Update on EU regulatory developments

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IMDRF – 19

Health

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The EU single market for medical devices

1. EU

2. EFTA/EEA:
   Norway, Liechtenstein, Iceland

3. Turkey

4. Switzerland

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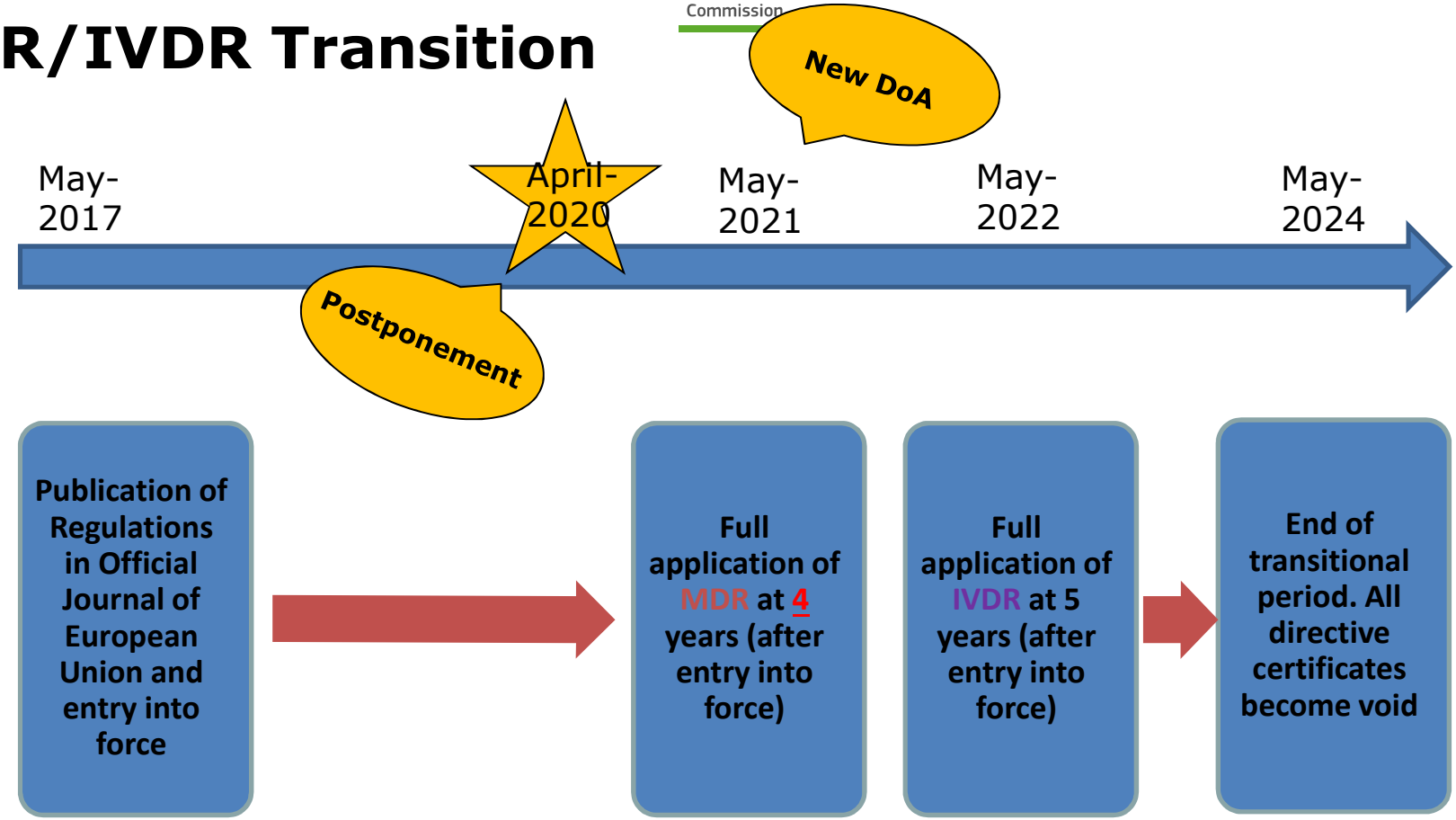
MDR/IVDR Transition



COM implementation priorities (1)

- **Notified Bodies**
  - ✓ 60 (46+14) applications received up to date. Full scope of MDR and IVR covered
  - ✓ 23 (19+4) 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**
  - ✓ Expert panels designated (2019)
  - ✓ Publication of designated experts to expert panels (Q1 2021)
  - ✓ Expert laboratories and reference labs (timelines under revision)
- **Design and establishment of the new EUDAMED - Staged approach**
  - ✓ Core actor registration module of database made available Q4 2020
  - ✓ UDI module in Q2 2021
- **Establishment of UDI system**
  - ✓ 10 guidelines published, designation of issuing entities finalised in Jun 2019, release of Q/A in Aug 2019

COM implementation priorities (2)

- **European Medical Device Nomenclature official publication** (Q1-Q2 2021)
- **Mandate for revision of standards** (Q1 2021)
- **Communication campaign**
  - ✓ Dedicated website, factsheets in all EU languages and some major non-EU languages
  - ✓ Specific factsheets for competent authorities in non-EU/EEA countries
- **Common specifications on devices without medical purpose** (Q2-Q3 2021)
- **Common specifications on reprocessing of single-use devices** (Q3 2020)

Planning of activities:

- **Publication of Commission's rolling plan on DG SANTE website**

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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

November 2020

- ✓ Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

December 2020

- ✓ MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
- ✓ Questions and Answers related to MDCG 2020-4: "Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions"

January 2021

- ✓ Guidance on Management of legacy devices in EUDAMED.

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Covid-19 (1) - Shortages

- Ramping up of production
- Many European Standards made freely available
- Combatting export restrictions
- Derogations
- Joint procurement Agreement
- Clearing House

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Covid-19 (2) – main MDR and MDD 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

- Commission notice the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment

Covid-19 (3) - 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.

Thank you for your attention !

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