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

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Some figures on the medical device sector

- Over 500,000 types of medical devices on the market
- Over 500,000 people employed in the EU in about 25,000 companies
- Global market €500 billion in annual sales
Main features of medical device regulations globally

- Classification in risk classes
- Clinical investigations
- Premarket approval
- Quality management system
- Postmarket management
- Use of international standards
In the EU paired with the principles of the “New Approach” for regulating products

• **Essential requirements** (safety, performance, etc.)

• **Harmonised standards** (voluntary) presumption of conformity with the essential requirements

• **CE Marking**

• **Third-party assessment** by Notified Bodies

• **Market surveillance** by Member States
The new EU Regulations on medical devices
(adopted 5 April 2017 and published 5 May 2017)

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- Regulation on medical devices (MDR)
- Directive 98/79/EC on \textit{in vitro} diagnostic medical devices
- Regulation on \textit{in vitro} diagnostic medical devices (IVDR)
The new Regulations

- Increased protection of patients and health
- Greater transparency and information available
- Supports continued innovation and access to new technologies
- Improved requirements for clinical data and evaluation
- Increased consistency and predictability
- Promote confidence, increased stability and greater fairness
The EU single market for medical devices

1. EU

2. EFTA/EEA: Norway, Liechtenstein, Iceland

3. Turkey

4. Switzerland
The global picture

WHO survey of members 2015/2016:

- 58 % have Regulations
- 27 % no Regulations
- 15 % no answer
International multilateral cooperation

- **The International Medical Device Regulators Forum (IMDRF)**
- **Mission:** Accelerate international medical device regulatory *convergence*... - whereby the requirements and approaches become more *similar or aligned* as a result of the adoption of the same technical documents, standards and scientific principles and similar regulatory practices and procedures.
# Membership of IMDRF

<table>
<thead>
<tr>
<th>Members</th>
<th>Official observers</th>
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<tbody>
<tr>
<td>Australia</td>
<td>World Health organisation (WHO)</td>
</tr>
<tr>
<td>Brazil</td>
<td>Asian-Pacific Economic Cooperation (APEC)</td>
</tr>
<tr>
<td>Canada</td>
<td><strong>Affiliate organisations</strong></td>
</tr>
<tr>
<td>China</td>
<td>Asian harmonisation Working Party (AHWP)</td>
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<tr>
<td>European Union</td>
<td>Pan American Health Organisation (PAHO)</td>
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<tr>
<td>Japan</td>
<td><strong>Invited observers to MC meetings</strong></td>
</tr>
<tr>
<td>Russian Federation</td>
<td>Pan African Harmonisation Working Party (PAHWP)</td>
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<tr>
<td>Singapore</td>
<td>Global Medical Technology alliance (GMTA)</td>
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<tr>
<td>South Korea</td>
<td>Global Diagnostic Imaging, Healthcare IT &amp; Radiation Therapy Trade Association (DITTA)</td>
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<tr>
<td>United States</td>
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# IMDRF work items

<table>
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<tr>
<th>Work item</th>
<th>Relevance</th>
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<tr>
<td><strong>ONGOING</strong></td>
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<tr>
<td>Adverse event terminology (AE)</td>
<td>Improved analysis of safety information and reporting of safety issues</td>
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<td>Good regulatory review practices (GRRP) – Medical Device Single Review Process</td>
<td>Development of principles for recognition of entities that will perform the review of premarket submissions of medical devices on behalf of Regulatory Authorities</td>
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<td>Regulated Product Submissions (RPS)</td>
<td>Standard &quot;language&quot; and consistency of content for regulatory submissions. &quot;One form for all&quot;.</td>
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<td>Quality of International Medical Device Standards for Regulatory Use</td>
<td>Improved process and dialogue on standards development Increased recognition of standards</td>
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<td>IVD Classification</td>
<td>Update IVD classification guidance to reflect recent international developments</td>
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<td>Personalized Medical Devices</td>
<td>Develop approach for regulating medical devices that are manufactured for individual patients.</td>
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## IMDRF work items (cont'd)

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| Medical device clinical evaluation | Essential requirements for demonstrating equivalency of clinical trials  
Decision making principles for triggering clinical trials  
Acceptance of oversea trials       |
| Cybersecurity                      | Facilitate international regulatory convergence on medical device cybersecurity                                                           |
Example: Make international standards fit regulatory requirements of multiple jurisdictions

- Map national/regional approaches to the use of standards under regulations
- Recommendations for how to develop “regulatory-ready” standards
- Enhance (co-ordinate?) regulatory authorities participation in standards development processes
- Develop and formalise liaisons with ISO and IEC
IMDRF National Competent Authorities Report (NCAR) Exchange Program

- Global market – same risks everywhere
- Risks reported or discovered nationally
- Exchange facilitates risk detection
- Co-operation on risk assessment
- Risk-management can vary
- 21 years of existence – 7 members - more coming
- Criteria and forms for reporting through a secretariat
- Difficulty: confidentiality restrictions
Results

- From 7 to 10 members, approx. 45 technical documents
- Voluntary cooperation
- Informal – no binding instruments
- Flexible and quick
- Best practices
- Used within limitations of national/regional legal environments
- EU-specific: The new EU regulations in several respects based on IMDRF principles
Thank you for your attention!