European Commission

Latest Update on MDR Implementation and special measures in COVID-19 context for Medical Devices

European Chamber Medical Device Forum
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Erik Hansson

European Commission

Health

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EU legislation on medical devices

- **Current Directives and new Regulations**:
  - Directive 90/385/EEC on active implantable medical devices (AIMDD)
  - Directive 93/42/EEC on medical devices (MDD)

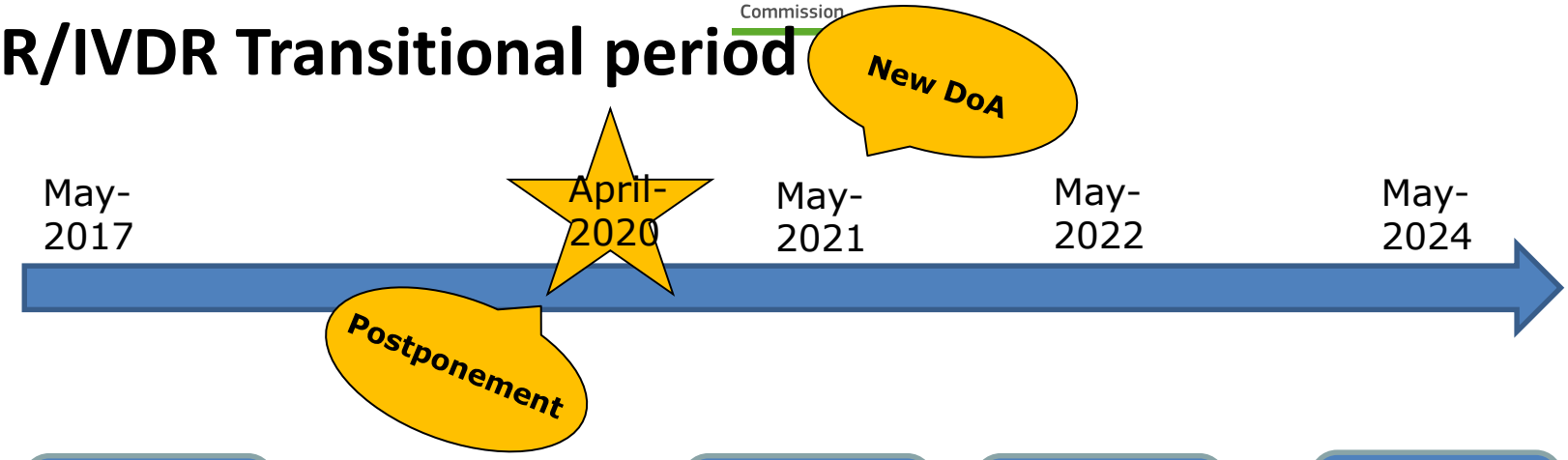
  Regulation (EU) 2017/745 on medical devices (MDR) adopted in April 2017, fully applicable from **26 May 2021**

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

  Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) adopted in April 2017 fully applicable from **26 May 2022**

- **Specific transitional provisions** (Articles 120 MDR and 110 IVDR)

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

Ongoing implementation of the new EU Regulations

Shared responsibility between the Commission, Member States, notified bodies, economic operators, health care providers

- **Commission Implementing acts**:
  - on notified bodies, expert panels, reprocessing, standardisation, common specifications, expert and reference laboratories, European Medical Device Nomenclature (EMDN), Unique Device Identification (UDI), European database on medical devices (Eudamed)…
- **Conformity assessment bodies (notified bodies)**:
  - 21 notified bodies up to date (17 under MDR and 4 under IVDR), more designations ongoing
- **Guidance documents**:

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COM implementation priorities

Examples of 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

COM implementation priorities (1)

- **Implementing acts and guidance**
- **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

COM implementation priorities (2)

- **Mandate for revision of standards**
- **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
- **Communication campaign**
  - ✓ Dedicated website, factsheets in all EU languages and some major non-EU languages

Planning of activities:

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

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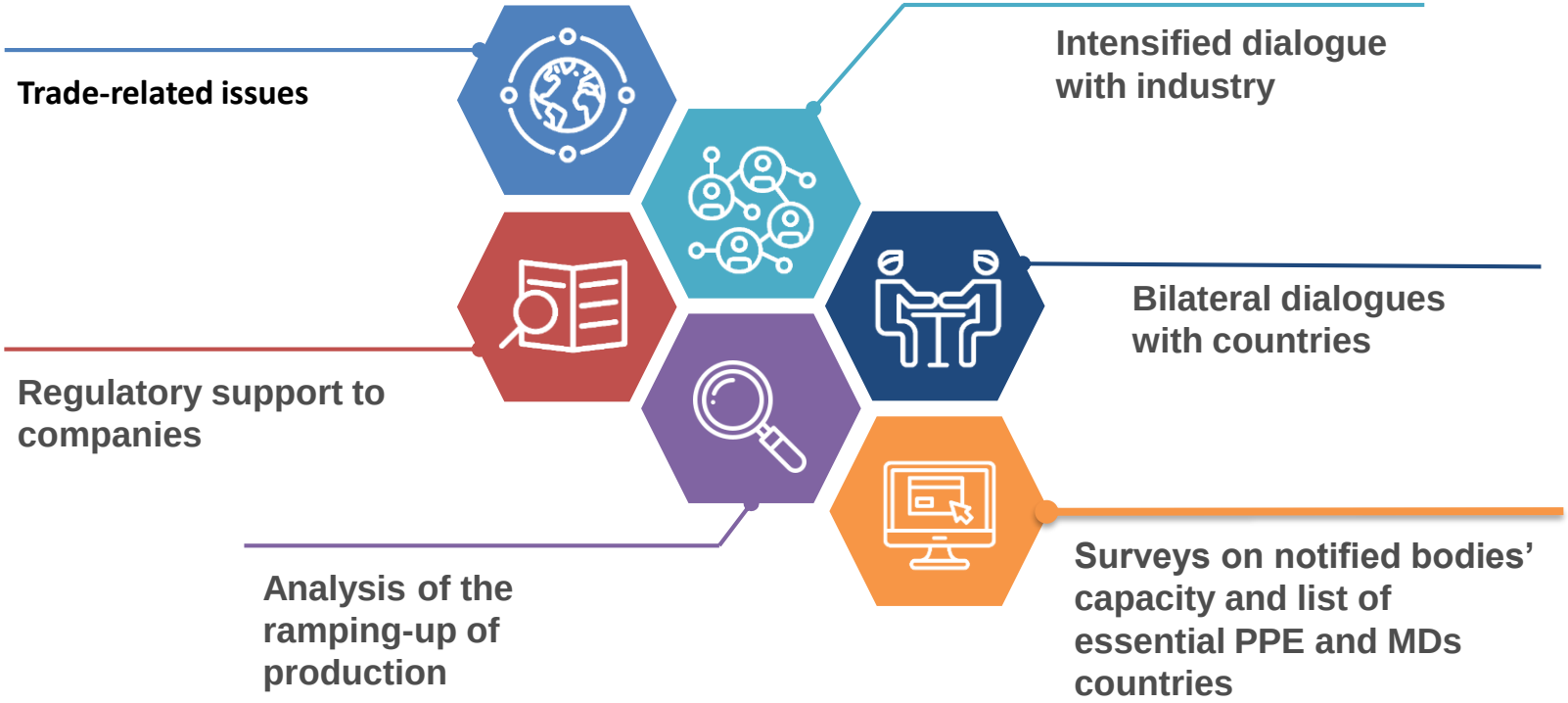
Covid-19

Shortages

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

- Emergency Support Instrument
- Joint procurement Agreement
- Clearing House

Overview of Clearing House activities



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Experiences on ramping up medical equipment production

- Importance of **keeping trade flows open**, both within the Single Market and with main trade partners.
- Importance of having **pre-existing structured communication channels** with industries.
- **Main bottlenecks:** increased prices for raw material and production input; lack of components and parts for ventilators; lack of consumables for testing kits; lack of capacity of Notified Bodies for certification of products, standards and certifications.
- Importance of policy for **strategic reserves** (striking the balance between production capabilities and strategic reserves is key), mostly for PPE, but in some cases it was pre-existing to the COVID-19 crisis.
- Importance of **sustainability aspect** as pivotal to deal with the ramped-up production of medical equipment.

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

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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.

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A stronger European Health Union

State of the Union Address by President von der Leyen

- Build on first lessons from the health crisis:
- Increased funding through future proof EU4Health programme
- Strengthen crisis preparedness and management of cross-border health threats.
- As a first step, reinforce and empower EMA and ECDC
- As a second step, build a European BARDA – an agency for biomedical advanced research and development.
- Strategic stockpiling to address supply chain dependencies, notably for pharmaceutical products.
- Question of health competences (Conference on the Future of Europe).
- Learn the global lessons: Global Health Summit next year in Italy.

Thank you for your attention !

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Medical Devices and Health Technology Assessment Unit