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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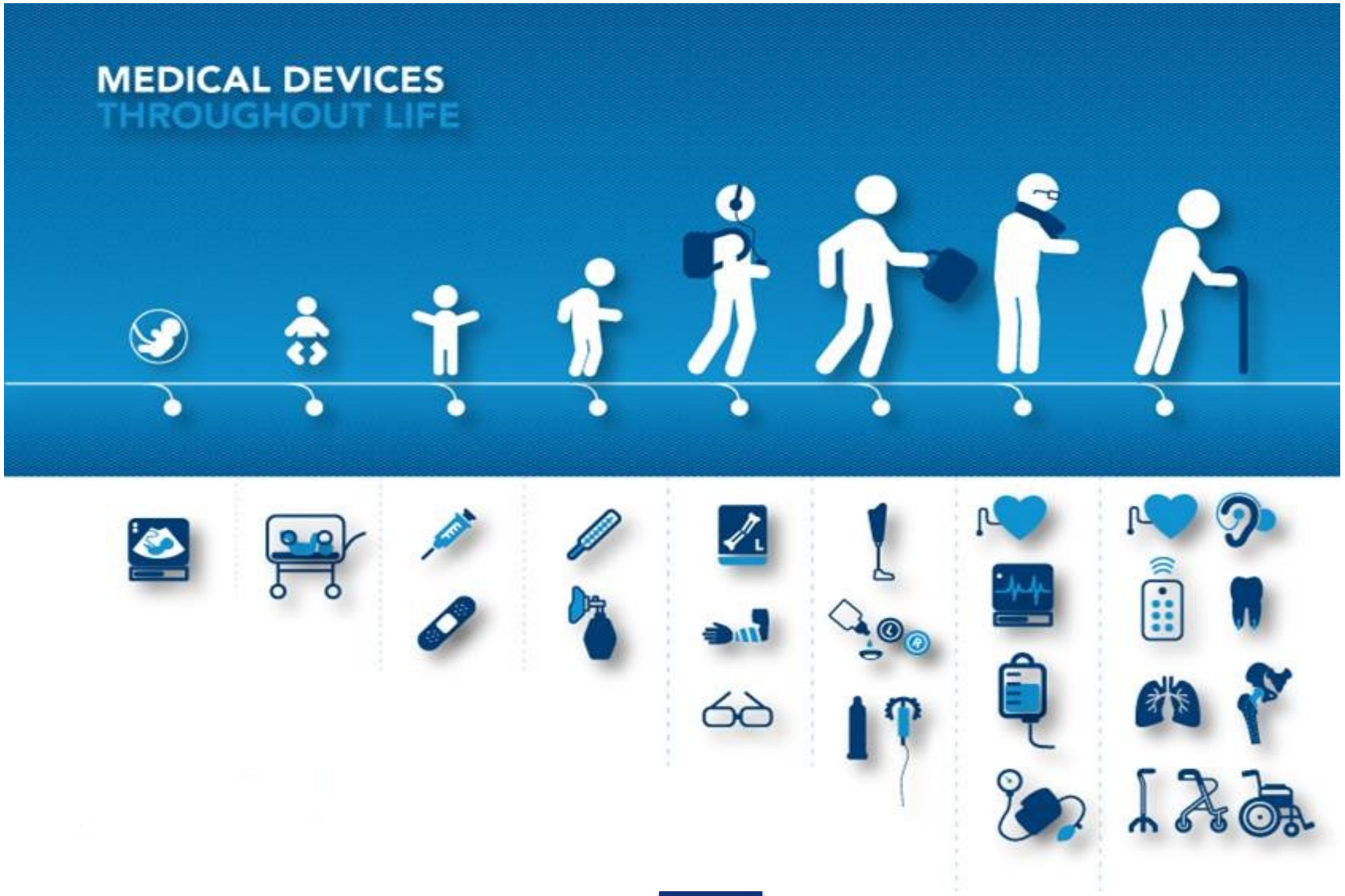

Some figures on the medical device sector

- 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
- Postmarked 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 *in vitro* diagnostic medical devices

→ Regulation on *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

Members	Official observers
Australia	World Health organisation (WHO)
Brazil	Asian-Pacific Economic Cooperation (APEC)
Canada	**Affiliate organisations**
China	Asian harmonisation Working Party (AHWP)
European Union	Pan American Health Organisation (PAHO)
Japan	**Invited observers to MC meetings**
Russian Federation	Pan African Harmonisation Working party (PAHWP)
Singapore	Global Medical Technology alliance (GMTA)
South Korea	Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
United States	

Chart by HPRA

IMDRF work items

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

Chart by HPRA

IMDRF work items (cont'd)

Work item	Relevance
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

Chart by HPRA

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!