Commission/CAMD Stakeholder meeting

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Revision of the EU Medical Devices Legislation

Background

Directive 90/385/EEC on active implantable medical devices
Directive 93/42/EEC on medical devices

Regulation on medical devices

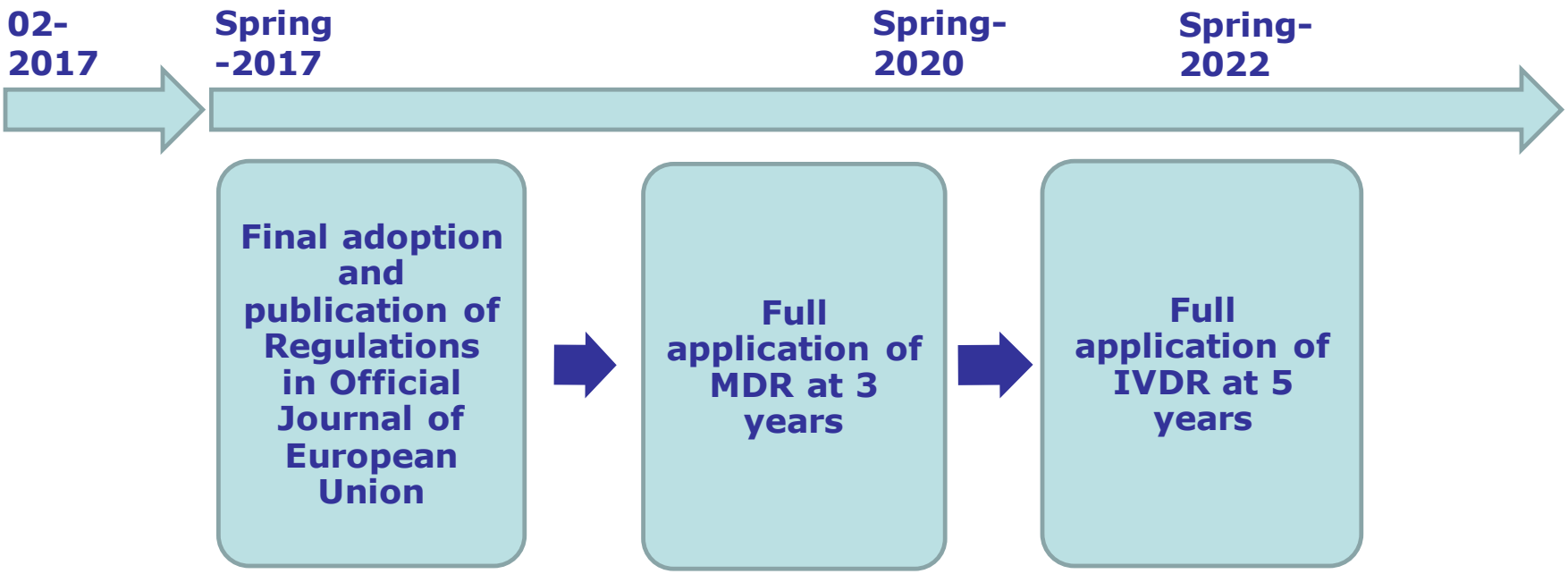
Directive 98/79/EC on *in vitro* diagnostic medical devices

Regulation on *in vitro* diagnostic medical devices

State of play and next steps

- 7 March 2017: Adoption of Council's 1st reading position
- 21 March 2017: Discussion and vote in ENVI Committee
- 4-5 April 2017 (expected): EP second-reading vote
- End of April/beginning of May 2017 (expected): publication of the Regulations in the OJ

Transitional period



Key derogations

- 6 months after entry into force: Requirements on Notified Bodies; designation of Competent Authorities; establishment of the MDCG
- 12 months after entry into force: Cooperation among Competent Authorities
- 18 months after date of application: Registration of devices
- 1-5 years after date of application: Placement of UDI carrier
- 2(IVD)/4(MD) years after date of application: Maximum period of validity of certificates issued under current Directives
- 3(IVD)/5(MD) years after date of application: Making available of devices placed on the market pursuant to current Directives
- 7 years after date of application: Coordinated procedure for clinical investigations

Main features of the new texts

- ✓ **Stricter pre-market control** of high-risk devices with the involvement of a pool of experts at EU level.
- ✓ Inclusion of **certain aesthetic devices** within the **scope**.
- ✓ EU minimum requirements related to **reprocessing of single-use devices**.
- ✓ **Reinforced designation and oversight** processes of **notified bodies.**
- ✓ Reinforcement of the rules on **clinical evaluation** (and performance evaluation) and **clinical investigation** (and performance studies).
- ✓ **New classification system for IVDs** based on international guidance (80% of IVDs to be assessed by a Notified Body).
- ✓ **Establishment of a comprehensive EU database on medical devices (EUDAMED)** with large part of information to be made publicly available.
- ✓ Stricter requirements related to the **use of hazardous substances** for certain devices.
- ✓ Clarification of the role and responsibilities of **economic operators**.
- ✓ Introduction of a **UDI system**.

Towards implementation: some key aspects

- **More than 80 empowerments for DAs/IAs (18 mandatory) to be adopted**
  - Implementing acts and delegated acts to be adopted according to the new Better Regulation framework, which normally includes a 4-week public feedback
  - Depending on type and sensitivity of the act possible Impact Assessment and 12-week public consultation at an early stage of the procedure
  - Guidance (e.g. MEDDEV) to be possibly adopted only for matters which are not covered by Commission's empowerment
- **Governance: MDCG to be established 6 months after entry into force**
  - It will be set as a Commission's expert group (in line with rules laid down in COM decision C(2016)3301)
  - Technical subgroups of MDCG can include stakeholders. Intention to make sure that our current expert groups are carried over to the new regime, though in a more simplified and functional structure

Implementation: priorities

- Notified Bodies (IA on scope of designation, applications, fees and reimbursements related to JAs)
- Governance: Setting up of the Medical Device Coordination Group (MDCG)* and setting of expert panels and reference laboratories
- Common specifications on devices without a medical purpose ("aesthetic devices") and reprocessing of single-use devices
- EUDAMED and UDI system
- OTHER: Mandate to SCHEER to produce guidelines on phtalates

*The MDCG is the main body supporting the Commission in implementing the future Regulations. It comprises representatives from National Competent Authorities and is chaired by the Commission

EU governance laid down in the new Regulations

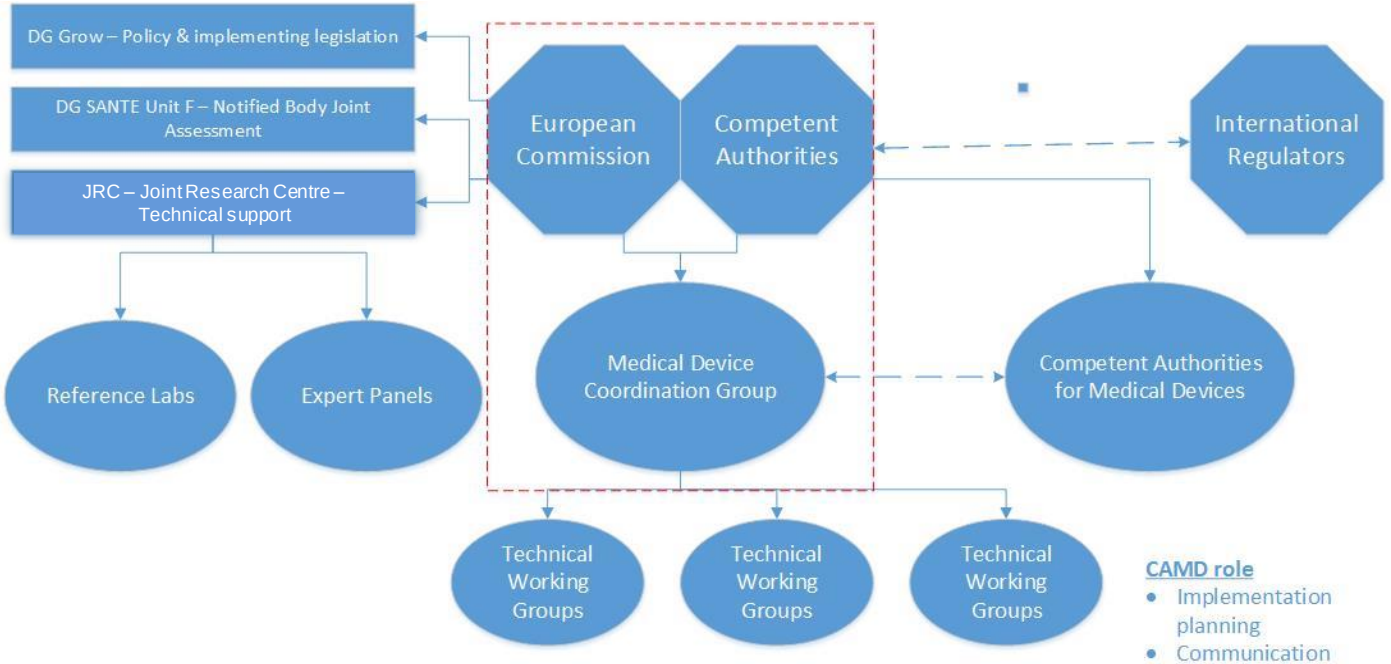
Reinforced coordination

- **Medical Device Coordination Group (MDCG) and subgroups**
  - Experts representing national authorities (MD and IVD)
  - Chaired by the European Commission
- **Technical, scientific and logistic support**
  - European Commission: DG GROW, DG SANTE and JRC
  - Expert panels / expert laboratories / reference laboratories

Committee on Medical Devices

- **"Comitology" Committee**
  - For medical devices and IVDs together

The European governance map



MDCG tasks

Oversight
Guidance development
System development
Policy advice

- Classification
- Clinical
- EUDAMED
- Notified bodies
- Market surveillance
- Vigilance
- Standardisation/CTS

CAMD role

- Implementation planning
- Communication
- Best practice development
- Training
- Peer review
- Joint actions
- Coordination
- Strategic development

Chart by HPRA

Partners in the EU system for devices

1. EU

2. EFTA/EEA:
   Norway, Liechtenstein, Iceland

3. Turkey

4. Switzerland

International cooperation

Multilateral – IMDRF (International Medical Device Regulators Forum)

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-Africa Harmonisation Working Party (PAHWP)
Singapore	Global Medical Technology Alliance (GMTA)
United States	Global Diagnostic Imaging, Healthcare IT & radiation therapy Trade Association (DITTA)

Chart by HPRA

Bilateral relations

- Australia (MRA+dialogue)
- Canada (CETA+)
- China (WGs with CFDA and AQSIQ)
- India (WG with MoHWF)
- Japan (FTA/EPA negotiations)
- Singapore (FTA)
- South Korea (FTA with WG)
- USA (MRA+TTIP)

Thank you
for your attention