Strengthening the Internal Market – time for a 'new deal' for European standardisation?

2 June 2020

orgalim | EUROPE'S TECHNOLOGY INDUSTRIES

Our panellists

Caterina Brusasco

R&D Compliance Domain Expert, **IBA** Medical Devices (**COCIR**) CEB-BEC Belgian chairperson of TC 62, Belgian national expert to several IEC and ISO committees

Mette Peetz-Schou

Leading Senior Adviser, **Danish Industries** & Chair of **Orgalim** Technical Committee. More than 25 years of experience with making cross-sectors/ stakeholders solutions

Paul Coebergh van den Braak

Chair of **BusinessEurope**'s Free movement of Goods; Standardisation Manager, **Philips** Intellectual Property & Standards

Philippe Portalier

Director Better Regulation, Compliance and Standards, **Orgalim**; 22 years experience in conformity assessment for the technology industries

Standards for medical devices: practical application issues

Caterina Brusasco

R&D Compliance Domain Expert,
IBA Medical Devices (**COCIR**)

Strengthening the Internal Market – time for a 'new deal' for European standardisation?

2 June 2020

orgalim | EUROPE'S TECHNOLOGY INDUSTRIES

Introduction to COCIR & medical devices

- Medical devices represent devices employed in healthcare with a **high variety of complexity and large diversity of technologies**
- Medical devices are placed on the market in a **highly-regulated environment**: Medical Device Directives replaced by Medical Device Regulation in May 2021; follow the New Approach
- **COCIR covers four sectors**: medical imaging, radiotherapy, electro-medical equipment & digital health

COCIR engagement in standardisation

COCIR members actively participate

- to **international standardization (IEC and ISO)**
- in various **European Commission expert groups on standardization**, both specific to medical devices and at horizontal level
- in discussions on standardization with **international regulators for medical devices** (IMDRF)

COCIR

- is funding the secretariat of **IEC TC 62 "Electrical equipment in medical practice"**
- has a long-standing Category A liaisons with **IEC TC 62 and ISO TC 215 "Health Informatics"**

Importance of standards in the medical device sector

- **European hospitals, healthcare professionals & patients** need rapid access to medical innovation that has proven to be beneficial and safe
- Standards document the **state of the art**
- **International technical alignment** is the reference for state of the art for medical devices
  - A large majority (between 80% and 99% depending on the product area) of today's European Norms for medical devices are technically **identical copies of ISO or IEC international standards**
- **The harmonization of EN standards facilitates rapid access of medical devices** to the European single market

Current challenges in the harmonization of standards for medical devices

Lengthy and bureaucratic process to prepare and assess the detailed mapping of the standard against the requirements of the legislation

- Example: it took a COCIR-led team 5 years to get Annexes Z approved for 5 standards

Serious **delay in the harmonisation of standards** under the Medical Device Directives

- Example: from the EN IEC 60601-series (safety and essential performance of medical electrical equipment), at least 80% of the OJEU listed editions is outdated. Newly published standards since 2012 have not even been included.

The **standardisation request** for the new Medical Device Regulation will make the harmonisation process even more problematic

- Presumes a European-led development of standards while today most standards are developed at international level
- Triggers a divergence in the technical content between European and International Standards without any technological justification

Impact of a burdensome harmonisation process on the European Single Market for medical devices

Without Harmonised Standards,

- there is no presumption of conformity
- and each manufacturer has to interpret the legal requirements on how to demonstrate conformity.

- ❑ **Uneven quality** of devices placed on the EU market
- ❑ **Additional burden on manufacturers** and increased **time-to-market** for medical devices
- ❑ **Legal uncertainty** for manufacturers

Impact of a burdensome harmonisation process on international alignment

Facts

1. Deviation of European standards from international standards while state of the art in technology is the same as at the international level

2. Lack of new EU standards linked to EU legislation as international standardization committees increasingly ask for decoupling from EU standardization request

3. EU Technical Committees stop asking for publication in the Official Journal

- Example: CEN/TC 215 Respiratory and anaesthetic equipment

Consequences

- Decreased European influence **at international level**
- Reduced **international convergence** of technical requirements
- Endangered **global competitiveness** of European medical device manufacturers that support additional costs for analysis of EU deviations
- Possible **shortage of medical devices** if non-EU manufacturers do not support the additional costs for analysis of EU deviations

Medical device manufacturers need:

- **EU regulatory process** showing commitment to harmonised standards as the preferred option for demonstrating conformity
- **European recognition** of international standards according to the WTO principle
- **Timely harmonisation** of state-of-the-art standards with rapid publication and adequate transition times
- **Legal certainty** based on presumption of conformity

Polling time

To what extent do you believe it is important to resolve the current challenges to the European standardisation system?

- Not really important
- Somewhat important
- Important
- Very important?

Questions?