Strengthening International Regulatory Cooperation for Medical Supplies in Times of Medical Emergencies

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**Towards Model Provisions for Trade in Times of Crisis and Pandemic in Regional and Other Trade Agreements**

**Webinar Series - 28, 29, 30 October and 2 November 2020**

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Introduction/Motivation
Introduction / Motivation

Impact of COVID-19 to trade in medical supplies, medicines, medical equipment/technology, and personal protective equipment (PPE).

Challenges:

- Comply with a myriad of technical regulations, standards, and conformity assessments (often different across countries).
- Delays caused by multiple conformity assessment procedures.
- Cost of multiple conformity assessment and procedural delays.
- Cost associated to gathering information on regulatory requirements in target markets which are different from national regulations.
Regulatory Cooperation

- Regulatory cooperation can be achieved by **unilateral**, **bilateral**, and **multilateral** means.

- RTAs can be an important tool in deepening regulatory cooperation by enabling countries to cooperate on standard and conformity assessment in a systematic manner – *in-build provisions*.

- RTAs can be especially useful during emergency and crisis situations.
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Our Approach
Our Approach

With a focus on **mutual recognition**, **equivalence** and **harmonization** of standards and conformity assessment, our study:

1) Review existing RTAs to identify provisions on regulatory cooperation, in general and for medical products.

2) Review of country practices during COVID-19 to eliminate regulatory burden.
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Assessment of Provisions in Existing RTAs to Ease Regulatory Burden
Assessment of Provisions in RTAs

Steps taken:

1. Review **107 RTAs** entered into force after 2010 (*aside from RTAs from Latin American countries where the text is only available in Spanish*) and scrutinize elements of mutual recognition, equivalence, and harmonization.

2. Develop a **scoring system** to evaluate mapped provisions in RTAs and rate the content against the benchmark score → assess to which **extent** the three elements have been **promoted** based on how **binding the language** in the provision is (a score on a scale of 0-4 is given for each element).

3. Review provisions specific to medical and pharmaceutical products and identify if there are any provisions (**emergency/temporary**) that addresses regulatory cooperation during **crisis**.
Summary of Findings

Mutual Recognition on Standards and Conformity Assessment

1. TBT Chapter:
   - Over 70% of RTAs mentioned mutual recognition on either standards or conformity assessment. Mutual recognition on conformity assessment is more prevalent than on standards. Only several (18 out of 107) mentioned both.
   - RTAs promoting both mutual recognition of standards and conformity assessment are mainly concluded by countries with similar development statuses including the EU, Australia, Singapore, Japan, etc.
   - Commitment level (based on language) for mutual recognition on conformity assessment is rather high in comparison to standards.

2. SPS Chapter:
   - Mutual recognition of either standards and/or conformity assessment are not mentioned explicitly (probably due to the nature of mutual recognition relates more to the objective of TBT than SPS. However, the implication is just as relevant for SPS as for TBT chapters).
Summary of Findings

1. **TBT Chapter:**
   - Over 51% encouraged acceptance of technical regulations of other members as equivalent. RTAs with *high commitment level* are mainly concluded by the EU, Japan, Canada, Georgia, Ukraine, etc.
   - 4 RTAs with rather strong commitment level mentioned explicitly mutual recognition, approximation, alignment and equivalence of technical regulations/standards and conformity assessment for *medical devices and pharmaceutical products*.
   - Equivalence provisions have its advantages as it ‘tolerates’ regulatory diversity and permits different rules among members as long as regulatory objective is similar.

2. **SPS Chapter:**
   - 42% of RTAs include an equivalence provision. Most of such provisions have a *relative high level of commitment*.
   - These RTAs come mainly from EU, New Zealand, Australia and China.
Summary of Findings

Harmonization in Standards and Conformity Assessment

1. TBT Chapter:
   - Majority (65%) recommended adopting international/regional/country standards for rules and conformity assessment.
   - Harmonization is less mentioned (25%) compared to making reference to international standards/regional standards (i.e. EU is one of the main party that favors harmonization).
   - Seems to be more difficult to achieve as it requires countries to implement the same measures based on the same regulatory goals, in contrast to the other two approaches where different kinds of measures can be accepted as long as regulatory goals are the same.

2. SPS Chapter:
   - Reference to international standards, regional or country standards has been promoted in about 52% RTAs.
   - Margin of discretion allowed, where Parties shall harmonize to international standards when possible, but can deviate if rational scientific evidence is provided.
Summary of Findings

Additional Findings

- There are **17 RTAs** that mentioned explicitly in their texts or Annexes about regulatory cooperation for medical devices and pharmaceutical products.

- **Temporary or emergency provisions** on mutual recognition, equivalence and harmonization on either standards or conformity assessment to ease regulatory burden during crisis **does not exist**. There is however a provision, which is the Emergency Provision under the SPS chapter that refers to situations when the importing country reports an urgent problem arises from the product imported and applies emergency SPS measures (16% of RTAs checked). **Contrary to promoting regulatory cooperation, it justifies adoption of additional measures in times of crisis to protect human life and health.**
04
Country Cases to Reduce Regulatory Burden
Assessment and Six Findings

- Identify and assess new regulatory cooperation measures taken during the COVID-19, from the WTO SPS and TBT notifications, media press and government websites.

- **Nine** countries (Brazil, Canada, Kenya, Kuwait, the EU, Namibia, Switzerland, Uganda and the US).

- Regulatory cooperation measures during the COVID-19
  1. are equivalence and harmonization. No MR. (on top of pre-COVID cooperation!)
  2. concern technical regulations, standards and/or conformity assessment.
  3. target well-defined medical supplies and non-medical PPEs.
  4. refer to (a group of) foreign countries or international organizations.
  5. in case of equivalence measures, apply temporarily.
  6. if necessary, are complemented by other measures. (e.g. market surveillance)
Examples

- **US Emergency Use Authorization**: Filtering facepiece respirators that meet the performance standard, etc. defined in six countries can be authorized for import until the termination of emergency declaration. In addition, market surveillance requirements should be met.

- **Brazil Resolution No. 349**: GMP certification of medical device manufacturers issued by the Health Ministry can be replaced with ISO Quality Management System Certification 13485, etc. for 180 days (since the publication of the resolution).

- **Kuwait Standards**: 15 new standards were adopted under license from ISO or the British Standards Institution. They concern test methods, labelling symbols, etc. of respiratory protective devices, chemical disinfectants, etc.
<table>
<thead>
<tr>
<th>Foreign countries</th>
<th>International organizations</th>
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<tr>
<td>MR</td>
<td>-</td>
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<tr>
<td><strong>Equivalence</strong></td>
<td></td>
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<td>US: EUA (7 countries)</td>
<td>EU: Commission Recommendation 2017/745 (WHO)</td>
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<td>Until the termination of declaration of emergency</td>
<td>Brazil: RDC No. 349 (ISO); RDC No. 379 (ISO)</td>
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<td>Brazil: RDC No. 346 (PIC/S or MDSAP); RDC No. 349 (MDSAP); RDC No. 379 (IMDRF)</td>
<td>180 days</td>
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<td>180 days</td>
<td>Brazil: RDC No. 392 (WHO)</td>
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<td>Brazil: RDC No. 392 (EU, PIC/S)</td>
<td>Until the recognition of the end of emergency situation</td>
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<td>Until the recognition of the end of emergency situation</td>
<td>Canada: Interim orders (IEC, ISO)</td>
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<td>for a limited period of time</td>
<td>for a limited period of time</td>
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<tr>
<td>Until the declaration of the termination of ECUA circumstances</td>
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<td>Switzerland: Ordinance 3 (EU, US, China)</td>
<td>Switzerland: Ordinance 3 (WHO)</td>
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<td>Until 22 September</td>
<td>Until 22 September</td>
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<tr>
<td><strong>Harmonization</strong></td>
<td></td>
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<td>Uganda: 2 standards (EU)</td>
<td>Uganda: 5 standards (ISO)</td>
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<td>Kuwait: 9 standards (UK)</td>
<td>Kuwait: 6 standards (ISO)</td>
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<td>Namibia: 5 standards (South Africa)</td>
<td>Namibia: 1 standard (WHO)</td>
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Recommendations – A Menu of Provisions for RTAs
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A Menu of Provisions for RTAs

A La Carte Menu
- General recommendations (from RTAs)
- Medical-and pharmaceutical product specific recommendations (from RTAs)
- Emergency specific recommendations (from country practices)

Sample Provisions
- Sample provisions
**A La Carte Menu - General recommendations**

| 1. Use most appropriate or cost-efficient approach |
| 2. Sharing information on regulations and standards |
| 3. Training/assisting other Parties in regulatory compliance |
| 4. Requiring adherence to WTO SPS/TBT Agreements |
| 5. Requiring to provide reasons for rejecting conformity assessment results |
| 6. Requiring 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 |
| 7. Encouraging consultations on matters of regulatory compliance |
| 8. Requiring notification of temporary measures |
| 9. Promoting mutual recognition of technical regulations and standards |
| 10. Requiring Parties to harmonize standards with international/regional standards or national standards of the other Party/Parties |
| 11. Accept conformity assessment results by other Party’s conformity assessment bodies |
A La Carte Menu - **Medical-product specific provisions**

1. Sharing information through various means such as establishment of working group

2. Encouraging cooperation among health authorities on regulations and standards

3. Aligning technical regulations, regulatory activities, and the use of scientific and technical guiding documents for medical devices

4. Accepting registration of medicines without evaluation/approval if evaluated/approved by regulatory authorities in other countries with similar regulatory systems
1. Define criteria for determining public health emergency situations
2. Establishing need for regulatory cooperation in situations of "shortage"
3. Defining a list of products (at HS6 digit level)
4. Adopt international standards as a basis for regulatory cooperation temporarily
5. Treating standards of jurisdictions with similar regulatory frameworks as equivalent
6. Simplifying import of products manufactured by a foreign entity that carries approval of one’s national conformity assessment body for another product
7. Encouraging developing country partner to accept developed country’s CA procedures
8. Forgoing labelling/marking requirements when there is adequate evidence to believe that the product can ensure adequate level of health and safety
### Specific Sample Provisions: Some Examples

<table>
<thead>
<tr>
<th>Example No.</th>
<th>Provision Text</th>
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<tbody>
<tr>
<td>1</td>
<td>During <em>the emergency situation</em>, Parties would consider a request to recognize the results of conformity assessment procedures conducted by bodies in the other Party's territory.</td>
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<td>2</td>
<td>Parties <em>shall</em> undertake to agree on a common list of <em>standards and conformity assessment procedures</em> for a specified list of critical medical products that can be applicable during <em>an emergency situation</em>, based on <em>one-another's standards/standards of member countries to a specified association/international standards</em>.</td>
</tr>
<tr>
<td>3</td>
<td>During <em>the emergency situation</em>, <em>agreeing</em> Parties <em>shall</em> treat as equivalent/recognize <em>standards and conformity assessments procedures</em> of another Party to the agreement if the latter <em>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</em> for <em>medical</em> products included in a pre-defined list of critical products for <em>XX days/a number of days considered suitable and necessary at that point in time</em>, provided the following conditions are satisfied [...].</td>
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### Specific Sample Provisions: Some Examples (ctd.)

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<th>Example No.</th>
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<tr>
<td>4</td>
<td>During <em>the emergency situation</em>, if a Party recognizes <em>standards and/or conformity assessment procedures</em> of <em>other Parties/ member countries to an association/ international organizations</em>, in addition to those specified in the common list, the Party <em>shall</em> notify other Parties of its decision within <em>XX number of days</em> of such recognition.</td>
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<td>5</td>
<td>Upon <em>the development of emergency situations,</em> Parties <em>shall</em> review the common list <em>standards and/or conformity assessment</em> within a period of <em>XX days</em> from the day when the emergency situation is first established.</td>
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<td>6</td>
<td>During <em>the emergency situation</em>, Parties shall establish <em>emergency registration/licensing/certification scheme</em> for the other Parties provided their products have been evaluated and approved by any one of the regulatory authorities in the <em>Specify list of countries. E.g.: United States, the United Kingdom, Australia, the European Union and Canada</em></td>
</tr>
</tbody>
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Thank you!