment. https://www.bbc.com/news/world-europe-52092395.

Center for Devices and Radiological Health. (n.d.). Coronavirus Disease 2019 (COVID-19) Emergency Use Authorization (EUA). Retrieved July 27, 2020, from https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices.

Center for Devices and Radiological Health. (n.d.). Personal Protective Equipment EUAs. Retrieved July 27, 2020, from https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas.

De Brito, C., Kauffmann, C., & Pelkmans, J. (2016). The contribution of mutual recognition to international regulatory co-operation. *OECD Regulatory Policy Working Papers,* (No. 2)

Emergency Use Authorization (EUA) information (202, and list of all current EUAs. The United States Food and Drug Administration. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-autorization.

Food and Drug Administration. (2020). *Umbrella EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs)* (The United States, Food and Drug Administration). Retrieved July 27, 2020, from https://www.fda.gov/media/136403/download.

German ZLS (Central Body of the Federal States for Safety Technology). (2020). Testing principle for Corona SARS-CoV-2 pandemic respiratory masks. Retrieved July 27, 2020, from http://www.zls-muenchen.de/Corona/Atemschutzmasken/200206_Entwurf_2-Pruefgrundsatz-final_englisch.pdf.

Health Canada. (2020a). Notice: Importation or sale of ventilators - use of the United States FDA guidance and Canadian requirements for authorization under the Interim Order. Retrieved July 27, 2020, from https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/covid19-notice-importation-sale-ventilators.html.

Health Canada. (2020b). Hard-surface disinfectants and hand sanitizers (COVID-19): Disinfectants and hand sanitizers accepted under COVID-19 interim measure. Retrieved July 27, 2020, from https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/products-accepted-under-interim-measure.html.

Health Canada. (2020c). COVID-19 medical masks and respirators: Information for health professionals. Retrieved July 27, 2020, from https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators/health-professionals.html.

Health Canada. (2020d). Explanatory note. Retrieved July 27, 2020, from https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/note.html.

International Medical Device Regulators Forum. (n.d.). About IMDRF. Retrieved July 27, 2020, from http://www.imdrf.org/about/about.asp.

Jensen, Michael Friis; Sela, Shane; Brenton, Paul and Keyser, John (2020). Trade and COVID-19: Streamlining Technical Measures on Medical Products to combat COVID-19. The World Bank Group. http://documents1.worldbank.org/curated/en/304931590509092851/pdf/Streamlining-Technical-Measured-on-Medical-Products-to-Combat-COVID-19.pdf.

Kauffmann, Céline and Nikolai Malyshev (2015). International Regulatory Co-operation: The Menu of Approaches. E15 Initiative. Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, http://e15initiative.org/wp-content/uploads/2015/09/3.-E15-Think-Piece-Regulatory-Coherence-Kauffmann-and-Malyshev.pdf.

REFERENCES

Kuwait WTO TBT Notifications (2020). WTO TBT Notifications G/TBT/N/KWT/539, G/TBT/N/KWT/540, G/TBT/N/KWT/541, G/TBT/N/KWT/542, G/TBT/N/KWT/543, G/TBT/N/KWT/544, G/TBT/N/KWT/546, G/TBT/N/KWT/547, G/TBT/N/KWT/548, G/TBT/N/KWT/549, G/TBT/N/KWT/533, G/TBT/N/KWT/534, G/TBT/N/KWT/535, G/TBT/N/KWT/536, G/TBT/N/KWT/538

Lejárraga, I. (2014), "Deep Provisions in Regional Trade Agreements: How Multilateral-friendly?: An Overview of OECD Findings", OECD Trade Policy Papers, No. 168, OECD Publishing, Paris. http://dx.doi.org/10.1787/5jxvgfn4bjf0-en.

Ministry of Health. (2020). *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* (Canada, Ministry of Health). Retrieved July 27, 2020, from https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.html.

Maryann M. D'Alessandro; John Powers, BS; and Jaclyn Krah Cichowicz (2020) Understanding the Use of Imported Non-NIOSH-Approved Respirators. Centers for Disease Control and Prevention. https://blogs.cdc.gov/niosh-science-blog/2020/04/23/imported-respirators/.

Ministry of Health, Canada (2020). *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19*. Retrieved July 27, 2020, from https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html.

Namibia WTO TBT Notification (2020) WTO TBT Notification G/TBT/N/NAM/2

Namibian Standards Institution. (2020). *Public Enquiry Notice on the setting, establishing and issue of Namibian Standards including their full particulars and the description of each of the Namibian Standards* (No. 147) (Namibia, Namibian Standards Institution). Government Gazette of the Republic of Namibia No. 7186. Retrieved July 27, 2020, from https://gazettes.africa/archive/na/2020/na-government-gazette-dated-2020-04-22-no-7186.pdf.

National Health Surveillance Agency. (2020a). *Resolution RDC No. 346 of 12 March 2020* (Brazil, Ministry of Health, National Health Surveillance Agency). Retrieved July 27, 2020, from https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-346-de-12-de-marco-de-2020-247801951.

National Health Surveillance Agency. (2020b). *Resolution RDC No. 349 of 19 March 2020* (Brazil, Ministry of Health, National Health Surveillance Agency). Retrieved July 27, 2020, from https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-349-de-19-de-marco-de-2020-249028270.

National Health Surveillance Agency. (2020c). *Resolution RDC No. 379 of April 30, 2020* (Brazil, Ministry of Health, National Health Surveillance Agency). Retrieved July 27, 2020, from https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-379-de-30-de-abril-de-2020-254764712.

National Health Surveillance Agency, Ministry of Health, Brazil (2020d). *Resolution RDC No. 392 of May 26, 2020)*. Retrieved July 27, 2020, from https://www.in.gov.br/en/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-392-de-26-de-maio-de-2020-258912696.

OECD (2017), International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264275942-en.

OECD/WTO. (2019). Facilitating Trade through Regulatory Cooperation: The Case of the WTO's TBT/SPS Agreements and Committees. OECD Publishing. doi:10.1787/ad3c655f-en

OECD (2020). Covid-19 crisis underscores the need to address trade in fake pharmaceuticals, say OECD & EUIPO. http://www.oecd.org/health/covid-19-crisis-underscores-need-to-address-trade-in-fake-pharmaceuticals-say-oecd-and-euipo.htm.

Official Journal of the European Union (2020). Retrieved July 27, 2020, from http://data.europa.eu/eli/reco/2020/403/oj.

REFERENCES

Pharmacy and Poisons Board. Ministry of Health, Kenya (2020). *Guidelines for Emergency & Compassionate Use Authorization (ECUA) of Health Products and Health Technologies, Pharmacy and Poisons Board)*. Retrieved July 27, 2020, from https://pharmacyboardkenya.org/covid19-material.

Pharmacy and Poisons Board. (2020). *Requirements for Emergency Use Authorisation of COVID-19 Rapid Test Kits* (Kenya, Ministry of Health, Pharmacy and Poisons Board). Retrieved July 27, 2020, from https://infotradekenya.go.ke/media/COVID%2019%20RAPID%20TEST%20KITS%20(1).pdf.

Schroder, H. Z. (2011). *Harmonization, equivalence and mutual recognition of standards in WTO law* (Vol. 36, Global trade law series). Alphen aan den Rijn: Kluwer Law International.

SECO - Staatssekretariat für Wirtschaft. (2020, July 10). FAQ Atemschutzmaske und andere PSA. Retrieved July 27, 2020, from https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit/produktesicherheit_faq_covid19.html.

Swiss Federal Council. (2020). *Ordinance 3 on Measures to Combat the Coronavirus (COVID-19)* (SR 818.101.24) (Switzerland, Swiss Federal Council). Retrieved July 27, 2020, from https://www.admin.ch/opc/en/classified-compilation/20201773/index.html.

Swissmedic. (2020). Out-of-Stock – COVID-19 – Authorisations for the temporary import and distribution of human medicines – Update. Retrieved July 27, 2020, from https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/out-of-stock-covid-19.html.

The E15 initiative (2017) Regulatory Coherence and the Multilateral Trading System: Lessons from RTAs and options to promote regulatory convergence. RTA Exchange Dialogues. http://e15initiative.org/events/regulatory-coherence-and-the-multilateral-trade-system-lessons-from-rtas-and-options-to-promote-convergence/.

The World Bank (2018). Regional Trade Agreements. Policy Brief. https://www.worldbank.org/en/topic/regional-integration/brief/regional-trade-agreements.

Trivedi, J., Duval, Y., Bajt, D., & Yoo, J. (2019). Non-Tariff Measures in Regional Trade Agreements in Asia and the Pacific: SPS, TBT and Government Procurement. *Trade, Investment and Innovation Working Paper* No. 03/2019, ESCAP Trade, Investment and Innovation Division, September 2019. Bangkok.

The European Commission. (2020). *Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat* (Vol. 63, OJ L 79I, pp. 1-5) (The European Union, The European Commission).

Uganda Gazette. (2020). General Notice No. 517 and 518 of 2020 on Uganda National Bureau of Standards Notice for the Declaration of Compulsory Standards. Retrieved October 16, 2020, from https://unbs.go.ug//attachments/alerts/1/Gazzette%20on%20facemasks%20standards.pdf.

Uganda National Bureau of Standards. (2020). *Mandatory Facemask Standards Enforcement For Importers* (Uganda, Uganda National Bureau of Standards). Kampala: Uganda National Bureau of Standards. Retrieved July 27, 2020, from https://unbs.go.ug//attachments/alerts/1/UNBS%20ADVER%201%20color%20Mandatory%20face%20Masks.pdf.

Uganda National Bureau of Standards. (2020). *Uganda Standards Catalogue as at 30 June 2020* (Uganda, Uganda National Bureau of Standards). Kampala: Uganda National Bureau of Standards. Retrieved July 27, 2020, from https://unbs.go.ug//attachments/menus/27/Uganda-Standards-Catalogue-as-at-30-June-2020.pdf.

UNCTAD. (2018). Regional Integration and Non-Tariff Measures in the Economic Community of West African States (ECOWAS)United Nations, Geneva. https://unctad.org/en/PublicationsLibrary/ditctab2018d1_en.pdf.

UNCTAD (2020a). Global Trade Update. https://unctad.org/system/files/official-document/ditcinf2020d4_en.pdf.

UNCTAD. (2020b). How to Encode Non-Tariff Measures in Regional Trade Agreements. United Nations, Geneva. https://unctad.org/system/files/official-document/ditctab2020d2_en.pdf.

REFERENCES

The United States Food and Drug Administration. (n.d.). Federal Food, Drug, and Cosmetic Act (FD&C Act). Retrieved July 27, 2020, from https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act.

Veggeland, F., Elvestad, C. (2004). Equivalence and Mutual Recognition in Trade Arrangements: Relevance for the WTO and the Codex Alimentarius Commission, Oslo: Norwegian Agricultural Economics Research Institute.

WTO SPS Agreement. (n.d.). Retrieved July 27, 2020, from https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

WTO TBT Agreement. (n.d.). Retrieved July 27, 2020, from https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.

APPENDICES

APPENDICES

Appendix 1:	Level of commitment of mutual recognition and equivalence of technical regulations, standards, and conformity assessments
Score	Criteria
0	A score of 0 is given if there is **no mentioning** of SPS/TBT for mutual recognition/equivalence of standards and/or conformity assessments in the RTAs.
1	A score of 1 is given if the text indicates a loose level of commitment. Those wordings will fall into this category: **'Parties shall take into account'**, **'will discuss about'**, **'will publish information'**, **'Parties are encouraged to'**. However, these provisions are either unenforceable (i.e. will discuss about) or fall under Recommendations, where there is no legal enforceability. Parties are encouraged to implement them if they have the political will to do so.
2	A score of 2 is given if the text aims for a commitment. In this category are RTAs that employ the wordings such as: **'may'**, **'might'**, or **'shall give positive consideration to'**. These provisions serve as Recommendations as well, where they are non-enforceable and are rather in the spirit of encouragement. Though the language of commitment used is stronger than those under score 1.
3	A score of 3 is given if the text indicates a strong level of commitment, typically when Parties use the words **'shall'**, or **'will'**. Such provisions are enforceable as the legally enforceable language "shall" is used. Provisions with weak enforceability are also included in this score category, where sometimes the text uses "shall", "will", but provides some exceptions for the imposition of the relevant provision.
4	A score of 4 is given if a **strong level of commitment** is shown in the language (same with a score of 3, excluding the "exceptions"), with **a detailed implementation scheme** outlined in the RTA. This type of provision uses legally enforceable language in which Parties to the agreement are obliged to comply.

Appendix 2: Level of commitment for referring to/aligning/harmonizing standards (international, regional, or national) and conformity assessments	
Score	Criteria
0	A score of 0 is given if there is no mentioning of international standards/regional standards adoption/harmonization or harmonization of standards of the other member within the agreement text.
1	A score of 1 is given if Parties mention international standards/regional standards or standards of another member as a subject to study further on and give consideration to. Such provisions are either unenforceable (i.e. will discuss about) or fall under Recommendations, where there is no legal enforceability. Parties are encouraged to implement them if they have the political will to do so.
2	A score of 2 is given if recommendation on the adoption/harmonization of international standards/regional standards/standards of the other member, or adapting existing standards-based international standards, is mentioned in the agreement text. The language can still be vague, such as **'Parties might'**, **'Parties will look into'**. These provisions serve as Recommendations as well, where they are non-enforceable and are rather in the spirit of encouragement. Though the language of commitment used is stronger than those under score 1.
3	A score of 3 is given if the RTA calls for Parties to adopt/harmonize with international standards/regional standards/standards of the other member wherever applicable. The language should be clear, such as **'Parties will'**, **'Parties shall'**. These provisions are enforceable as the legally enforceable language "shall" is used. Provisions with weak enforceability are also included in this score category, where sometimes the text uses "shall", "will", but provides some exceptions for the imposition of the relevant provision.
4	A score of 4 is given when the RTA confirms the adoption/harmonization of international standards/regional standards, or good practices from other members unless there are substantial reasons based on scientific or technical information why such standards, practices, or guidelines should be ineffective or inappropriate for the fulfilment of legitimate objectives pursued. This type of provision uses legally enforceable language in which Parties to the agreement are obliged to comply.

Appendix 3: General provisions on regulatory cooperation

Nature of revision (from basic to most complex)	Recommendation	Example in regional trade agreement text
Agreement to use most "appropriate" regulations	Require Parties to use the *most appropriate or cost-efficient approach to the removal of regulatory barriers*	**New Zealand–Singapore CEP (2001)** – *"each Party shall implement the principles of mutual recognition, unilateral recognition or harmonization that provide the most appropriate or cost-efficient approach to the removal of regulatory barriers."* (Article 35, Part 7)
Information exchange on regulations	Encourage Parties to share information regulations and standards with a view to increase transparency	**China–Georgia (2018):** "2. The Parties agree, upon request, ***to exchange information on conformity assessment procedures***, including testing, certification and accreditation. 3. When cooperating in conformity assessment, the Parties shall take into consideration their participation in the relevant international and/or regional organizations." (Article 6.7, Chapter 6)
Openness to consultations for regulatory cooperation	Encourage consultations for effecting mutual recognition/equivalence	**ASEAN–Australia–New Zealand FTA (2010):** *"Members shall also, upon request, enter into consultations with the aim of achieving bilateral and/or regional recognition agreements of the equivalence of specified SPS measures."* (Article 5, Chapter 5) **The European Union–Singapore FTA (2019):** *"**Engage in consultations with a** view to defining sectoral initiatives regarding the use of conformity assessment procedures or the facilitation of acceptance of conformity assessment results that are appropriate for the respective sectors."* (Article 4.7, Chapter 4)
Notification requirement	Impose requirements to notify temporary measures for enhancing transparency	**Comprehensive and Progressive Agreement for Trans-Pacific Partnership (2018):** "1. *If a Party adopts an emergency measure that is necessary for the protection of human, animal or plant life or health, the **Party shall promptly notify the other Parties of that measure through the primary representative and the relevant contact point** [...] 2. If a Party adopts an emergency measure, it shall review the scientific basis of that measure within six months and make available the results of the review to any Party on request. If the emergency measure is maintained after the review, because the reason for its adoption remains, the Party should review the measure periodically."* (Article 7.14, Chapter 7)
Assistance to other Parties in complying with regulations	Requiring Parties (especially in case of developed-developing country agreements) to train/assist other Parties in regulatory compliance	**ASEAN-Australia-New Zealand FTA (2010):** *"Member States shall further **strengthen cooperation for control and eradication of disease outbreak as well as other emergency cases related to SPS measures**. Members shall also assist other signature Parties to comply with SPS requirements."* (Article 5, Chapter 5)
Concurrence to WTO SPS/ TBT Agreement	Require Parties to adhere to WTO SPS/TBT Agreements	**New Zealand–Singapore CEP (2001):** *"Each Party **shall** follow WTO's SPS and TBT agreement to use international standards as basis for their mandatory requirements when such international standards exist, except when they are deemed as ineffective or inappropriate."* (Article 41, Part 7) **EFTA - Georgia (2017):** *"Except as otherwise provided for in this Chapter, the SPS Agreement **shall apply** and is hereby incorporated into and made part of this Agreement"* (Article 4.3, Chapter 4) [...] *"Except as otherwise provided for in this Article, with respect to technical regulations, standards and conformity assessments, the WTO TBT Agreement **shall apply** and is hereby incorporated and made part of this Agreement, mutatis mutandis."* (Article 2.9, Chapter 2)

Appendix 3: General provisions on regulatory cooperation *(cont.)*

Nature of revision (from basic to most complex)	Recommendation	Example in regional trade agreement text
Setting grounds for mutual recognition of conformity assessment bodies establishing without obligation	Require any Party to provide reasons for rejecting conformity assessment results of the other Party/ Parties.	**Colombia–the Republic of Korea FTA (2016):** *"A Party shall give positive consideration to a request by the other Party to negotiate agreements for the mutual recognition of the results of their respective conformity assessment procedures. Where a Party declines such request, it shall, upon request of the other Party, explain in writing the reasons for its decision.[…]".* (Article 6.6, Chapter 6)
A more concrete obligation for mutual recognition of conformity assessment bodies	Accept conformity assessment results by other Party's conformity assessment bodies	**China–Hong Kong SAR CEPA (2018)** – *"The two sides shall seek to facilitate the acceptance of the* ***results of conformity assessment procedures conducted in the other side****, with a view to increasing efficiency and ensuring cost effectiveness of conformity assessments."* (Article 58, Chapter 7) **Japan–Mongolia EP (2016):** *"Each Party shall ensure, whenever possible, that* ***results of the conformity assessment procedures in the other Party are accepted, even when those procedures differ from its own****, provided it is satisfied that the procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to its own procedures."* (Article 6.7, Chapter 6) **Canada–Ukraine (2017) FTA:** *"Each Party shall recognize conformity assessment bodies located in the territory of the other Party on conditions no less favorable than those that it applies for the recognition of conformity assessment bodies in its own territory. […]".* (Article 7.6, Chapter 7)
Mutual recognition of standards and regulations	Mutual recognition of technical regulations and standards	**ASEAN–Australia–New Zealand FTA (2010):** *"Member States shall take all necessary measures to ensure implementation of all the ASEAN Sectoral Mutual Recognition Arrangements, ASEAN Harmonised Regulatory Regimes and the relevant provisions of this Agreement within the time frame stipulated in the aforesaid agreements and to ensure compliance with aforesaid harmonised requirements."* (Article 78)
Conditional equivalence	Require importing Party to accept measures of exporting party as equivalent if the latter is able to demonstrate that it meets the same level of protection as importing Parties measures (SPS)/ or having compatible objectives (TBT)	**New Zealand–Taiwan Province of China CEP (2013):** *"importing Party shall accept SPS measures of the exporting Party as* ***equivalent*** *if the exporting Party objectively demonstrates that its measure achieves* ***the same level of protection*** *as the importing Party's measure, or it has the same effect."* (Article 8, Chapter 6) **The European Union–Singapore FTA (2019):** *"the importing Party* ***shall*** *accept SPS measures of the exporting Party as equivalent if it demonstrates the* ***same level of protection****."* (Article 5.14, Chapter 5) **The European Union–Canada FTA (2007):** *"A Party that has prepared a technical regulation that it considers to be equivalent to a technical regulation of the other Party* ***having compatible objective and product scope*** *may request that the other Party recognise the* ***technical regulation as equivalent****.[…]"* (Article 4.4, Chapter 4)

Appendix 3: General provisions on regulatory cooperation *(cont.)*

Nature of revision (from basic to most complex)	Recommendation	Example in regional trade agreement text
Harmonization	Require Parties to harmonize standards with international/regional standards or national standards of the other member	**EAEU Treaty (2015):** *"Sanitary, veterinary and sanitary and phytosanitary quarantine measures applied within EAEU **shall be based on international and regional standards**, except there is scientific evidence to justify a higher level of protection." (Article 56, Section XI)* **The European Union–Japan EPA (2019):** "With a view to harmonising standards on as wide a basis as possible, Parties shall ***encourage regional or national standardising bodies*** to [.....] 2) use relevant ***international standards as a basis for the standards they develop, except where such international standards would be ineffective or inappropriate***, for instance because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems;*"* [....](Article 7.6, Chapter 7) **The European Union–Ukraine (2014):** *"Ukraine shall take the necessary measures in order **to gradually** achieve conformity with the European Union technical regulations and the European Union standardisation, metrology, accreditation, conformity assessment procedures and the market surveillance system, and undertakes to follow the principles and practices laid down in relevant E.U. Decisions and Regulation [.....] 8. Ukraine shall progressively transpose the corpus of European standards (EN) as national standards, including the harmonised European standards, the voluntary use of which shall be presumed to be in conformity with legislation listed in Annex III to this Agreement."* (Article 56, Section 7)

Appendix 4: Medical products specific provisions

Nature of provision (from basic to most complex)	Recommendation	Example in regional trade agreement text
Transparency and information exchange	Require Parties to share information through various means such as establishment of working groups to ensure transparency	**India–Japan CEPA (2011) – promote *exchange of information* for generic medicine aiming** at regulatory cooperation and building mutual confidence in regulatory measures. **United States–Singapore (2004)** – Commit the ***establishment of a Working Group on Medical Products to provide a forum for cooperation through means other than MRA or binding commitments***. Ensures that regulatory procedures for medical products is transparent and based on generally accepted international scientific standards, such as the International Conference on Harmonization and based on conformity assessment
Cooperation between health authorities	Encourage health authorities of each Party to cooperate on regulations and standards	**The European Union-Singapore FTA (2019)** – The Agreement agrees to **enhance *cooperation* between their respective health authorities**, based on international standards and practice.
Science-based collaboration for alignment and harmonization of regulations.	Promote alignment of technical regulations, regulatory activities, and the use of scientific and technical guiding documents for medical devices across Parties	**Australia–Singapore FTA (2003)** – The Agreement stipulates that members are encouraged to **collaborate through *international or regional initiatives to improve the alignment of regulations and regulatory activities*** for medical devices. Furthermore, when members develop implementation regulations for marketing authorisation of medical devices, they should consider relevant scientific or technical guidance documents developed through international collaborative efforts (consider also regionally-developed scientific documents). **Australia–Singapore FTA (2003) – Seek to collaborate through relevant international initiatives for harmonization and aligning regulations and regulatory activities for medical devices.** When developing or implementing regulations for marketing authorization, *"Parties shall consider relevant scientific or technical guidance documents developed through international collaborative efforts"*.
Establishing a loose scope for mutual recognition of standards/conformity assessment procedures	Encourage Parties to consider mutual recognition of technical regulations and accept the results of conformity assessment	**The Republic of Korea–United States FTA (2012)** – Parties agreed they would **consider a request to recognize the results of conformity assessment procedures** conducted by bodies in the other Party's territory. **New Zealand–Taiwan Province of China FTA (2013)** – Promote Parties to **conclude further implementation arrangements on mutual recognition of standards and conformity assessment** for product sectors of interest to the signature Parties that include medical devices and pharmaceuticals.

Appendix 4: Medical products specific provisions *(cont.)*

Nature of provision (from basic to most complex)	Recommendation	Example in regional trade agreement text
Allowing conditional mutual recognition of conformity assessment procedures based on similarity in regulatory systems	Accepting registration of medicines without evaluation/approval provided it has been evaluated/approved by regulatory authorities in other specified countries with similar regulatory systems	**India-Singapore Comprehensive Economic Cooperation Agreement (2005)** – The Agreement 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.**

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreemet text

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Treaty on the Eurasian Economic Union	Jan 01 2015	Y	3		0	Y	2
Agreement between New Zealand and the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu on Economic Cooperation	Dec 01 2013	Y	4	Y	3	Y	3
Agreement between New Zealand and Singapore on a Closer Economic Partnership	Jan 01 2001	Y	4		2		3
Agreement Establishing the ASEAN – Australia – New Zealand Free Trade Area	Jan 01 1993	Y	3		0		0
Free Trade Agreement between the European Union and the Republic of Singapore	Nov 21 2019	Y	2		0		0
Eurasian Economic Union-the Islamic Republic of Iran Free Trade Agreement	Oct 27 2019	Y	3		0	Y	4
Comprehensive and Progressive Agreement for Trans-Pacific Partnership	Dec 20 2018	Y	3	Y	1	Y	1
Free Trade Agreement between the Government of the People's Republic of China and the Government of Georgia	Jan 01 2018	Y	3		0		0
Association Agreement between Central America and the European Union	Aug 01 2013	Y	2		0		3
Trade Agreement between the European Union and Colombia and Peru	Mar 01 2013	Y	2		0	Y	1
New Zealand–Malaysia Free Trade Agreement	Aug 01 2010	Y	4		2		1
The Comprehensive Economic Cooperation Agreement between the Republic of India and the Republic of Singapore	Aug 01 2005	Y	4	Y	2	Y	3
Australia – Hong Kong, China Free Trade Agreement	Jan 17 2020	Y	2	Y	2	Y	2

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Comprehensive Economic Cooperation Agreement between the Government of Malaysia and the Government of the Republic of India	Jul 01 2011	Y	3	Y	2		0
Agreement between the European Union and Japan for an Economic Partnership	Feb 01 2019	Y	3	Y	3		4
The Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union	Sep 21 2017	Y	4	Y	3		0
Costa Rica–China Free Trade Agreement	Aug 01 2011	Y	2		2		0
New Zealand–Hong Kong, China Closer Economic Partnership Agreement	Jan 01 2011	Y	2	Y	2	Y	1
China-Peru Free Trade Agreement	Mar 01 2010	Y	3	Y	2		0
New Zealand–China Free Trade Agreement	Oct 01 2008	Y	2	Y	2		0
Mainland and Hong Kong, China Closer Economic Partnership Agreement	Jun 29 2003	Y	3		0		0
The China–Australia Free Trade Agreement	Dec 20 2015	Y	3	Y	2		0
Thailand–New Zealand Closer Economic Partnership Agreement	Jul 01 2005	Y	2		2		0
Free Trade Agreement between Hong Kong, China and Georgia	Feb 13 2019	Y	3		0		0
Free Trade Agreement between the Eurasian Economic Union (EAEU) and Viet Nam	Oct 05 2016	Y	2		1		1
Free Trade Agreement between Hong Kong, China and Chile	Oct 09 2014	Y	2	Y	2		0
Singapore–Costa Rica Free Trade Agreement	Jul 01 2013	Y	2	Y	2		0
Republic of Peru–Republic of Korea Free Trade Agreement	Aug 01 2011	Y	3	Y	2		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Free Trade Agreement Between The European Union And The Republic Of Korea	Jul 01 2011		0		0		3
Agreement Establishing the ASEAN–Australia–New Zealand Free Trade Area	Jan 01 2010	Y	2	Y	2		1
Singapore–Australia Free Trade Agreement	Jul 28 2003	Y	3	Y	4		4
Economic Partnership Agreement between the European Union and the SADC EPA States	Oct 10 2016	Y	3		0		0
Agreement between Japan and Mongolia for an Economic Partnership	Jun 07 2016	Y	4	Y	2		0
Association Agreement between the European Union and the European Atomic Energy Community and Georgia	Sep 01 2014	Y	3	Y	3	Y	3
Association Agreement between the European Union and the European Atomic Energy Community and Ukraine	Apr 23 2014	Y	3		3		3
Association Agreement between the European Union and the European Atomic Energy Community and the Republic of Moldova	Sep 01 2014	Y	3		3		3
Thailand–Australia Free Trade Agreement	Jan 01 2005	Y	3	Y	2		0
The Comprehensive Economic Partnership Agreement between Chile and Indonesia (CEPA)	Aug 10 2019	Y	1	Y	2		0
Free Trade Agreement between the Government of the People's Republic of China and the Government of the Republic of Korea	Dec 20 2015		1	Y	2		0
Free Trade Agreement between the Government of the People's Republic of China and the Government of Iceland	Jul 01 2014	Y	2	Y	2		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Agreement between Singapore and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu on Economic Partnership	Apr 19 2014	Y	2		0		0
Free Trade Agreement between the EFTA States and the Philippines	Jun 01 2018		0		0		0
Turkey–Singapore Free Trade Agreement (TRSFTA)	Oct 012017	Y	1		0		0
Free Trade Agreement between the Government of Malaysia and the Government of the Republic of Turkey	Aug 012015	Y	1	Y	2		0
Free Trade Agreement between the Government of the Socialist Republic of Viet Nam and the Government of the Republic of Korea	Dec 20 2015		1	Y	2		0
Canada–Peru Free Trade Agreement	Aug 01 2009	Y	1	Y	2		0
Switzerland–China Free Trade Agreement	Jul 01 2014		0		0		0
Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and the Republic of Armenia	Jun 01 2018		0	Y	2	Y	2
Canada–Ukraine Free Trade Agreement	Aug 01 2017		0		0		0
Free Trade Agreement between the EFTA States and Georgia	Sep 01 2017		0	Y	2	Y	2
India–Republic of Korea Comprehensive Economic Partnership Agreement	Jan 01 2010	Y	2		0		0
United States–Singapore Free Trade Agreement	Jan 01 2004		0		0		0
Free Trade Agreement between the Republic of Colombia and the Republic of Korea	Jul 15 2016		0	Y	2		0
Free Trade Agreement between the Republic of Korea and New Zealand	Dec 20 2015		0	Y	2		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Free Trade Agreement between The Government of the Republic of Chile and the Government of the Socialist Republic of Viet Nam	Jan 01 2014		0	Y	2		0
Free Trade Agreement between The Republic of Peru and the EFTA States	Jul 01 2011		0	Y	2	Y	2
Free Trade Agreement between the Republic of Korea and Singapore	Mar 02 2006		0		0		0
Free Trade Agreement between the Republic of Korea and Canada	Jan 01 2015		0		0		0
Agreement between Japan and Canada for an Economic Partnership	Jan 15 2015		0	Y	2		0
Free Trade Agreement between the Republic of Korea and Australia	Dec 122014		0	Y	2		0
Chile–Malaysia Free Trade Agreement	Feb 25 2012		0	Y	2		0
The United States–the Republic of Korea (KORUS) Free Trade Agreement	Mar 15 2012		0		0		0
Agreement between Japan and the Republic of Peru for an Economic Partnership	Mar 01 2012		0	Y	2		0
Canada–Colombia Free Trade Agreement	Aug 15 2011		0	Y	2		0
Australia–United States Free Trade Agreement	Jan 01 2005		0	Y	2		0
Australia–Chile Free Trade Agreement	Mar 06 2009		0	Y	2		0
United States–Morocco Free Trade Agreement	Jan 01 2006		0	Y	1	Y	1
United States–Panama Free Trade Agreement	Oct 31 2012		0	Y	2	Y	1
Free Trade Agreement between the Republic of Colombia and the EFTA States	Jul 01 2011		0		0		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Stepping Stone Economic Partnership Agreement between Ghana and the European Community	Dec 15 2016		0	Y	3	Y	3
Comprehensive Economic Partnership Agreement between Japan and the Republic of India	Aug 01 2011		0		1		0
Preferential Trade Agreement (PTA) between the Common Market of the South (MERCOSUR) and the Southern African Customs Union (SACU)	Apr 01 2016		0		2		2
Free Trade Agreement between the Republic of Turkey and the Republic of Chile	Mar 01 2011		0	Y	2	Y	2
Canada–Panama Free Trade Agreement	Apr 01 2013		0		0		0
Agreement between Japan and The Kingdom of Thailand for an Economic Partnership	Nov 01 2007		0		0		0
Free Trade Agreement between the Republic of Turkey and the Republic of Moldova	Nov 01 2016		0		0		0
Preferential Trade Agreement between the Government of the Republic of Indonesia and the Government of the Islamic Republic of Pakistan	Sep 01 2013		0		0		0
Mexico–Bolivia Economic Complementation Agreement	Jun 07 2010						
Peru–Honduras Free Trade Agreement	Jan 01 2017						
El Salvador–Ecuador Partial Scope Economic Complementation Agreement	Nov 16 2017						
Mercosur–Egypt free trade agreement	Sep 01 2017		0		0		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within tregional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Hong Kong Special Administrative Region and Macao Special Administrative Region Closer Economic Partnership Arrangement	Oct 27 2017		0		0		0
Chile–Thailand Free Trade Agreement	Nov 05 2015						
Pacific Alliance Free Trade Agreement (DFAT)	May 01 2016						
Free Trade Agreement between the Republic of Colombia and the Republic of Costa Rica	Aug 01 2016						
Gulf Cooperation Council–Singapore Free Trade Agreement	Sep 01 2013		0		0		0
Canada–Honduras Free Trade Agreement	Oct 01 2014		0		0		0
Free Trade Agreement between the EFTA States and Bosnia and Herzegovina	Aug 19 2014		0		0		0
Free Trade Agreement between Mexico and Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua	Sep 01 2012						
Partial Scope Agreement between the Republic of El Salvador and the Republic of Cuba	Aug 01 2012						
Chile–Nicaragua Free Trade Agreement (Free Trade Agreement between the Governments of the Central American States and the Government of the Republic of Chile)	Oct 19 2012						
Treaty on a Free Trade Area between members of the Commonwealth of Independent States (CIS)	Sep 20 2012		0		0		0
Free Trade Agreement between the Republic of Peru and the Republic of Costa Rica	Jun 01 2013						
Free Trade Agreement between the Republic of Turkey and the Republic of Mauritius	Jun 01 2013		0		0		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Malaysia–Australia Free Trade Agreement	Jan 01 2013		0	Y	2	Y	2
Republic of Korea–Turkey Free Trade Agreement	May 01 2013		0	Y	2	Y	2
Free Trade Agreement between the Government of Ukraine and the Government of Montenegro	Jan 01 2013		0		0		0
Canada–Jordan Free Trade Agreement	Oct 01 2012		0		0		0
Free Trade Agreement between the EFTA States and Montenegro	Sep 01 2012		0		0		0
Free Trade Agreement between the EFTA States and Hong Kong, China	Oct 01 2012		0	Y	1	Y	1
Free Trade Agreement between the EFTA States and Ukraine	Jun 01 2012		0		0		0
The United States–Colombia Trade Promotion Agreement (TPA)	May 15 2012		0		0		0
Panama–Peru Free Trade Agreement	May 01 2012						
Chile–Nicaragua Free Trade Agreement (Free Trade Agreement between the Governments of the Central American States and the Government of the Republic of Chile)	Mar 23 2010						
Peru–Mexico Free Trade Agreement	Feb 01 2012						
Interim Agreement establishing a framework for an Economic Partnership Agreement between the Eastern and Southern Africa States and the European Community and its Member States	May 14 2012		0		0		0
Free Trade Agreement between the EFTA States and Albania	Nov 01 2010		0		0		0
Free Trade Agreement between the EFTA States and the Republic of Serbia	Oct 01 2010		0		0		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
Trade in Goods Agreement under the Framework Agreement on Comprehensive Economic Cooperation between the Republic of India and the Association of Southeast Asian Nation	Jul 01 2015		0		0		0
Free Trade Agreement. Between the Republic of Turkey and the Republic of Serbia	Sep 01 2010		0		0		0
Agreement on Trade in Goods Under the Framework Agreement on Comprehensive Economic Cooperation Among the Governments of the Member Countries of the Association of Southeast Asian Nations and the Republic of Korea	Oct 14 2010		0		0		0
Stabilisation and Association Agreement between the European Communities and their Member States and the Republic of Serbia	Sep 01 2013		0		0		0
Free Trade Agreement between the Republic of Turkey and Montenegro	Mar 01 2010		0		0		0
Free Trade Agreement between the EFTA States and the Republic of Chile	Dec 01 2004		0		0		0
Free Trade Agreement between the EFTA States and Turkey	Apr 01 1992		0		0		0
ASEAN–India Agreement on Comprehensive Economic Cooperation	Jul 01 2015		0		0		0
Agreement on Comprehensive Economic Co-operation between China and ASEAN	Jul 01 2007		0		0		0
Agreement on Comprehensive Economic Partnership among Japan and Member States of The Association of Southeast Asian Nations	Dec 01 2008		0	Y	2		0
Agreement on Trade in Goods Under the Framework Agreement on Comprehensive Economic Cooperation Among the Governments of the Member Countries of the Association of Southeast Asian Nations and the Republic of Korea	Oct 14 2010		0		0		0

Appendix 5: Reviewed regional trade agreements and the existence of mutual recognition provisions within the regional trade agreement text *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	Equivalence in Sanitary and Phytosanitary chapter	Commitment level of reviewed regional trade agreements (0-4) Equivalence (SPS)	Equivalence of standards (TBT)	Commitment level of equivalence for standards (TBT)	Equivalence conformity assessment (TBT)	Commitment level of equivalence for conformity assessment (TBT)
ASEAN–Hong Kong, China Free Trade Agreement (AHKFTA)	Jun 11 2019		0		0		0
Chile–Mexico Free Trade Agreement	Aug 01 1999	Y					
Free Trade Agreement between the United Mexican States and the Republic of Colombia	Jan 01 1995						
Chile–Peru Free Trade Agreement	Mar 01 2009						

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
Treaty on the Eurasian Economic Union	Jan 01 2015	Y	4	3
Agreement between New Zealand and the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu on Economic Cooperation	Dec 01 2013	Y	3	3
Agreement between New Zealand and Singapore on a Closer Economic Partnership	Jan 01 2001	Y	4	4
Agreement Establishing the ASEAN–Australia–New Zealand Free Trade Area	Jan 01 1993	Y	3	4
Free Trade Agreement between the European Union and the Republic of Singapore	Nov 21 2019	Y	1	4
Eurasian Economic Union-the Islamic Republic of Iran Free Trade Agreement	Oct 27 2019	Y	2	4
Comprehensive and Progressive Agreement for Trans-Pacific Partnership	Dec 20 2018	Y	2	2
Free Trade Agreement between the Government of the People's Republic of China and the Government of Georgia	Jan 01 2018	Y	3	4
Association Agreement between Central America and the European Union	Aug 01 2013	Y	3	3
Trade Agreement between the European Union and Colombia and Peru	Mar 01 2013	Y	3	3
New Zealand–Malaysia Free Trade Agreement	Aug 01 2010	Y	1	4
The Comprehensive Economic Cooperation Agreement between the Republic of India and the Republic of Singapore	Aug 01 2005	Y	3	3
Australia–Hong Kong, China Free Trade Agreement	Jan 17 2020	y	1	4
Comprehensive Economic Cooperation Agreement between the Government of Malaysia and the Government of the Republic of India	Jul 01 2011	Y	4	3
Agreement between the European Union and Japan for an Economic Partnership	Feb 01 2019	Y	1	4
The Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union	Sep 21 2017	Y	2	0
Costa Rica-China Free Trade Agreement	Aug 01 2011	Y	3	4
New Zealand–Hong Kong, China Closer Economic Partnership Agreement	Jan 01 2011	Y	1	4
China-Peru Free Trade Agreement	Mar 01 2010	Y	3	3

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
New Zealand–China Free Trade Agreement	Oct 01 2008	Y	3	4
Mainland and Hong Kong, China Closer Economic Partnership Agreement	Jun 29 2003	Y	3	3
The China–Australia Free Trade Agreement	Dec 20 2015	Y	1	4
Thailand–New Zealand Closer Economic Partnership Agreement	Jul 01 2005	Y	1	3
Free Trade Agreement between Hong Kong, China and Georgia	Feb 13 2019	y	3	4
Free Trade Agreement between the Eurasian Economic Union (EAEU) and Viet Nam	Oct 05 2016	Y	3	0
Free Trade Agreement between Hong Kong, China and Chile	Oct 09 2014	Y	1	4
Singapore–Costa Rica Free Trade Agreement	Jul 01 2013	Y	3	3
The Republic of Peru–the Republic of Korea Free Trade Agreement	Aug 01 2011	Y	1	3
Free Trade Agreement Between The European Union And The Republic Of Korea	Jul 01 2011	Y	3	4
Agreement Establishing the ASEAN-Australia- New Zealand Free Trade Area	Jan 01 2010	Y	2	4
Singapore-Australia Free Trade Agreement	Jul 28 2003	Y	1	3
Economic Partnership Agreement between the European Union and the SADC EPA States	Oct 10 2016	Y	1	3
Agreement between Japan and Mongolia for an Economic Partnership	Jun 07 2016	Y	0	3
Association Agreement between the European Union and the European Atomic Energy Community and Georgia	Sep 01 2014	Y	3	3
Association Agreement between the European Union and the European Atomic Energy Community and Ukraine	Apr 23 2014	Y	3	3
Association Agreement between the European Union and the European Atomic Energy Community and the Republic of Moldova	Sep 01 2014	Y	3	3
Thailand–Australia Free Trade Agreement	Jan 01 2005	Y	1	1
The Comprehensive Economic Partnership Agreement between Chile and Indonesia (CEPA)	Aug 10 2019	Y	1	4

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
Free Trade Agreement between the Government of the People's Republic of China and the Government of the Republic of Korea	Dec 20 2015	Y	1	4
Free Trade Agreement between the Government of the People's Republic of China and the Government of Iceland	Jul 01 2014	Y	0	4
Agreement between Singapore and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu on Economic Partnership	Apr 19 2014	Y	0	3
Free Trade Agreement between the EFTA States and the Philippines	Jun 01 2018	Y	3	3
Turkey–Singapore Free Trade Agreement (TRSFTA)	Oct 012017	Y	1	4
Free Trade Agreement between the Government of Malaysia and the Government of the Republic of Turkey	Aug 012015	Y	1	3
Free Trade Agreement between the Government of the Socialist Republic of Vietnam and the Government of the Republic of Korea	Dec 20 2015	Y	1	3
Canada–Peru Free Trade Agreement	Aug 01 2009	Y	0	4
Switzerland–China Free Trade Agreement	Jul 01 2014	Y	3	3
Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and the Republic of Armenia	Jun 01 2018	y	4	1
Canada–Ukraine Free Trade Agreement	Aug 01 2017	Y	0	3
Free Trade Agreement between the EFTA States and Georgia	Sep 01 2017		3	0
India–the Republic of Korea Comprehensive Economic Partnership Agreement	Jan 01 2010	Y	1	1
United States–Singapore Free Trade Agreement	Jan 01 2004	Y	0	3
Free Trade Agreement between the Republic of Colombia and the Republic of Korea	Jul 15 2016	Y	1	3
Free Trade Agreement between the Republic of Korea and New Zealand	Dec 20 2015	Y	1	3
Free Trade Agreement between The Government of the Republic of Chile and the Government of the Socialist Republic of Viet Nam	Jan 01 2014	Y	1	3

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
Free Trade Agreement between The Republic of Peru and the EFTA States	Jul 01 2011	Y	0	3
Free Trade Agreement between the Republic of Korea and Singapore	Mar 02 2006	y	0	2
Free Trade Agreement between the Republic of Korea and Canada	Jan 01 2015	Y	1	3
Agreement between Japan and Canada for an Economic Partnership	Jan 15 2015	Y	0	3
Free Trade Agreement between the Republic of Korea and Australia	Dec 122014	Y	0	3
Chile–Malaysia Free Trade Agreement	Feb 25 2012	Y	1	3
The United States–the Republic of Korea (KORUS) Free Trade Agreement	Mar 15 2012	Y	1	3
Agreement between Japan and the Republic of Peru for an Economic Partnership	Mar 01 2012	Y	0	3
Canada–Colombia Free Trade Agreement	Aug 15 2011	Y	0	3
Australia–United States Free Trade Agreement	Jan 01 2005	Y	1	3
Australia–Chile Free Trade Agreement	Mar 06 2009	Y	1	3
United States–Morocco Free Trade Agreement	Jan 01 2006	Y	0	3
United States–Panama Free Trade Agreement	Oct 31 2012	Y	0	3
Free Trade Agreement between the Republic of Colombia and the EFTA States	Jul 01 2011	Y	0	1
Stepping Stone Economic Partnership Agreement between Ghana and the European Community	Dec 15 2016	Y	2	0
Comprehensive Economic Partnership Agreement between Japan and the Republic of India	Aug 01 2011		0	1
Preferential Trade Agreement (PTA) between the Common Market of the South (MERCOSUR) and the Southern African Customs Union (SACU)	Apr 01 2016	Y	0	1
Free Trade Agreement between the Republic of Turkey and the Republic of Chile	Mar 01 2011	Y	0	1
Canada–Panama Free Trade Agreement	Apr 01 2013	Y	0	3

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
Agreement between Japan and The Kingdom of Thailand for an Economic Partnership	Nov 01 2007		0	
Free Trade Agreement between the Republic of Turkey and the Republic of Moldova	Nov 01 2016		0	0
Preferential Trade Agreement between the Government of the Republic of Indonesia and the Government of the Islamic Republic of Pakistan	Sep 01 2013		0	0
Mexico–Bolivia Economic Complementation Agreement	Jun 07 2010			
Peru–Honduras Free Trade Agreement	Jan 01 2017			
El Salvador–Ecuador Partial Scope Economic Complementation Agreement	Nov 16 2017			
Mercosur–Egypt free trade agreement	Sep 01 2017		0	0
Hong Kong Special Administrative Region and Macao Special Administrative Region Closer Economic Partnership Arrangement	Oct 27 2017		0	0
Chile–Thailand Free Trade Agreement	Nov 05 2015			
Pacific Alliance Free Trade Agreement (DFAT)	May 01 2016			
Free Trade Agreement between the Republic of Colombia and the Republic of Costa Rica	Aug 01 2016			
Gulf Cooperation Council–Singapore Free Trade Agreement	Sep 01 2013		0	0
Canada–Honduras Free Trade Agreement	Oct 01 2014		0	0
Free Trade Agreement between the EFTA States and Bosnia and Herzegovina	Aug 19 2014		0	0
Free Trade Agreement between Mexico and Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua	Sep 01 2012			
Partial Scope Agreement between the Republic of El Salvador and the Republic of Cuba	Aug 01 2012			
Chile–Nicaragua Free Trade Agreement (Free Trade Agreement between the Governments of the Central American States and the Government of the Republic of Chile)	Oct 19 2012			
Treaty on a Free Trade Area between members of the Commonwealth of Independent States (CIS)	Sep 20 2012		0	0

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
Free Trade Agreement between the Republic of Peru and the Republic of Costa Rica	Jun 01 2013			
Free Trade Agreement between the Republic of Turkey and the Republic of Mauritius	Jun 01 2013		0	0
Malaysia–Australia Free Trade Agreement	Jan 01 2013		0	0
The Republic of Korea–Turkey Free Trade Agreement	May 01 2013		0	0
Free Trade Agreement between the Government of Ukraine and the Government of Montenegro	Jan 01 2013		0	0
Canada–Jordan Free Trade Agreement	Oct 01 2012		0	0
Free Trade Agreement between the EFTA States and Montenegro	Sep 01 2012		0	0
Free Trade Agreement between the EFTA States and Hong Kong, China	Oct 01 2012		0	0
Free Trade Agreement between the EFTA States and Ukraine	Jun 01 2012		0	0
The United States–Colombia Trade Promotion Agreement (TPA)	May 15 2012		0	0
Panama–Peru Free Trade Agreement	May 01 2012			
Chile–Nicaragua Free Trade Agreement (Free Trade Agreement between the Governments of the Central American States and the Government of the Republic of Chile)	Mar 23 2010			
Peru–Mexico Free Trade Agreement	Feb 01 2012			
Interim Agreement establishing a framework for an Economic Partnership Agreement between the Eastern and Southern Africa States and the European Community and its Member States	May 14 2012		0	0
Free Trade Agreement between the EFTA States and Albania	Nov 01 2010		0	0
Free Trade Agreement between the EFTA States and the Republic of Serbia	Oct 01 2010		0	0
Trade in Goods Agreement under the Framework Agreement on Comprehensive Economic Cooperation between the Republic of India and the Association of Southeast Asian Nation	Jul 01 2015		0	0
Free Trade Agreement. Between the Republic of Turkey and the Republic of Serbia	Sep 01 2010		0	0

Appendix 6: Reviewed regional trade agreements and the existence of harmonization/alignment of international/regional or national standards *(cont.)*

Name of regional trade agreement with hyperlink to document text	Date of its entry into force	International standards inclination	International standards inclination (0-4) (SPS)	International standards inclination (0-4) (TBT)
Agreement on Trade in Goods Under the Framework Agreement on Comprehensive Economic Cooperation Among the Governments of the Member Countries of the Association of Southeast Asian Nations and the Republic of Korea	Oct 14 2010		0	0
Stabilisation and Association Agreement between the European Communities and their Member States and the Republic of Serbia	Sep 01 2013		0	0
Free Trade Agreement between the Republic of Turkey and Montenegro	Mar 01 2010		0	0
Free Trade Agreement between the EFTA States and the Republic of Chile	Dec 01 2004		0	0
Free Trade Agreement between the EFTA States and Turkey	Apr 01 1992		0	0
ASEAN–India Agreement on Comprehensive Economic Cooperation	Jul 01 2015		0	0
Agreement on Comprehensive Economic Co-operation between China and ASEAN	Jul 01 2007		0	0
Agreement on Comprehensive Economic Partnership among Japan and Member States of The Association of Southeast Asian Nations	Dec 01 2008		0	
Agreement on Trade in Goods Under the Framework Agreement on Comprehensive Economic Cooperation Among the Governments of the Member Countries of the Association of Southeast Asian Nations and the Republic of Korea	Oct 14 2010		0	
ASEAN–Hong Kong, China Free Trade Agreement (AHKFTA)	June 11 2019		0	0
Chile–Mexico Free Trade Agreement	Aug 01 1999	Y		
Free Trade Agreement between the United Mexican States and the Republic of Colombia	Jan 01 1995			
Chile–Peru Free Trade Agreement	Mar 01 2009			

Appendix 7: Summary of country practices of adopting measures for regulatory cooperation

1. Equivalence

(i) The United States Emergency Use Authorization – Temporarily equivalence *vis-a-vis* Australia, Brazil, China, the European Union, Japan, the Republic Korea and Mexico

Under the Federal Food, Drug, and Cosmetic Act, the US Food and Drug Administration (FDA) Commissioner may authorize unapproved medical products to be used in emergency situations when there are no adequate, approved, and available alternatives. One of the defined emergency situations is *"Public health emergencies, or situations where a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a chemical, biological, radiological and nuclear agent or agents, or a disease or condition that may be attributable to such agent(s)."*

As the existence of a public health emergency was determined on 31 January 2020 under the Public Health Service Act, the FDA issued Emergency Use Authorizations to facilitate the supply of medical products to healthcare workers. The FDA issued multiple Emergency Use Authorizations of diagnostic and therapeutic medical devices including filtering facepiece respirators (FFR).[18] Before the pandemic, all FFR imported into the United States required approval of the National Institute for Occupational Safety and Health (NIOSH) and, in order to be used by health workers, an approval by the FDA. After the COVID-19 outbreak, several EUAs regarding FFRs allowed the use of non-NIOSH approved FFRs *"where the devices are evaluated using methods similar to those used by NIOSH and are expected to provide adequate protection for healthcare personnel."* (D'Alessandro, Powers & Krah, 2020). To be imported without NIOSH approval, FFRs must meet one of the following three criteria.[19]

1. FFRs meeting the performance standard, and acceptable product classifications defined in six countries (Australia, Brazil, the European Union, Japan, the Republic of Korea and Mexico)
2. Disposable FFRs that conform to regulations of the European Union, as evidenced by a Conformitè Europëenne (CE) mark, and the CE mark has been authenticated and verified by FDA
3. Disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals, have been verified by FDA for FFRs and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country (Food and Drug Administration, 2020).

The United States complemented the Emergency Use Authorizations with authorization of importers or manufacturers, as well as market surveillance and monitoring such as random sampling and filtration efficiency performance testing upon importation into the country.

In addition, the FDA issued Emergency Use Authorizations dedicated to products manufactured in China. The Emergency Use Authorization system is similar but imposes stricter complementary requirements such as additional validation and reviews on importer or manufacturer. The FDA has listed authorized products for import on its website.[20]

(ii) Kenya Emergency and Compassionate Use Authorization – Temporarily equivalence *vis-a-vis* Australia, Brazil, Canada, the European Union, Japan, South Africa, the United States and ISO

Pursuant to the Public Health Act, Kenya's Cabinet Secretary of Health declared the COVID-19 a public health emergency. Consequently, based on the Pharmacy and Poisons Act and amended by the Health Laws (Amendment) Act, the Pharmacy and Poison Board established the system of Emergency and Compassionate Use Authorization through the Guidelines for Emergency and Compassionate Use Authorization of Health Products and Health Technologies on April 20 and started the authorization of COVID-19 testing kits through the Requirements for Emergency Use Authorisation of COVID-19 Rapid Test Kits.

The Requirements asked the authorization applicants of COVID-19 Rapid Test Kits to submit the following.

1. Evidence of pre-market approval or registration in one of the six jurisdictions (South Africa, Australia, Brazil, Canada, the European Union, Japan and the United States);
2. Certificate of free sale confirming that the kits are legally sold and approved by the regulatory authority from the country of origin; and
3. Evidence of ISO 13485:2016 certification of the original manufacturer (Pharmacy and Poisons Board, Ministry of Health, Kenya, 2020).

The Guidelines stated that the Emergency and Compassionate Use Authorization shall terminate when the Cabinet secretary, Ministry of Health and the National Security Council or the Pharmacy and Poisons Board declare the end of public health emergency (Pharmacy and Poisons Board, Ministry of Health, Kenya, 2020).

Appendix 7: Summary of country practices of adopting measures for regulatory cooperation *(cont.)*

(iii) Brazil ANVISA Resolutions – Temporarily equivalence *vis-a-vis* the European Union, PIC/S, MDSAP, IMDRF, ISO and WHO

Brazil declared the Public Health Emergency of National Importance through Act No. 188/GM/MS on 4 February 2020. Then, the Brazil's National Health Surveillance Agency, ANVISA issued a series of resolutions from March, which eased standards and conformity assessments to facilitate the supply of medical goods.

1. Resolution No. 346 of 12 March 2020: ANVISA eased the GMP Certification of Active Pharmaceutical Ingredients, medicines and healthcare products by accepting information received directly from other 50 foreign countries' regulators that participate in PIC/S or MDSAP.[21] The GMP certification granted based on foreign regulators' information is valid for two years since the date of publication and the resolution is valid for 180 days (National Health Surveillance Agency, Ministry of Health, Brazil, 2020a)

2. Resolution No. 349 of 19 March 2020: ANVISA adopted three relaxed measures with respect to the registration of protection equipment, medical equipment and other medical devices identified as strategic. Firstly, manufacturers' declaration that the products are regulated and marketed in the jurisdiction of 10 member countries of the IMDRF could replace a proof of registration.[22] Moreover, the MDSAP Quality Management System or ISO Quality Management System Certification 13485 could replace ANVISA's GMP Certification. Lastly, these products were exempt from Brazilian Compliance Assessment System certification. The registration granted under this resolution is valid for one year since the date of publication and the resolution is valid for 180 days (National Health Surveillance Agency, Ministry of Health, Brazil, 2020b).

3. Resolution No. 379 of 30 April 2020: ANVISA allowed import of novel and thus not-yet registered individual protection equipment, pulmonary ventilators and other medical devices, if they were regulated and marketed in the jurisdiction of a member of IMDRF. Moreover, the hospital garments needed to meet technical standards including ABNT NBR ISO 13688: 2017 – Protective clothing – General requirements, which is identical to ISO 13688:2013. The imported products were also subject to quality monitoring and a traceability requirement. The resolution is valid for 180 days (National Health Surveillance Agency, Ministry of Health, Brazil, 2020c).

4. Resolution No. 392 of 26 May 2020: After notification of ANVISA and as an exception, third party audit reports carried out by the European Directorate for the Quality of Medicines, WHO and members of PIC/S could replace on-side audits of suppliers for Good Practices. The resolution is valid until the Ministry of Health recognizes the end of the emergency situation (National Health Surveillance Agency, Ministry of Health, Brazil, 2020d).

iv) Canada Interim Orders – Temporary equivalence *vis-a-vis* China, the European Union, IEC and ISO

Pursuant to the Food and Drugs Act, Canada's Ministry of Health passed two Interim Orders, namely, the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 on 18 March 2020 and the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19 on 30 March 2020 (Ministry of Health, Canada, 2020).

According to these Interim Orders, certain medical products that meet "similar high quality and manufacturing standards to those required for Canadian approved products" could be eligible for exceptional importation and sale for a limited period of time, even though they may not fully meet regulatory requirements to be imported and sold in Canada (Health Canada, 2020a). Health Canada under the Ministry of Health made reference to internationally recognized specification, or authorization or registration in other jurisdictions where the regulatory frameworks and quality assurances are similar. For example, KN95 or medical FFP2 respirators that meet Chinese or European standards or ventilators that meet IEC, ISO or European standards (Health Canada 2020b). Also, disinfectants and hand sanitizers authorized or registered in other jurisdictions could be imported even if they did not meet bilingual labelling and packaging (Health Canada, 2020c). Complementary measures were taken together to monitor the post-market safety and effectiveness of the goods related to COVID-19 (Ministry of Health, Canada, 2020).

Health Canada tended to keep their list of quality and manufacturing standards open by stating 'for example', 'may include', 'this list of standards is not exclusive', etc. (Health Canada, 2020a). It contrasted to the United States' case of EUA criteria 1 and 2 where the FDA set an exhaustive list of recognized foreign standards.

Moreover, science-based approaches played a key role. For example, Health Canada conducted scientific review to authorize testing devices and PPE for medical purposes or to set requirements of ethanol sources to produce hand sanitizer. Especially for medical devices, Health Canada relied on the data such as scientific evidence provided by the National Microbiology Laboratory and provincial public health and laboratory partners.

Besides, the Interim Order on 30 March established a notification system to prepare for the shortage of medical devices. It required manufacturers of medical devices to notify the Minister of Health about shortages of those medical devices "within five days of becoming aware of a shortage in progress or of an anticipated shortage" (Ministry of Health, Canada, 2020).

Appendix 7: Summary of country practices of adopting measures for regulatory cooperation *(cont.)*

(v) Switzerland Ordinance 3 – Temporary equivalence *vis-a-vis* China, the European Union, the United States and WHO

The Swiss Federal Council issued the Ordinance on Measures to Combat the Coronavirus on 13 March 2020 pursuant to the Epidemics Act. The 3rd version of the Ordinance was in force on 22 June and would expire on 13 September 2020 (Swiss Federal Council, 2020).

According to Articles 21 to 24 of the Ordinance, if no medicinal product is authorised and available in Switzerland, Swissmedic may allow the temporary import and market entry of an essentially identical medicinal product as a short-term solution. Swissmedic listed the medicinal products that are allowed to import and place on the market (Swissmedic, 2020).

With respect to medical devices, conformity assessment procedures prescribed in other Swiss Ordinances were temporarily exempted and replaced with proofs of conformity such as below.

1. Demonstration of conformity with the essential requirements, including:
    a. Demonstration of compliance with the applicable (harmonised) medical device-specific (EN) ISO standards (*e.g.* EN 14683 for surgical masks);
    b. Demonstration of efficacy and performance of the device (*e.g.* EN 13612 for performance evaluation of in vitro diagnostic medical devices).
2. Demonstration of certification of the manufacturer's quality management system;
3. Demonstration of any authorisations in other non-European countries (*e.g.* the United States, China) (Swissmedic, 2020)

(vi) The European Union Commission Recommendation (EU) 2020/403 – Temporary equivalence *vis-a-vis* WHO

CE Marking is a manufacturer's claim that products including medical products meet safety and performance requirements specified under relevant European Directives. Regulation (EU) 2016/425 (PPE) stipulates that *"Before placing PPE on the market, (... importers) shall ensure that (...) that the PPE bears the CE marking and is accompanied by the required documents, (...)."* Likewise, Regulation (EU) 2017/745 (Medical Devices) states that *"In order to place a device on the market, importers shall verify that: (a) the device has been CE marked and that the EU declaration of conformity of the device (with all relevant EU-wide requirements) has been drawn up."*

However, the Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures was released within the context of the COVID-19. It eliminated this requirement to ensure that the member States can purchase essential medical products that are manufactured in accordance with WHO guidelines, even if they do not bear the CE mark, for a limited period of time (The European Commission, 2020).

"Where market surveillance authorities find that PPE or medical devices ensure an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC or Regulation (EU) 2017/745, even though the conformity assessment procedures, including the affixing of CE marking have not been fully finalised according to the harmonised rules, they may authorise the making available of these products on the Union market for a limited period of time and while the necessary procedures are being carried out (The European Commission, 2020)."

1. Harmonization

(i) Uganda Standards – Harmonization *vis-a-vis* the European Union and ISO

Uganda National Bureau of Standards (UNBS) issued standards for face masks on 12 May 2020 (Uganda Gazette, 2020). Among them, five standards (US ISO 6940:2004; US ISO 13934-2:2014; US ISO 11737-1:2018; US ISO 2859-1:1999; and US ISO 22609:2004) were based on ISO standards. Despite the name, they concerned 'conformity assessments', specifically, test methods of face masks to assure quality of standards. Two standards (US EN 149:2001+A1; and US EN 14683:2019+AC:2019) were an adoption of European standards and concerned specification 'standards' of respiratory protective devices and medical face masks. On the same day, UNBS initiated a procedure to make the first two harmonized standards mandatory (Uganda Gazette, 2020). Also, on 28 May, UNBS informed all importers through a public notice that the mandatory respiratory protective devices and medical face masks standards shall apply to all shipments (Uganda National Bureau of Standards, 2020).

Appendix 7: Summary of country practices of adopting measures for regulatory cooperation *(cont.)*

(ii) Kuwait Standards – Harmonization *vis-a-vis* the United Kingdom and ISO

Between 14 and 27 April, Kuwait Standard and Metrology Department of the Public Authority for Industry adopted 15 new standards under license from ISO or the British Standards Institution. Six standards that were an adoption of the ISO standards concern both 'standards' and 'conformity assessments', particularly test methods and labelling symbols, of respiratory protective devices, medical face masks, medical devices, etc. Similarly, nine documents that were an adoption of the British standards concern both aspects of respiratory protective devices, chemical disinfectants and antiseptics, and medical face masks (Kuwait WTO TBT Notifications, 2020).

(iii) Namibia Standards – Harmonization *vis-a-vis* South Africa and WHO

Pursuant to the Standards Act, Namibia replaced outdated standards on medical supplies through the government gazette no.7186 on 21 April 2020 (Namibian Standards Institution, 2020). Namibia has used harmonized standards with South Africa since before the COVID pandemic. In the same vein, resulting five standards (NAMS/SANS 1853:2020; NAMS/SANS 490:2020; DNAMS/SANS 1866-1:2020; NAMS/SANS 1866-2:2020; and NAMS/SANS 10220:2020) were an adoption of South African standards. The revision was mainly to ensure the safety and quality of concerned products during the pandemic. One standard (NAMS/SANS 490:2020) refers to the requirements of the WHO Recommendations for ethanol and/or isopropyl alcohol content and alcohol identification (Namibia WTO TBT Notification 2020).