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

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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

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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].