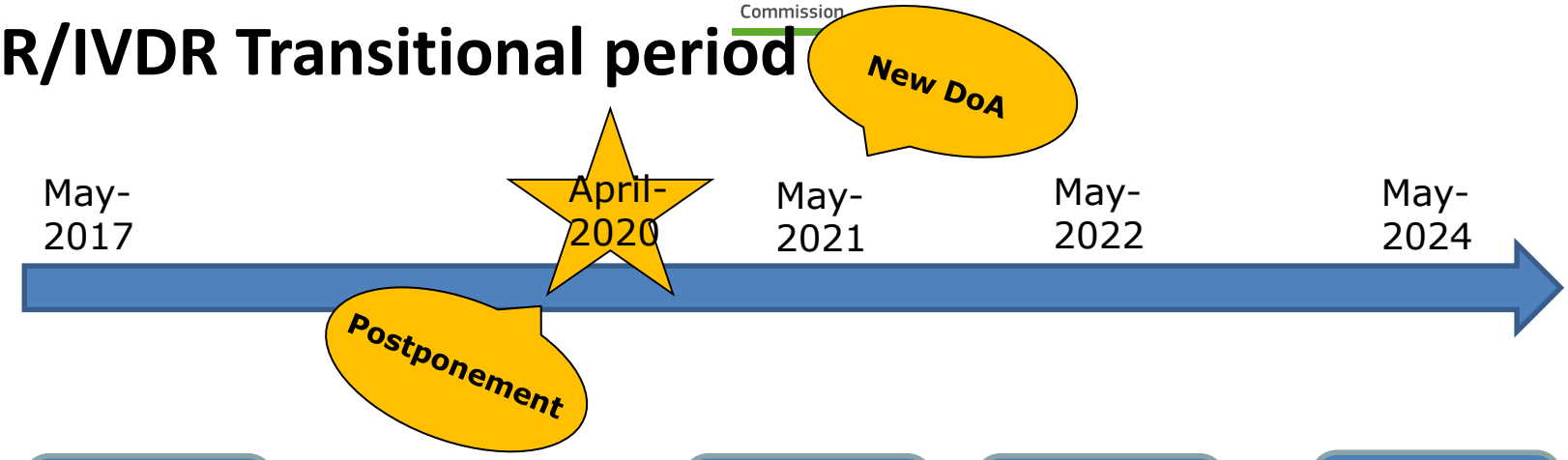
European Commission

Brief update on MDR and IVDR

Erik Hansson
European Commission
DG SANTE

Health

MDR/IVDR Transitional period



Publication of Regulations in Official Journal of European Union and entry into force

Full application of MDR at 4 years (after entry into force)

Full application of IVDR at 5 years (after entry into force)

End of transitional period. All directive certificates become void

European Commission

COM implementation priorities (1)

- **Notified Bodies**
  - ✓ 62 (47+15) applications received up to date. Full scope of MDR and IVDR covered
  - ✓ 21 (17+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**
  - ✓ Establishment of expert panels, expert laboratories and reference labs
  - ✓ Expert panels operational 4 q. 2020
- **Design and establishment of the new EUDAMED**
  - ✓ Core actor registration module of database to be available Q4 2020
  - ✓ Staged approach
- **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

COM implementation priorities (2)

- **Mandate for revision of standards**
- **Communication campaign**
  - ✓ Dedicated website, factsheets in all EU languages and some major non-EU languages
- **Common specifications on devices without medical purpose**
- **Common specifications on reprocessing of single-use devices** (adopted)

Planning of activities:

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

European Commission

COM implementation priorities (3)

Key guidance published March – August 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 sytems 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

European Commission

Some critical issues

- Availability of notified bodies
- Establishment of Eudamed
- Timelines, resources and expertise

In addition:

- Covid-19
- International aspects: MRA:s (CH, AU, NZ), Customs Union Agreements (TR), UK, unilateral CE-acceptance,

Thank you for your attention !

European Commission
Medical Devices and Health Technology Assessment Unit