Medicines & Healthcare products Regulatory Agency

New EU Regulation on medical devices

Summary of key changes and challenges for implementation

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Content

- Negotiations – latest state of play
- Key changes from current Directives – What's new?
- Implementation – timescale and challenges

A caveat: Positions based on outcome of trilogue discussions. Final text may differ following formal agreement.

State of the negotiations

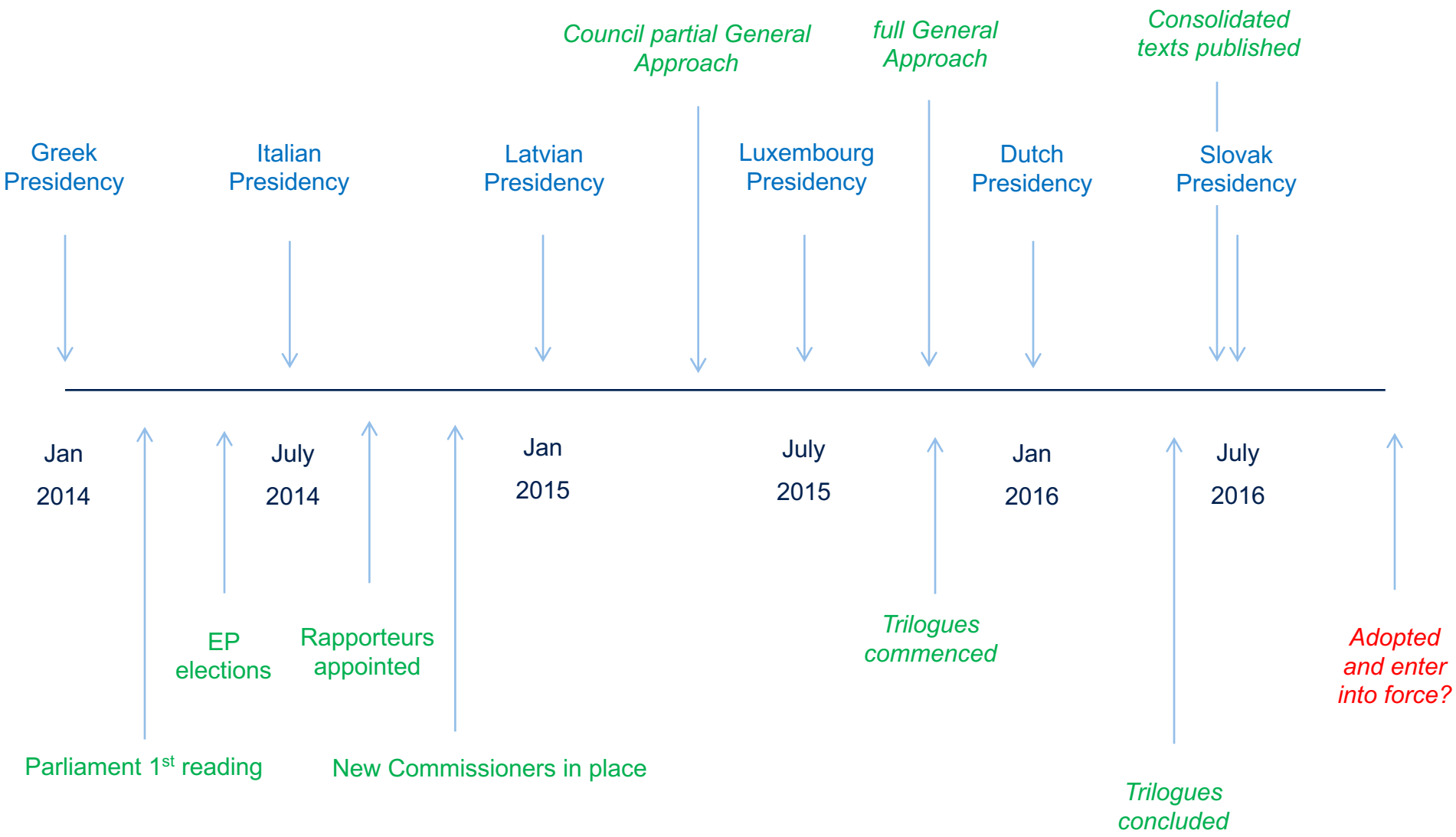
Dutch Presidency (January-June 2016)

- Successful conclusion to trilogue negotiations between Council and European Parliament
- 10 trilogue discussions in total, covering all issues of both Regulations

Slovak Presidency (July-December 2016)

- Translation and legal-linguistic checks (4 months?)
- Council formal First Reading Position (September 2016?)
- Accelerated 2nd reading by EP and adoption of final Regulations (Autumn 2016?)

The political timetable



Key Issues

Key issues - MDR

Pre-market scrutiny

- Class III, implantable devices & IIb that administer medicinal products
- Expert Panels – select from these categories based on criteria (and future guidance)
- Notified Body retains final decision
- Clinical Evaluation guidance & Common Specifications
- Novel devices only - exemptions for non-substantial modifications to existing devices

Key issues - MDR

Hazardous substances

- EP sought to ban all devices containing such substances
- Use must now be justified
- Commission to create scientific evidence-base

Re-processing of single-use devices

- Member States choose whether to allow re-processing
- Common specifications for product types
- National lists of SUDs that can never be re-processed?

Key issues - MDR

Eudamed & unique device identification (UDI)

- Single Registration Number (SRN) for economic operators
- Manufacturers, Importers, Distributors required to store UDI
- Healthcare institutions **not** required but some system needed to record Class III implantables (e.g. GS1)

Software

- Covered for first time
- New Classification rule
- Expect use of ‘in-house’ exemption for NHS labs (see IVDR)

Key issues - MDR

Medicine/Device combination products

- Consultation with medicines authority

Non-viable tissues & cells

- Device if tissues/cells perform action *ancillary* to main purpose of product, e.g. tissue-coated pacemakers
- Consultation with tissues authority

Key issues - MDR

Post-market surveillance

- Clearer requirements
- Regular reporting for higher-risk devices
- Periodic Safety Update Reports (PSURs)

Notified Bodies

- Strengthened criteria
- Joint audit & designation
- Role in vigilance & market surveillance
- Unannounced inspections

Key issues - MDR

Clinical evidence

- Significant alignment with Clinical Trials Regulation
- High risk devices – exemption from clinical investigations for ‘well-established technologies’
- Publication of safety & performance data
- PMCF

Implant card

- Provision of card vs provision of information

Key issues - MDR

Ingested etc. products

- Risk stratification – from class IIa to III
- Clinical evidence examined for all devices
- Consultation for very highest risk

Non-medical medical devices

- Will be covered
- Annex XV
- Common specifications as a trigger

Implementation and next steps

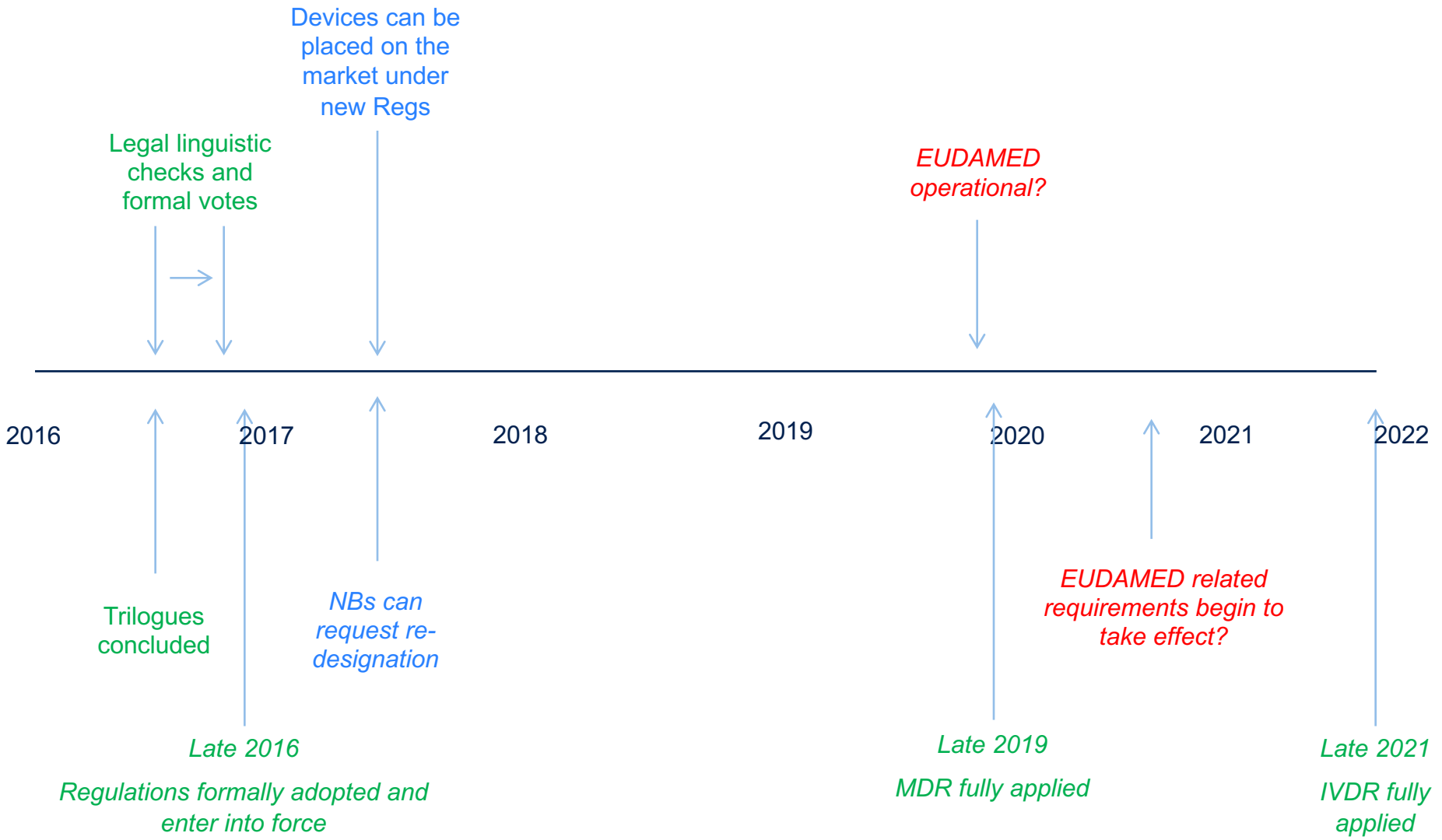
The transition period (EU)

3- year and 5-year transition periods for the MDR & IVDR means new Regulation expected to apply within the EU from (late) 2019 and 2021 respectively

Key dates

- 'Entry into force': Regulations published in Official Journal
- 6 months after entry into force:
  - Notified Bodies can apply for re-designation and start issuing certificates under new Regs, once re-designated
  - Devices in compliance with new Regs can be placed on the market
  - Certain requirements start to apply
- Date of application (DoA): 3 & 5 years after 'entry into force'
- Publication of notice of full functionality of Eudamed / UDI system (timing unclear)
  - Related requirements in most cases start applying 6 months later

Transition periods (EU)



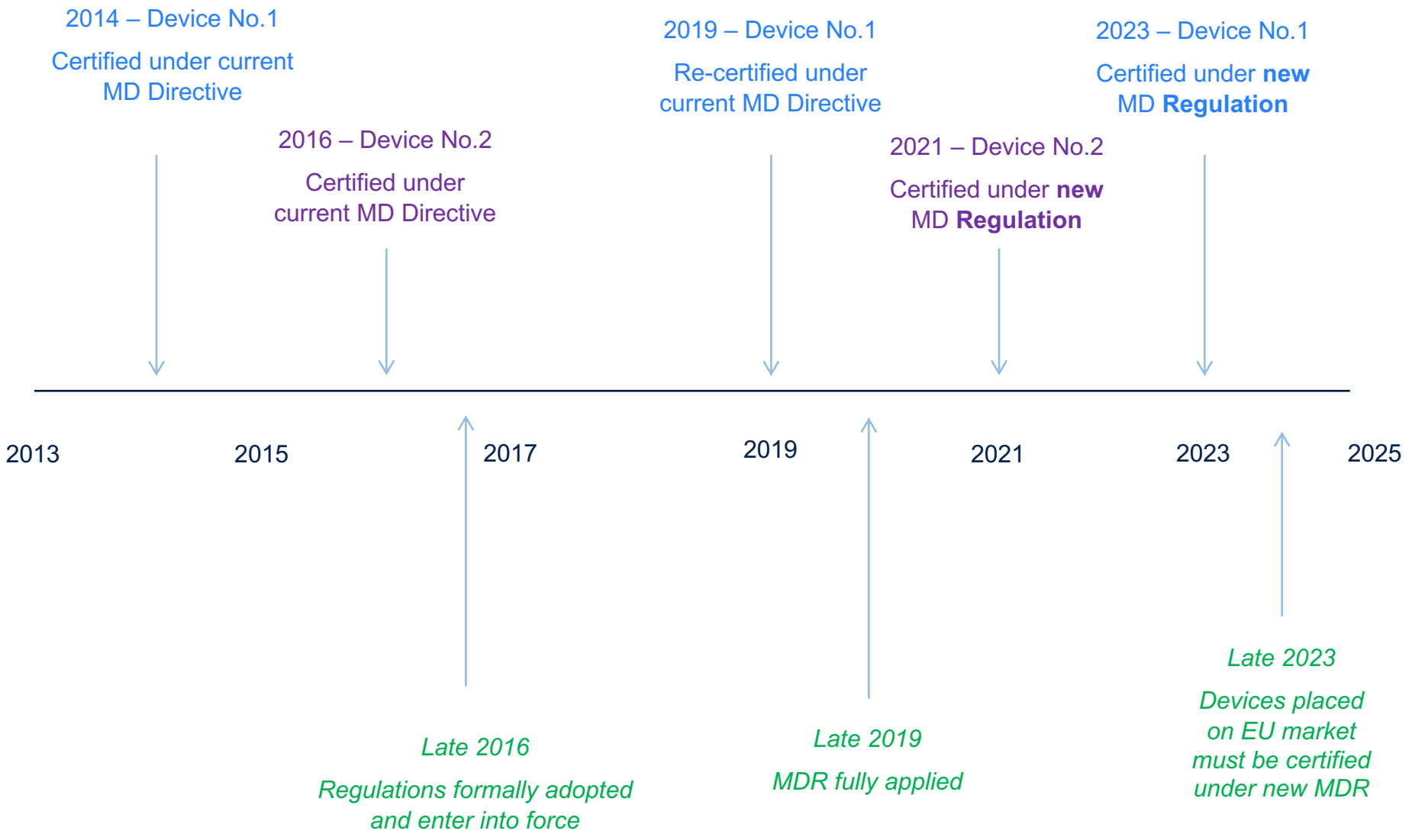
Certificate validity during the transition

There is no requirement that all devices must be re-certified under the MDR by the date of application of the new Regulation.

Transitional provisions for certificates issued under the old Directives:

- Certificates issued *prior* to the entry into force of MDR remain valid for the period indicated on the certificate.
  - Except certificates under Annex 4, Directive 90/385/EEC or Annex IV, Directive 93/42/EEC, which expire at the latest 2 years after the DoA.
- Certificates issued *during the transition period* remain valid for the period indicated (maximum 5 years), but expire at the latest 4 years after the DoA.
- Devices legally placed on the market under the Directives prior to the DoA may be made available up to 4 years after that date.
- Devices containing non-viable human or animal tissues / cells legally placed on the market prior to the DoA in accordance with national rules can continue to be sold / put into service in the Member State concerned.

MD Certificate validity - example



Implementation – priorities and challenges

European Commission:

- Eudamed & UDI system
- NBOG codes
- Expert panels
- Implementing / delegated acts (43 in MDR), common specs and guidance

National agencies:

- Defining national policy (where there are Member State derogations)
  - Re-processing
  - In-house manufacturing
- Re-designating Notified Bodies

MHRA:

- MHRA communicating closely with stakeholders on progress of implementation across EU and on measures within the UK
- Proposal setting out UK implementation expected to be open to public consultation

Questions and Discussion