



Committee on Technical Barriers to Trade

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

25 FEBRUARY 2020, 10:00-13:00

Programme¹

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

- 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.
- 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.
- 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.
- 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.

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](#).

- 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, 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.
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