WORLD TRADE ORGANIZATION

G/TBT/GEN/287

12 March 2020

(20-1962)

Committee on Technical Barriers to Trade

THEMATIC SESSION ON GOOD REGULATORY PRACTICE: ENCOURAGING REGULATORY COMPATIBILITY AND COOPERATION[1]

25 FEBRUARY 2020, 10:00-13:00

Moderator's Report[2]

The Moderator of the Thematic Session on Good Regulatory Practice delivered this Report at the WTO TBT Committee's meeting of 26-27 February 2020.

At the Eighth Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with its regular meetings during 2019 to 2021, with a view to further deepening the Committee's exchange of experiences on specific topics, and to hold a session on good regulatory practice (GRP) in February 2020 with a focus on: Encouraging regulatory compatibility and cooperation.[3] The programme for the thematic session is contained in the Annex of this report. The presentations summarized below are available through the WTO website.[4]

Panel 1: Medical devices

1.1. **Ms Melissa Torres**[5] (United States) described examples of regulatory cooperation in the medical devices sector: the International Medical Device Regulators Forum (IMDRF); and the Medical Device Single Audit Program (MDSAP). The IMDRF seeks to accelerate international medical device regulatory convergence, while addressing common public health regulatory challenges and supporting innovation. The IMDRF is comprised of regulatory authorities of the ten Management Committee members[6] and includes participation of observers and regional harmonization initiatives (e.g. APEC and the Asian Harmonisation Working Party), which extends participation to additional regulatory authorities. There are eight IMDRF working groups, which develop harmonized documents, procedures, or regulatory harmonization programs, thereby promoting greater regulatory alignment amongst IMDRF members. One example of an output of IMDRF work was the Medical Device Single Audit Program (MDSAP), which includes participation of five members[7], two affiliate members[8], and two observers[9]. MDSAP does away with the need for multiple audits of manufacturers, by allowing recognized "Auditing Organizations" to conduct a single on-site audit of a medical device manufacturer that will satisfy the relevant requirements of five participating Regulatory Authorities. MSDAP minimizes regulatory burden on industry, promotes more efficient and effective use of regulator resources, enhances global alignment of regulatory approaches and technical requirements, and ensures consistency, predictability and transparency for manufacturers.

---

[1] The final programme was circulated as G/TBT/GEN/285. It is also in Annex I of this document.
[2] Ms Renata Cristaldo (Paraguay). This Report is provided on the Moderator's own responsibility.
[3] G/TBT/41, para. 8.2.a.iv, footnote 300; JOB/TBT/350.
[4] https://www.wto.org/english/tratop_e/tbt_e/thematic_session_standard_121119_e.htm
[5] Associate Director for International Affairs, Office of the Center Director, Center for Devices and Radiological Health, US Food and Drug Administration
[6] Australia, Brazil, Canada, China, the European Union, Japan, Russian Federation, Singapore, Korea, and the United States
[7] Australia, Brazil, Canada, Japan, US
[8] Argentina and Korea
[9] EU and WHO

More than 5,100 medical device manufacturing sites participate in the program, and the audit model is publicly available, further contributing to predictability and transparency.

1.2. **Ms Nancy Shadeed**[10] (Canada) outlined the context for regulatory cooperation in the medical devices sector, which includes fast paced technological development, very rapid regulatory reviews for market approval, and a wide diversity and complexity of technologies which pose challenges for regulators. Canada cooperates with partners through the IMDRF and the MDSAP, which help to accelerate harmonization and convergence building. IMDRF documents developed by its working groups were increasingly being adopted by regulators, including in Canada. For instance, the working group on Adverse Event Terminology develops harmonized terminology and systems to code information about adverse events, which ensures that when safety situations do arise regulators are using the same coding and avoid discrepancies, to enable international tracking and trending of adverse events. Health Canada will adopt the IMDRF Adverse Event Terminology later in 2020, and other jurisdictions are doing the same. Another example was Health Canada accepting the IMDRF Common Table of Contents for Medical Device Regulatory Submissions in 2019, which ensures that regulators in different countries will receive the same package of information in submissions, facilitating regulator-to-regulator discussion. She explained how the MDSAP took several years to develop and was built from an initial pilot between the US FDA and Health Canada. This pilot proved that a single audit could work and satisfy requirements of both countries, and led to discussions with Australia, Japan and Brazil to eventually create the single audit program. The MDSAP global approach pools technology, resources, and services to improve the safety and oversight of medical devices on an international scale, while benefiting manufacturers. Reviewing and evaluating novel devices in an agile manner is a key challenge for regulators, and there is a continued need for international collaboration to deliver solutions that provide market access and health and safety for patients worldwide.

1.3. **Ms Renata Amaral**[11] (United States) introduced the Inter-American Coalition for Regulatory Convergence, which is composed of medical technology associations of the Western Hemisphere and other private and public sector stakeholders. The coalition will be launched in March 2020 in Mexico City, with the aim of promoting regulatory cooperation across the Western Hemisphere to achieve internationally aligned medical technology regulations, standards and conformity assessment requirements. In this respect, some of the key challenges facing the medical devices sector include: the enormous diversity of products and therefore diversity of standards and regulations; the multiple sites involved in the manufacturing of a single medical device and the need for multilingual/multi-country labels; and the very complex and lengthy registration processes which vary between countries. Two key regulatory and trade challenges are that medical device regulators are not aware of the TBT Agreement or are not required to implement its provisions by trade ministries, and that medical devices are often improperly regulated as drugs. She highlighted the importance of medical device regulations applying key elements of GRP, including stakeholder engagement; reliance on quality data and sound science when introducing new regulation, impact analysis of proposed and implemented regulations; use of international standards; and transparency such as regulatory forecasting. In this respect, she said the US-Mexico-Canada Agreement (USMCA) Chapter on Good Regulatory Practices represents the state of the art in codifying GRP in a trade agreement, and the USMCA Sector Annex on Medical Devices provided important benefits for industry. In addition, the TBT Agreement and TBT Committee provide a unique framework for international regulatory cooperation contributing to easing trade frictions through, for example, the notification of draft measures, harmonization with international standards, and discussion of specific trade concerns.

1.4. **Mr. Erik Hansson**[12] (European Union) spoke about efforts in the EU to support global regulatory convergence in the field of medical devices. He said that medical devices are a challenge to regulate: they cover a very wide area or products (over 500,000 types of medical devices on the market), are important economically (over 500 000 people employed in the EU – with about 25,000 companies) – and with significant annual sales (€500 billion). From a global perspective, the main features from a regulatory point of view are similar, there are three main stages: 1) the pre-market stage; 2) the on-market stage (labelling); and 3) the post market phase (about ensuring the continued safety and effectiveness of device). The "New Approach" applies to these regulations. This

[10] Manager, International Programs Division, Office of Policy and International Programs, Medical Device Directorate, Health Canada

[11] Visiting Scholar - American University Washington College of Law, Technical Secretariat – Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

[12] Deputy Head of Unit, Directorate-General for Health and Food Safety (SANTE), European Commission

means that essential requirements set out safety and performance requirements which are then implemented through harmonized (voluntary) standards. CE marks indicate that requirements are met, and conformity was done through third party assessment (by notified bodies). For market surveillance, much emphasis is put on market surveillance under the responsibility of member States. Two new EU Regulations were described which are aimed at increasing the protection of patients and health. These regulations, Mr. Hansson said, provide more transparency, support innovation and improve requirements for clinical data and evaluation. It was stressed that the EU single market for medical devices includes, aside from the EU, also EFTA/EAA, Turkey and Switzerland. At a global level, it was noted that a WHO survey (2015/16) showed that 58% of countries have regulations, 27% have none and 15% did not provide an answer to the survey. Mr Hansson then spoke of the International Medical Device Regulators Forum (IMDRF). This Forum, he said, has a mission to achieve more convergence. Membership of the forum comprises several countries[13], has several work items, including, for example: good regulatory review practices, quality of standards for regulatory use, and cybersecurity. Mr. Hansson provided a few examples of the results of this work and stressed, among other things, that this work was informal, non-binding, flexible, quick, and involves the establishment of best practices. Several new EU regulations are based on IMDRF principles.

1.5. **Mr. Minoru Iijima**[14] (Japan) spoke about regulatory cooperation on medical devices. While medical devices have been rapidly globalized, each regulatory authority has developed different regulations, including definitions, categorizations, quality, non-clinical and clinical requirements; this could result in overlap and deviation. It was important that each regulatory authority had the resources and capacity to keep up with rapid technical developments. Regulatory authorities around the world need to promote harmonization and reliance on common international standards. In this regard, WHO works on the regulatory system strengthening for medical products and promotes regulatory cooperation to strengthen capacity of national regulatory authorities. He explained the role of Japanese regulatory authorities including the Pharmaceutical Safety and Environmental Bureau (MHLW) and the Pharmaceutical and Medical Devices Agency (PMDA), the Japanese approval and certification system for medical devices, and risk-based classification of medical devices. Japan is a member of the IMDRF and is participating in the Medical Device Single Audit Programme (MDSAP), describing the benefits of its use from the view of both importing and exporting manufacturers. In addition, Japan has been providing capacity building seminars for other regulatory authorities through PMDA-Asia Training Centre.

Panel 2: New vehicle technologies

1.6. **Ms Ivone Kaizeler**[15] (European Commission) spoke about the UNECE World Forum for the harmonization of vehicle regulations: the WP.29. The presentation was essentially an example of how international guidance (work at UNECE WP.29) is used in EU legislation. In the automotive area, she said, this was about drafting regulations – based on international guidance – essentially for safety and environmental objectives. Before placing vehicles on the market, third party mandatory conformity assessment is required – or, "type approval". Three UNECE agreements had been adopted that establish regulatory measures for motor vehicles and motor vehicle equipment: the (i) the 1958 Agreement – UN Regulations; (ii) the 1998 Agreement - United Nations Global Technical Regulations (UN GTRs); and (iii) the 1997 Agreement - UN Rules (periodical technical inspections). Ms Kaizeler focused on the 1958 Agreement, which sets out uniform technical prescriptions for wheeled vehicles, equipment and parts and the conditions for reciprocal recognition of approvals – in around 150 regulations and over 60 contracting parties. These regulations govern, among other things, safety and environmental aspects. The 1958 Agreement is essentially, she said, a mutual recognition agreement done at the multilateral level with rules considered relevant under Article 2.4 of the TBT Agreement. The regulations were applicable to the EU – meaning that most of them are binding in EU law through incorporation of a reference in EU legislation. It was noted that automated and connected vehicles is an area that is not yet fully regulated. Several issues would need looking into, including how to assess new technologies such as automation, software updates, cybersecurity, event data recorders (accidents), awareness of "vulnerable road users' proximity", and measuring emissions. These were areas where several countries are active but there is no definitive regulation yet. In sum, UNECE work was a good, international forum to find ways and means of reducing

[13] http://www.imdrf.org/about/about.asp

[14] Ministry of Foreign Affairs, Ministry of Health, Labour and Welfare, Japan.

[15] Team Leader, Automotive Unit, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

unnecessary technical barriers to trade, to ensure equivalent standards of safety and environmental performance – thereby ensuring high level of consumers protection and at the same time making life easier for manufacturers and regulators.

1.7. **Mr. Kensuke Suzuki**[16] (Japan) spoke about Japanese policy on automated driving and its contribution to the international activities in this area. Mr Suzuki noted that automated driving is expected to significantly decrease traffic accidents caused by drivers' error. In Japan, up to 95% of accidents were due to driver error (in 2018) – thus there was significant scope for reducing mortality and injury with more automation. Also, automated driving could help Japan overcome challenges related to the shortage of professional drivers. There were several levels for automated driving, ranging from simple driving assistance (staying on the lane) to fully automated driving (the system performed the full driving). Mr Suzuki then explained the government's strategy to develop increasing automated driving towards 2025 which would, *inter alia*, reduce accidents, encourage innovation and enable societal goals (free movement of elderly). To realize these goals, it would be necessary to develop national laws compatible with automated driving – this included an amendment to the Road Vehicle Law (passed and enacted in May 2019). This included, for example, the domestic adoption and implementation of specific technical requirements set out in UNECE WP.29. Thus, at the international level, Japan was contributing to discussion held in the UNECE with the objective of promoting internationally harmonized regulations to the benefit of car manufacturers and consumers (motor vehicle users) in every country. This was a good way of collaborating at the international level because it was a more effective rule-making process. Indeed, G7 transport ministers, in a joint declaration (June 2017 in Cagliari, Italy) had reaffirmed their commitment to identify and remove potential barriers to the introduction of automated guidance technology – and to cooperate on existing regulation systems at international and country levels.

COMMENT BY MODERATOR

1.8. On a personal note, **the Moderator** made the following remarks.

1.9. Finally, let me make a few personal remarks. The presentations were useful in that they highlighted the application of good regulatory practices and regulatory cooperation in two very different sectors: medical devices and new vehicle technologies. In both cases, the importance of cooperation between regulatory authorities was emphasized, including through development of guidance and best practices at the international level, such as through the IMDRF for medical devices, or through work in UNECE for cars. The importance of cooperating – particularly in the area of new technologies – where regulation has not yet developed, was emphasized. We heard about the importance of using relevant international standards to promote regulatory convergence in approaches to regulating new technologies. Several presentations also emphasized the importance of following the principles of the TBT Agreement to ensure the avoidance of unnecessary barriers to trade while allowing regulations to achieve legitimate objectives in these two sectors, including the protection of human safety, as well as the environment. The use of good regulatory practices was highlighted, such as transparency, ensuring a scientific basis for regulation, impact analysis, and ensuring participation of all relevant stakeholders in the development of regulation. The discussion showed how regulatory cooperation in specific sectors can help regulators better meet public policy objectives with fewer resources, while also reducing burdens on industry.

[16] Ministry of Land, Infrastructure, Transport and Tourism in Japan

ANNEX

THEMATIC SESSION ON GOOD REGULATORY PRACTICE: ENCOURAGING REGULATORY COMPATIBILITY AND COOPERATION

25 FEBRUARY 2020, 10:00-13:00

Programme[1]

At the Eighth Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with its regular meetings during 2019 to 2021, with a view to further deepening the Committee's exchange of experiences on specific topics, and to hold a session on good regulatory practice (GRP) in February 2020 with a focus on: Encouraging regulatory compatibility and cooperation.[2]

This thematic session will be moderated by **Ms Renata Cristaldo (Paraguay)**.

Guiding questions:

- What are the key regulatory compatibility and cooperation challenges in the medical devices/new vehicles technologies sectors?
- What approaches to regulatory cooperation are most effective in promoting regulatory compatibility in the medical devices/new vehicle technologies sectors?

Panel 1: Medical devices

a. **United States**: *Examples of Regulatory Cooperation in the Medical Device Sector: The International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Program (MDSAP)*, Ms. Melissa Torres, Associate Director for International Affairs, Office of the Center Director, Center for Devices and Radiological Health, US Food and Drug Administration.

b. **Canada**: *Canada's Experience in Regulatory Cooperation in the Medical Devices Sector*, Ms. Nancy Shadeed, Manager, International Programs Division, Office of Policy and International Programs, Medical Device Directorate, Health Canada.

c. **United States**: *Good Regulatory Practices, Technical Barriers to Trade and the Impact for the Medical Technology Sector*, Ms Renata Amaral, Visiting Scholar - American University Washington College of Law, Technical Secretariat – Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector.

d. **European Union**: *Efforts to support global regulatory convergence in the field of medical devices and mechanisms for exchange of post market safety information on medical devices with global distribution*, Mr. Erik Hansson, Deputy Head of Unit, Medical Devices, Directorate-General for Health and Food Safety (SANTE), European Commission.

e. **Japan**: *Regulatory Cooperation on Medical Devices*, Mr. Minoru Iijima, Deputy Director for International Trade division, Economic Affairs Bureau, Ministry of Foreign Affairs of Japan, (on behalf of Ministry of Health, Labour and Welfare, Japan).

Panel 2: New vehicle technologies

a. **European Union**: *UNECE World Forum for the harmonization of vehicle regulations – a global standard bearer and blueprint for EU legislation*, Ms Ivone Kaizeler, Team Leader,

[1] The draft programme is contained in JOB/TBT/354/Rev.1.
[2] G/TBT/41, para. 8.2.a.iv, footnote 300; JOB/TBT/350.

Automotive and Mobility Industries, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (GROW), European Commission.

b. **Japan**: *Japanese Policy and contribution to the International Activities on Automated Driving*, Mr. Kensuke Suzuki, Deputy Director for Road Transport Policy Planning, General Affairs Division, Ministry of Land, Infrastructure, Transport and Tourism of Japan.