MHRA
Regulating Medicines and Medical Devices

Revision of the medical devices directives

Where are we now in the negotiations?

Medicines and Healthcare Products Regulatory Agency

Today's presentation

- The Commission's proposal
- EU negotiations and the political process
  - Council of Member States
  - the UK approach
  - European Parliament
- What next?

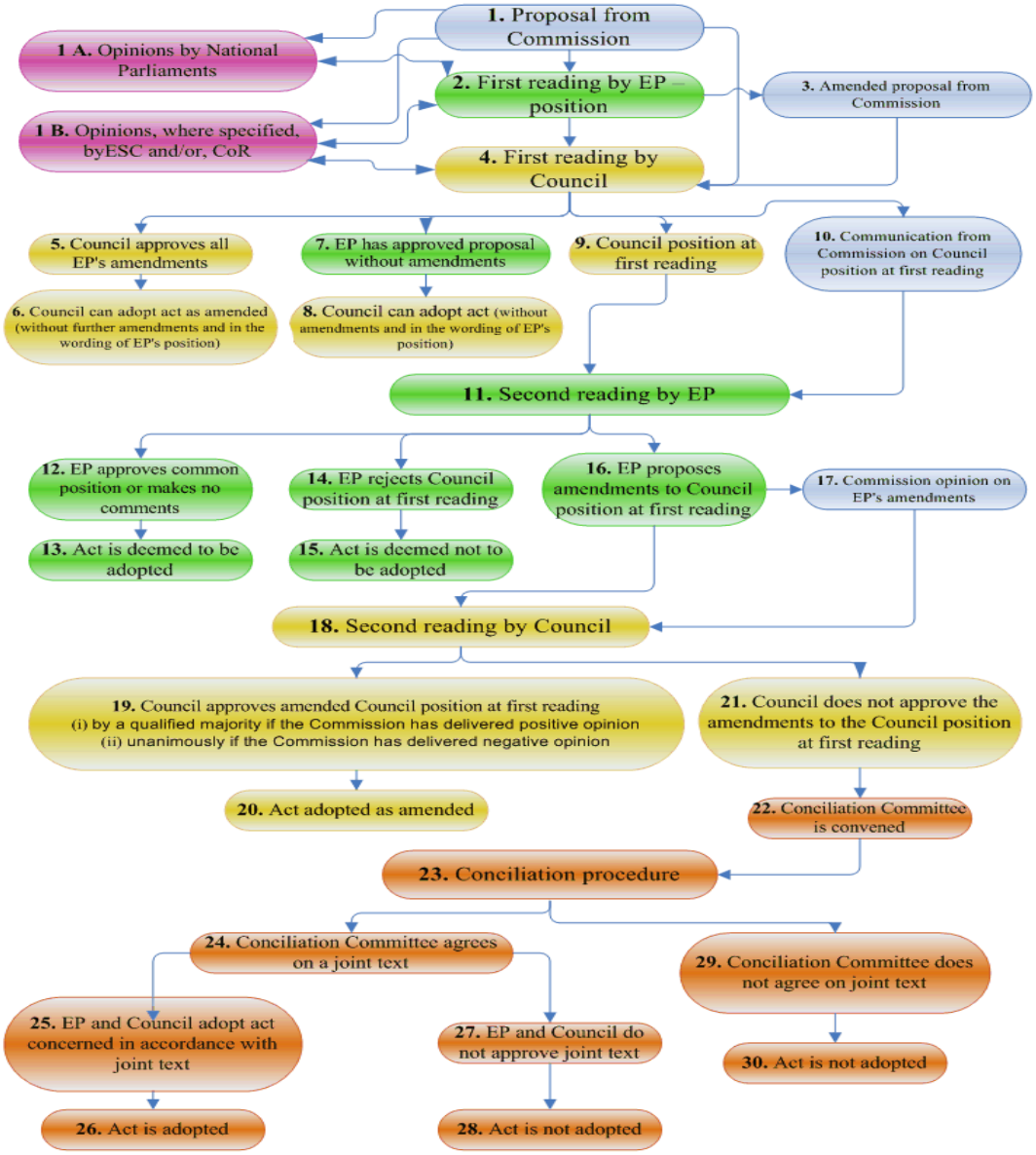
What the Commission has proposed – good

Improved coordination and cooperation between Member States	Alignment with the 'New Legislative Framework'	Rules-based system to classify IVDs	More rigorous designation and audit of notified bodies	Increased regulation of reprocessing of single-use devices
More effective governance structure of Member State experts	More traceability – UDI and implant cards	More information available on the quality and safety of devices on the market	Central reporting of serious incidents and field safety corrective actions	Clearer requirements for clinical evidence

What the Commission has proposed – less good

Additional pre-market scrutiny of high-risk devices by a centralised committee	Expanding the scope of the IVD Regulation to include Class D devices manufactured and used in-house
Where the default assumption is confidentiality rather than transparency	Erosion of national competence and too much left to tertiary legislation?

The EU negotiations



The EU negotiations

Commission publishes proposal in September 2012

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European Parliament & Member States discuss and propose changes to the proposals

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Aim to come to an agreed position on the text

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Negotiation any disagreements through a ‘conciliation committee’

Member States

Improving the UK position

- Public consultation
- Review of the regulation of cosmetic interventions
- Science & Technology committee
- Howe review

European Parliament

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EP: Medical devices

- Pre-market authorisation & other pharma concepts
- Reprocessing of SUDs
- Notified bodies

EP: IVDs

- Informed consent for genetic tests
- Self-tests
- Quick entry into force

EP: IMCO committee

- Aesthetic devices
- Article 44+
- Liability

Timeline

European Parliament

- 10 July: ENVI vote on draft report
- Autumn: plenary vote

Member States

?

Political change on the horizon

July 2013
Lithuanians chair Member State meetings

January 2014
Greeks chair Member State meetings

Spring 2014
European Parliament campaigns

June 2014
European Parliament elections

July 2014
Italians chair Member State meetings

October 2014
New European Commissioners

In the meantime…

Joint Plan for Immediate Action

- Voluntary joint audits of notified bodies
- Audits of notified bodies of class III devices
- Sharing information on market surveillance
- Vigilance teleconferences
- UDI pilot
- Encourage reporting

Thank you

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