IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

Erik Hansson

European Commission

IMDRF – 18

The EU single market for medical devices

1. EU

2. EFTA/EEA:
   Norway, Liechtenstein, Iceland

3. Turkey

4. Switzerland

Covid-19
Shortages

- Ramping up of production
- European Standards made freely available
- Combatting export restrictions
- Derogations

- Joint procurement Agreement
- Clearing House

Covid-19 – main MDR regulatory measures

- Regulation (EU) 2020/561 adopted on 23 April 2020 amending MDR, as regards **the dates of application** of certain of its provisions

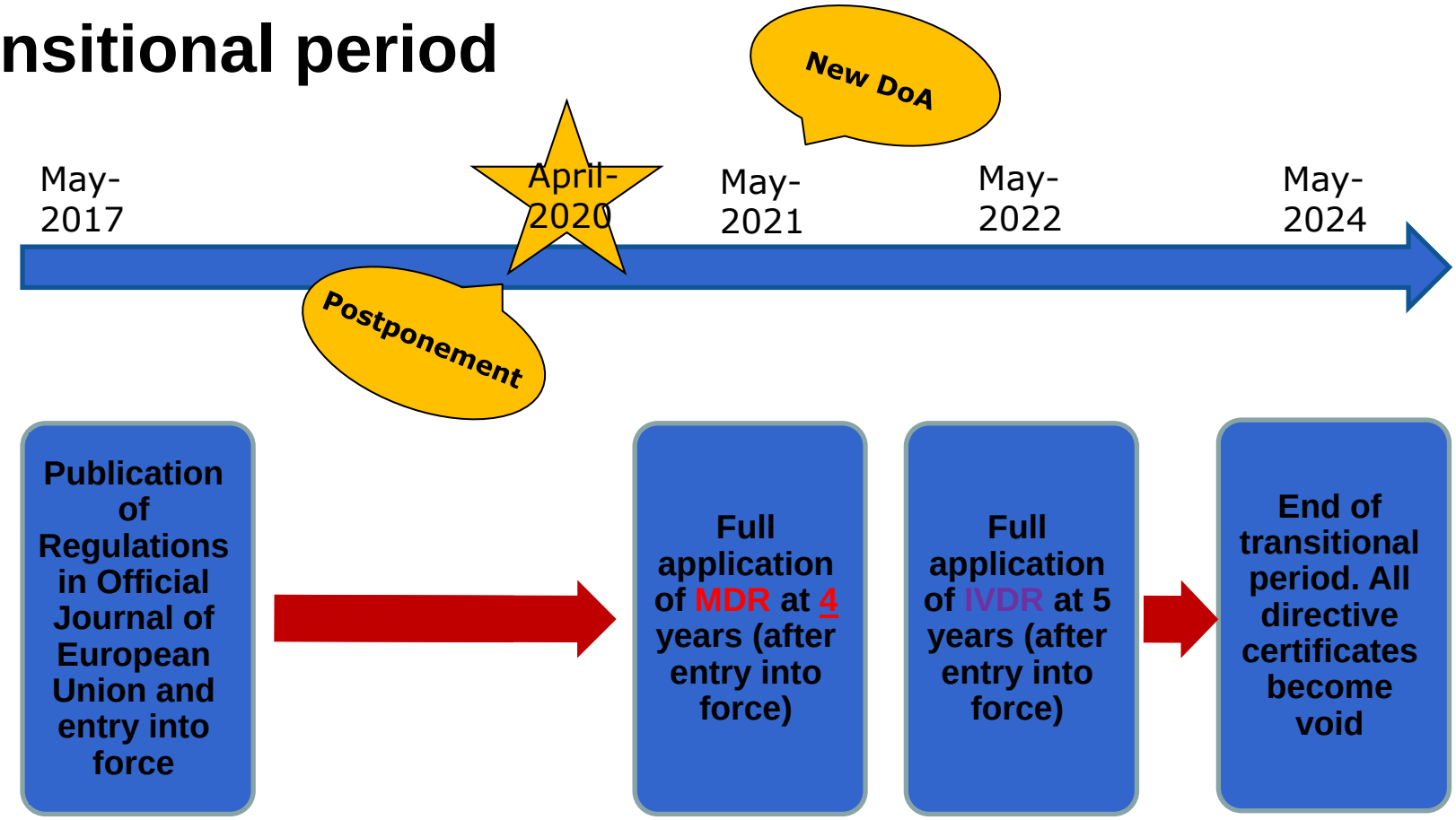
- Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the **renewal of designations** and the surveillance and monitoring of notified bodies

Covid-19 related guidance documents issued (selection)

- Guidance on placing medical devices and PPE on the EU market
- Guidance on Medical devices, Active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context
- Guidance to increase production of PPE, hand gel, 3D printing
- Guidance on regulatory requirements for ventilators
- Guidelines on COVID-19 IVD tests and their performance
- Working document on performance of COVID-19 test methods
- Database of publ. available performance data COVID-19 IVD
- Commission guidelines on Union-wide derogations
- Guidance on temporary measures on notified body audits during COVID-19 quarantine orders and travel restrictions + renewal designations.

Towards MDR/IVDR implementation

Transitional period



COM implementation priorities (1)

- **Notified Bodies**
  - ✓ 52 applications received up to date. Full scope of MDR and IVR covered
  - ✓ 20 notified bodies designated under new Regulations
- **Governance**
  - ✓ Setting up of MDCG (November 2017)
  - ✓ MDCG technical subgroups (13) operational as from 1st Mar 2019
  - ✓ Work on 70+ guidance documents ongoing or finalised
- **Scientific structures**
  - ✓ Establishment of expert panels, expert laboratories and reference labs (Q1 2020)
  - ✓ Expert panels operational Q4 2020
- **Design and establishment of the new EUDAMED**
  - ✓ Core actor registration module of database to be available Q4 2020
  - ✓ Staged approach

COM implementation priorities (2)

- **Establishment of UDI system**
  - ✓ 9 guidelines published, nomenclature selected in Feb 2019, designation of issuing entities finalised in Jun 2019, release of Q/A in Aug 2019
- **Mandate for revision of standards (Q3 2020)**
- **Communication campaign**
  - ✓ Dedicated website, factsheets in all EU languages and some major non-EU languages
- **Common specifications on devices without medical purpose (Q4 2020)**
- **Common specifications on reprocessing of single-use devices (Q3 2020)**

Planning of activities:

- Publication of Commission's rolling plan on DG SANTE website: https://ec.europa.eu/docsroom/documents/41501/attachments/1/translations/en/renditions/native

COM implementation priorities (3)

Key guidance published since March 2020

March 2020

- ✓ Update of guidance on implant card
- ✓ Transitional provisions of article 120 (3) and (4) for class I medical device
- ✓ Significant changes regarding transitional provisions in Art.120
- ✓ Clinical evaluation/ Performance evaluation of medical device software

April 2020

- ✓ Update of guidance on Article 54(2)b
- ✓ PMCF templates
- ✓ Sufficient clinical evidence for legacy devices
- ✓ Clinical evaluation – Equivalence

May 2020

- ✓ Safety reporting in clinical investigations

June 2020

- ✓ Consultations of authorities on devices with ancillary substances and TSE susceptible tissues
- ✓ Update of guidance on UDI for systems and procedure packs

July 2020

- ✓ Clinical evaluation assessment report template

August 2020

- ✓ MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
- ✓ Guidance for notified bodies on the use of MDSAP audit reports under MDR and IVDR

Thank you for your attention !

Erik Hansson

European Commission
Medical Devices and Health Technology Assessment Unit