Medicines & Healthcare products Regulatory Agency

New legislation on medical devices and *in vitro* diagnostics

John Wilkinson OBE

Director of Devices

CPRD NIBSC MHRA

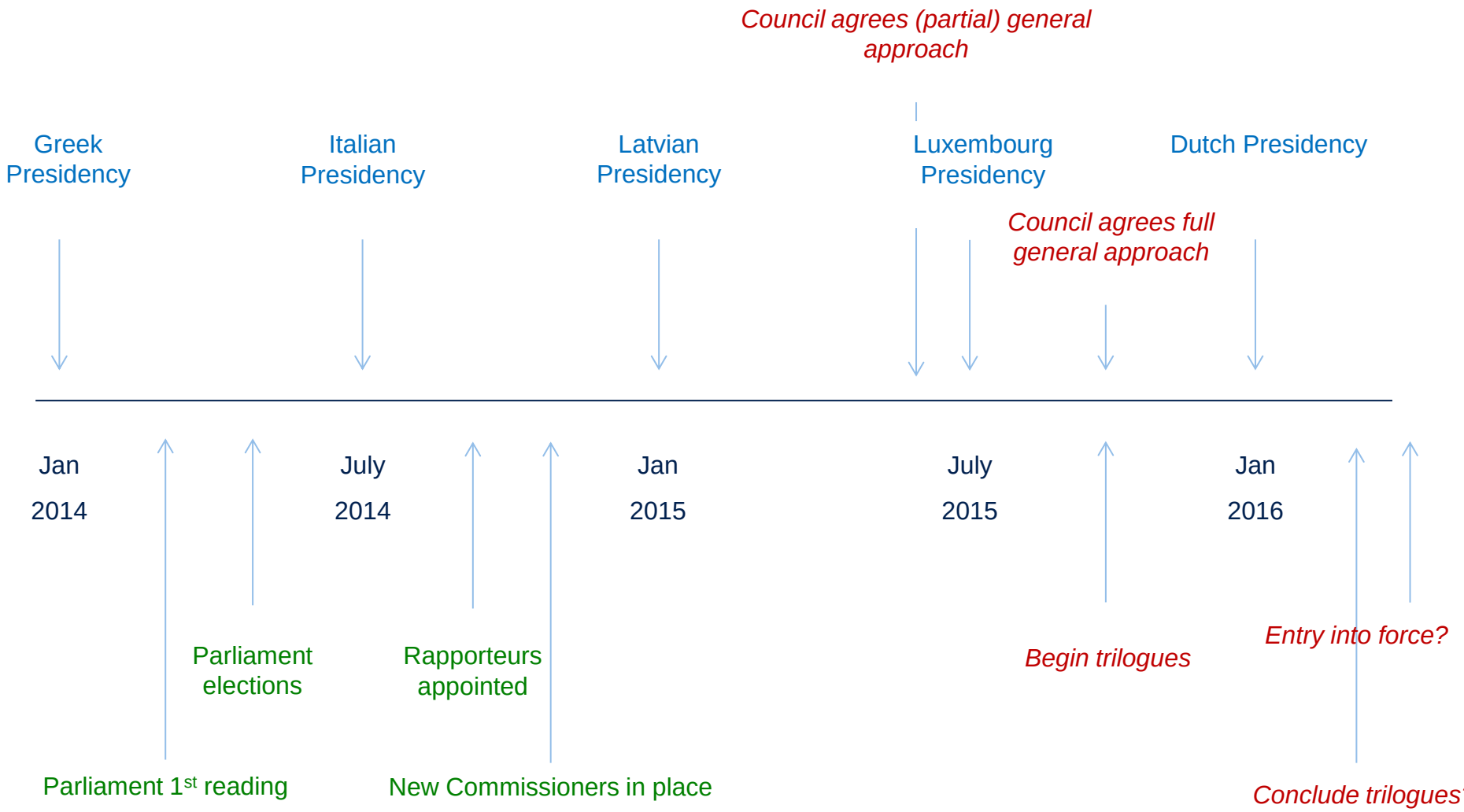
Council agreement - background

- *Partial* General Approach – political agreement of all substantive points in Articles and Annexes

- General Approach – includes Recitals, and all technical/drafting issues with texts

A long road…….too long

The political timetable



Trilogues

- Negotiations between European Parliament, Council and Commission
- 4 ‘blocks’ of negotiations October-December 2015
- Further blocks under NE presidency

MEP rapporteurs

The future

- **Revision of Legislation – Medical Devices Directives and conversion to regulation**
  - Level playing field across Europe – Notified Body Audit and management
  - Increased market surveillance obligations
  - More prescriptive clinical data requirements
  - More transparency

- **Better execution**
  - Increased collaboration on vigilance (the bigger the data pool the sooner the signal emerges)
  - Collaboration on science and analysis (EU Portal)
  - Unique device identifiers (UDI) and databases
  - Challenge of wider usage of registries

Just some of the issues…….

- Implementation timing and transition arrangements
  - Including re-designation of NB's
- Scrutiny process. How will it work?
- Eudamed and UDI database
- Reclassifications (particularly ivd's)
- Capacity of system to cope with new demands
- Common specifications and harmonised standards
- Substance-based products

Article 3(2)

"*The Commission shall ensure the sharing of expertise between MS in the fields of medical devices, IVDs, medicinal products, ….. ..to determine the appropriate regulatory status of a product or category or group of products*".

..possible interactions…side effects…risks of absorption…nature and levels of substance used…claims….confusion with medicinal products….where to report adverse incidents/reactions…interference with other medications…….

The future