Refurbishment ?
Re-use?
Single use ?

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AHC - AHWP, 19 November 2014, Seoul / Korea

Disclaimer

The following presentations reflect only the personal view of the author.

Thanks to some colleagues of whom I picked some slides (amended)!

Errors can only be attributed to myself.

Different legal status

- **Refurbishment**: complete “overhaul” of a used product by the manufacturer: replacement of all parts which could show wear and tear (batteries, used parts, …). Declared as such by the manufacturer.
- No new “placing on the marker” – no regulation (but maintenance obligations)
- **Second hand**: direct sale from one hospital to the next – no regulation (but maintenance obligations)
- **Single use** is single use is single use: as defined by the manufacturer
- **Re-use**: example instrument sets: usually cleaned (and sterilized) by the user, sent back to the manufacturer, sterilized again and functioning to be verified. Sent out again for next OP.
- Regulations on re-use differ by Member State but strict cleaning and sterilization standards, some Member States do not allow external 3rd party sterilization subcontractor.

European Medical Devices Regulations?

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Topics

I. Europe before the Directives
II. Reason and background on the Directives
    a. Free movement of goods
    b. Common regulations across Europe
    c. Authorities focus on clinical trials and post-market
III. Review of the experience with the Directives
IV. Scenarios for next steps: Regulations vs strengthening the system
V. Conclusions

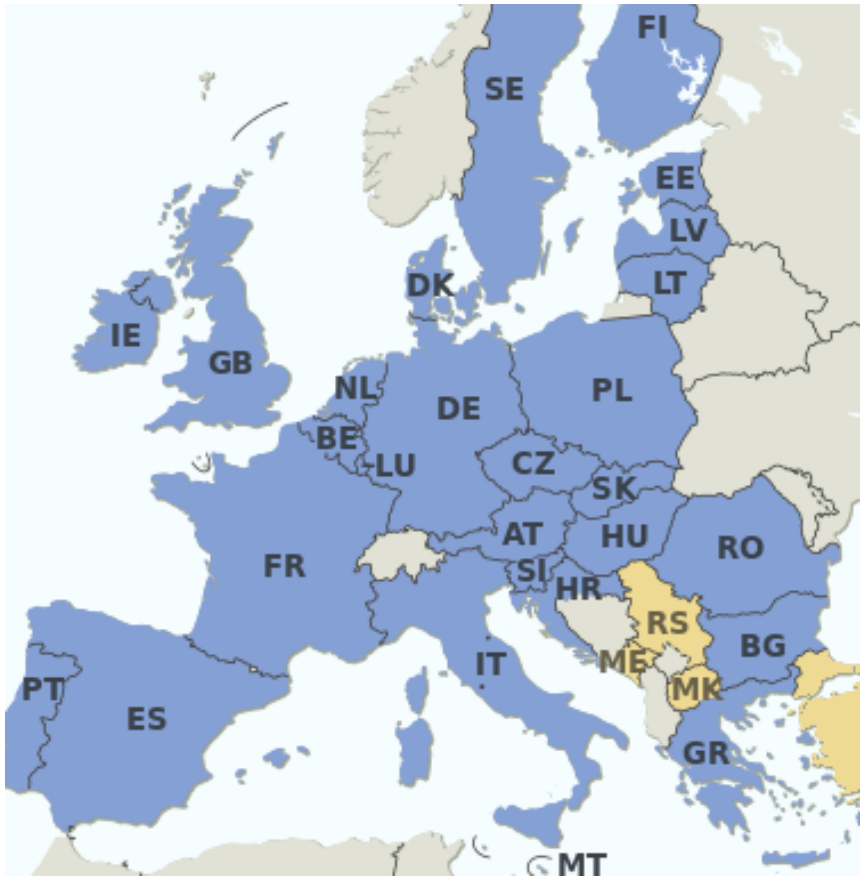
Europe:
the idea of free trade of CE marked medical devices

- “Passport” to verify quality and safety
- Single market
- Nothing on reimbursement
- Based on quality management system
- Split into Competent Authorities (Government) for clinical trials and post-market and Notified Bodies (private but controlled by Government Designating Authorities) for the pre-market QM standard certification and where necessary product type certificate

Europe end of 1980ies / 1990

EU with 12 Member States

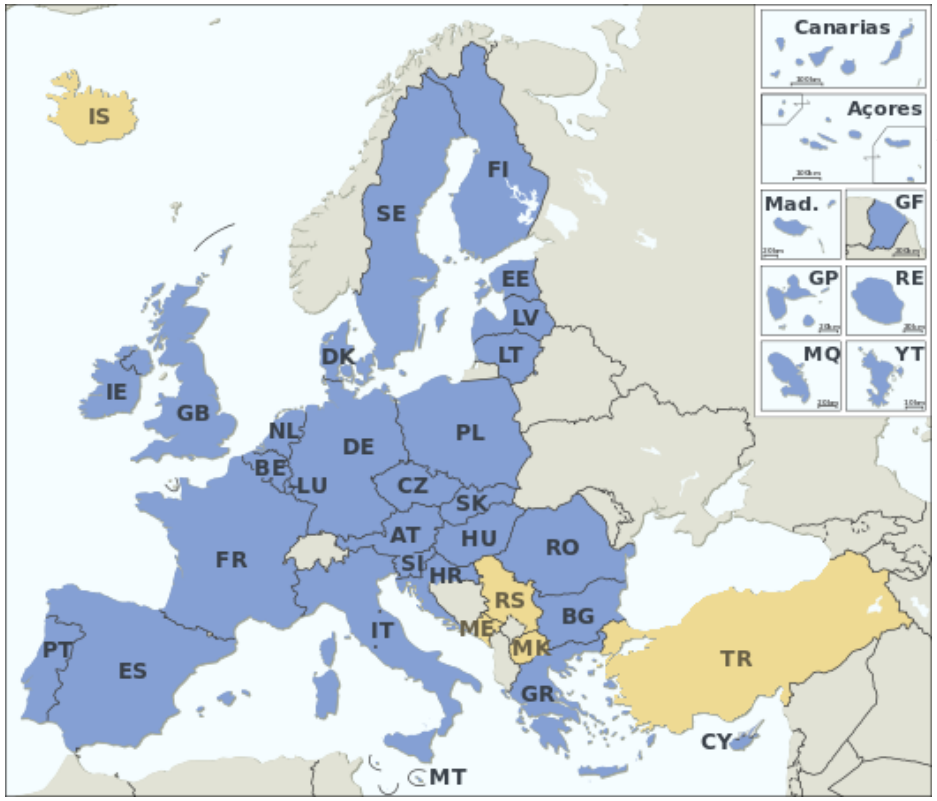
“New and Global Approach” developed



Early regulations (before 1990)

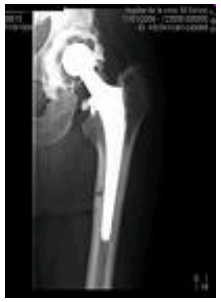
- Material tests (mostly joint implants) in some Member States
- Performance tests for batteries for pacemakers etc in some Member States
- General electrical safety requirements in some Member States
- Mechanical tests of prostheses in some Member States
- Each “approval”, verification, notification only valid in one Member State
- Only 12 EU Member States at that time
- Start of the New and Global Approach in the EU: one CE mark as sign of safety and quality means the free market access in all Member States
- No additional public service structure but out-sourcing to private bodies

European Directives
(1990 , 1993 and 1998)



active implantable Medical Devices
AIMDD
90/385/EEC

«classical» Medical Devices
MDD
93/42/EEC



In-vitro Diagnostic Medical Devices
IVDD
98/79/EC

Today: EU Directives & national implementations

Main Directives

- 90/385/EEC (AIMD)
- 93/42/EEC (MD)
- 98/79/EC (IVD)
- EU Reg Nr.765/2008 (Accr./Marketcontrol)
- EU Reg 920/2013 Control of NB

Amendments

- 2000/70/EC (Blood and plasma derivatives)
- 2003/12/EC (classification of breastimplants)
- …



Member States etc transpose into different National Laws

DE:

- MPG
- MPV
- MPSV
- MPKPV
- …

PT:

- …
- …

CH:

- HMG
- MepV
- HFG & VO's
- ……
- MRA
- …

Experience

- Variable implementation and interpretation in the Member States
- Common classification lacking
- From 12 to 28 Member States: lack of mandatory collaboration
- EU paved the way for QMS recognition through GHTF (now IMDRF)
- Too many Notified Bodies, each assessed by one national Designating Authority creates large variety across the EU
- Criticism from industry, public, politics
- Formal review with public consultation
- New “proposed regulations” in September 2012 (switch from Directives will mean mandatory collaboration, one and the same text for all member States, stricter and harmonized controls of NB’s)

European political process

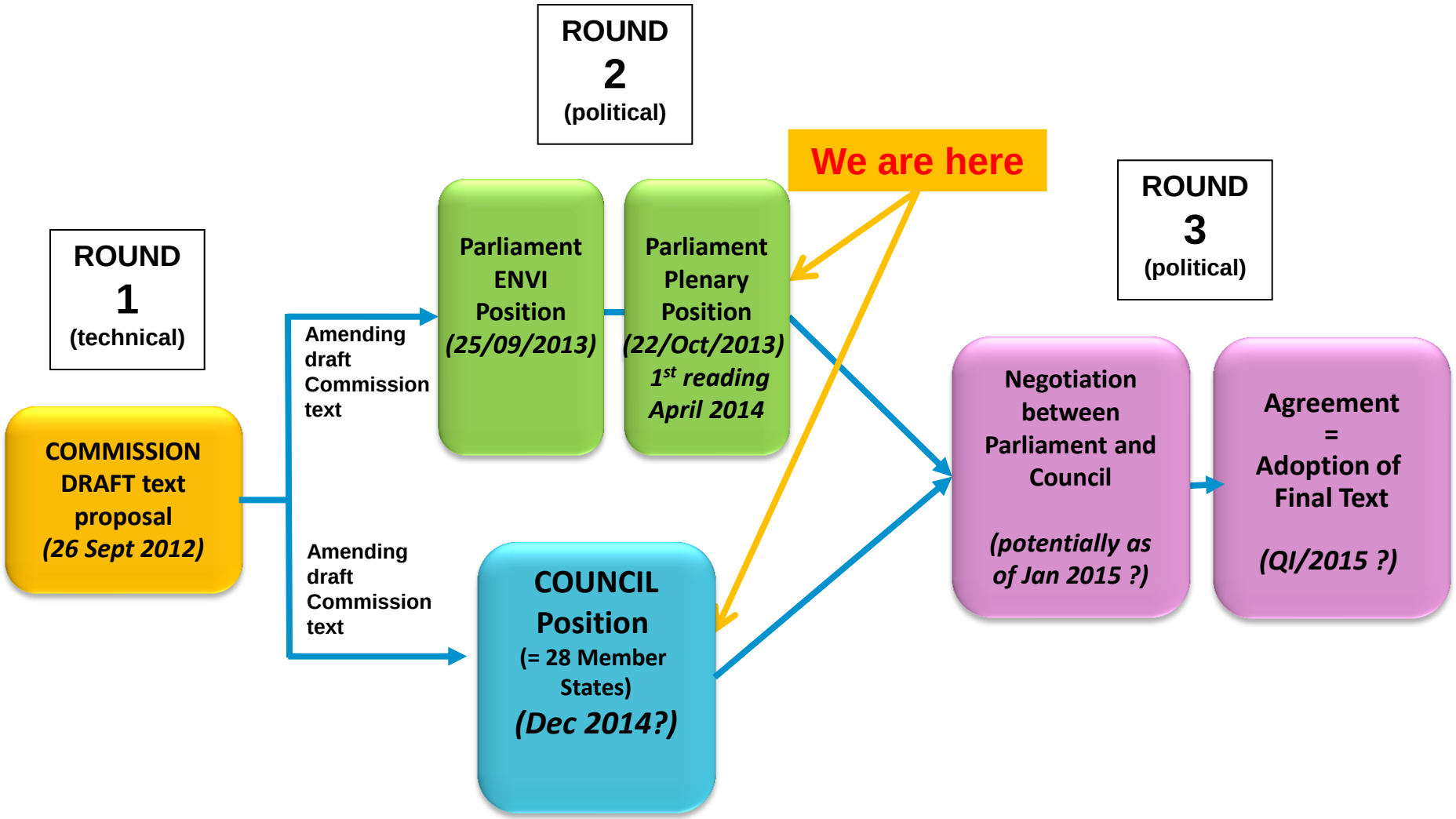
European Commission:
Proposes Legislation
TECHNICAL

European Parliament:
Proposes Amendments
POLITICAL

Council = 28 Member States: Proposes Amendments
TECHNICAL/Political

Negotiate and agree on final text

Current Status of the Process



The political timetable

Council reaches political agreement?

Greek Presidency

Italian Presidency

Latvian Presidency

Luxembourg Presidency

Dutch Presidency

Jan 2014

July 2014

Jan 2015

July 2015

Jan 2016

Parliament elections

Rapporteurs appointed

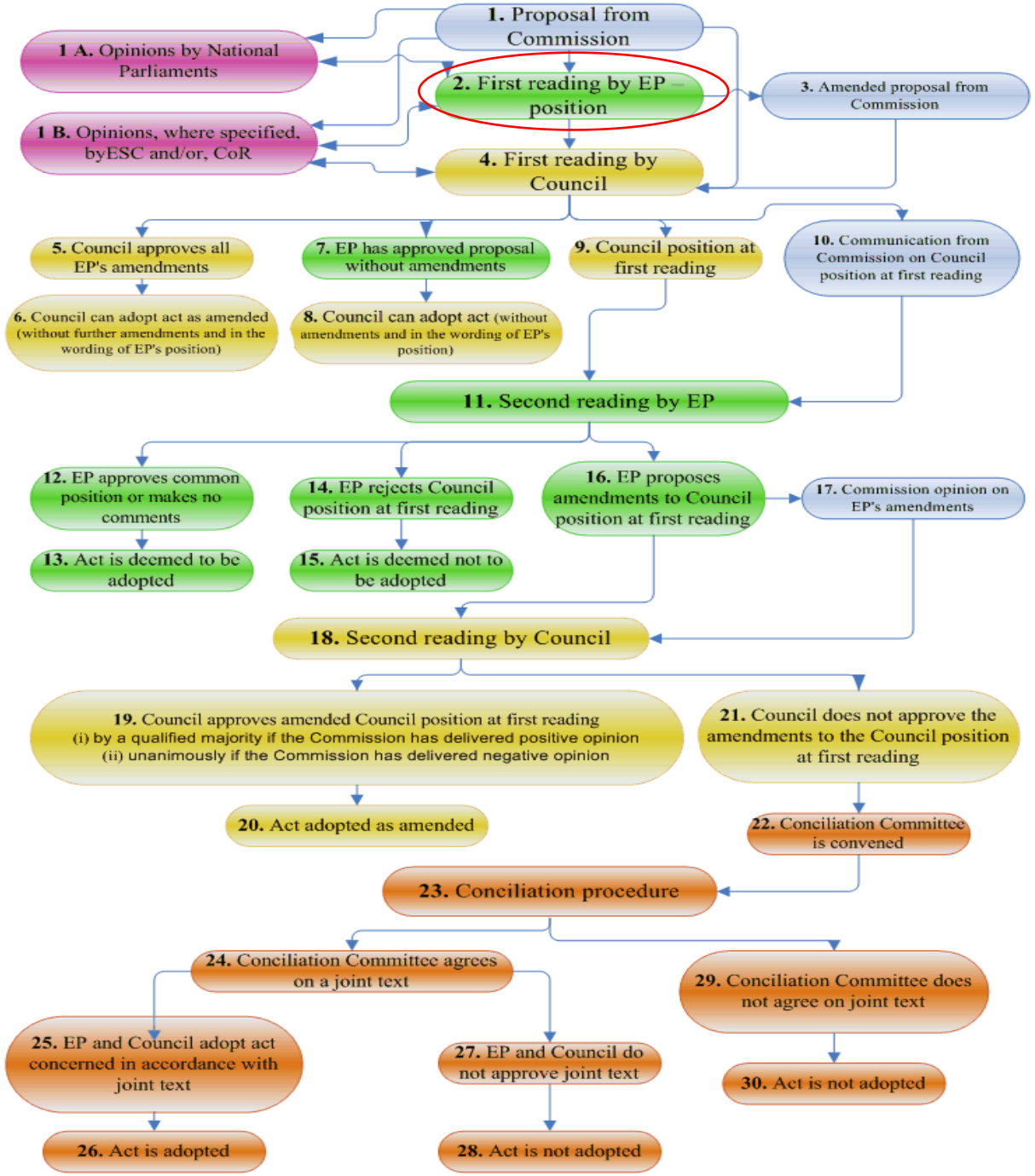
New Commissioners in place

Begin trilogues?

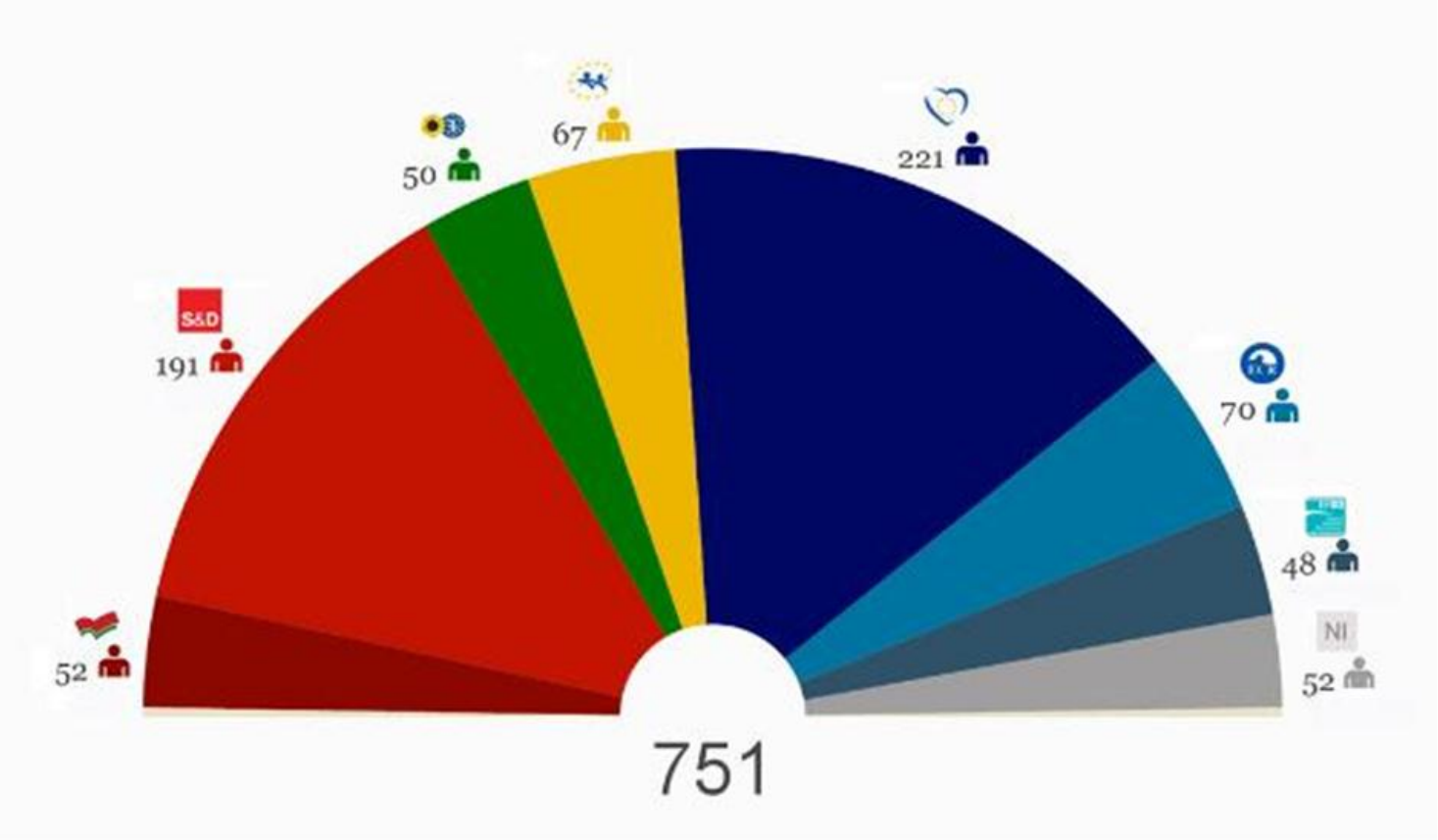
Conclude trilogues?

Entry into force?

The formal process

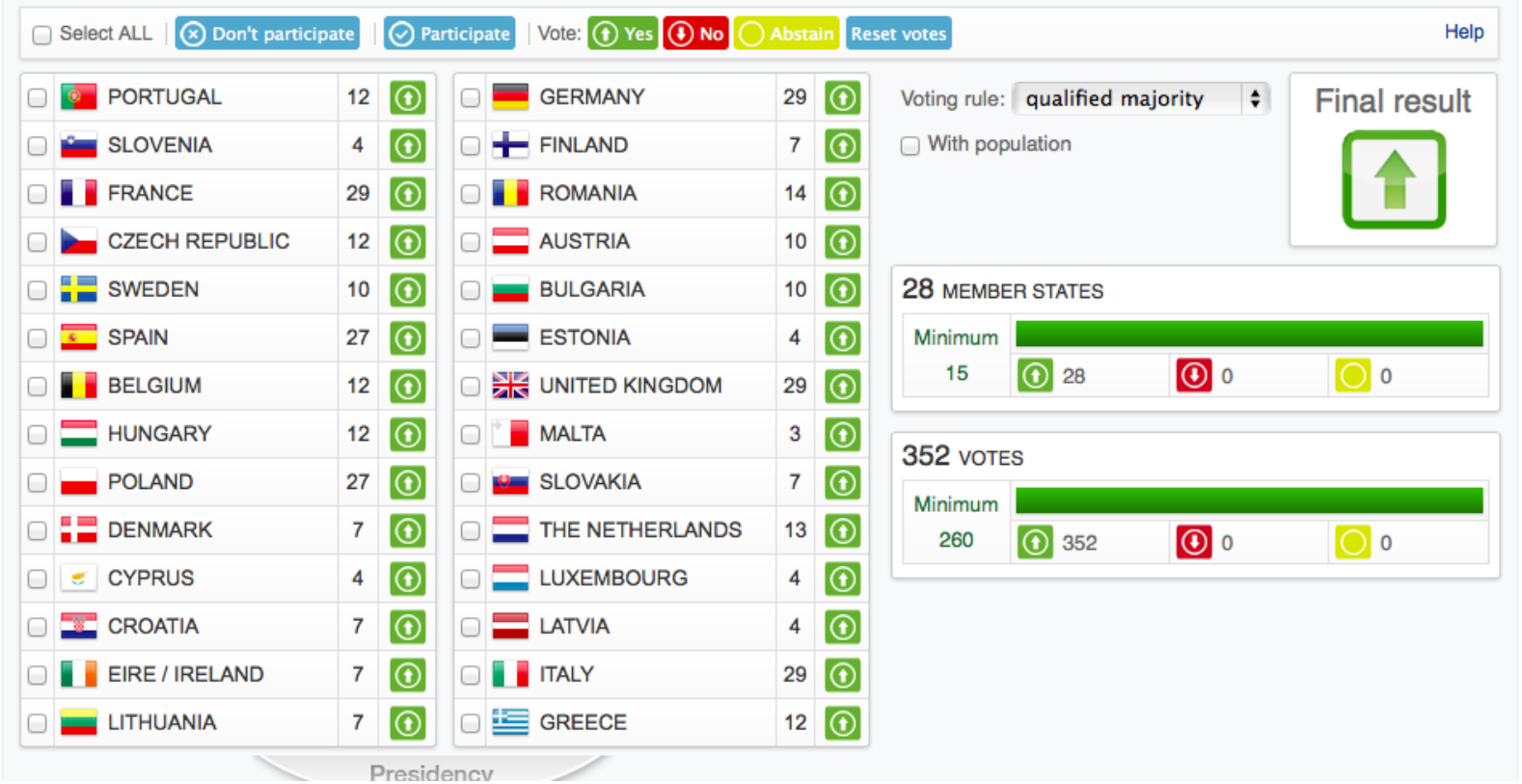


The European Parliament



Outlook

- Many combinations possible in Council
  - With the large member states' differences, coalitions of small member states can have impact



Proposal by the European Commission

EUROPEAN COMMISSION

Brussels, 26.9.2012
COM(2012) 542 final

2012/0266 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Tomorrow: EU regulations

Regulations

- Proposal IVD COM (2012)541 final
- Proposal on Medical Devices and... COM (2012)542 final
- Reg (EU) Nr.765/2008 (Accreditation/Market Surveilance)

Direct Application in the Member States (MS)

MS DE:

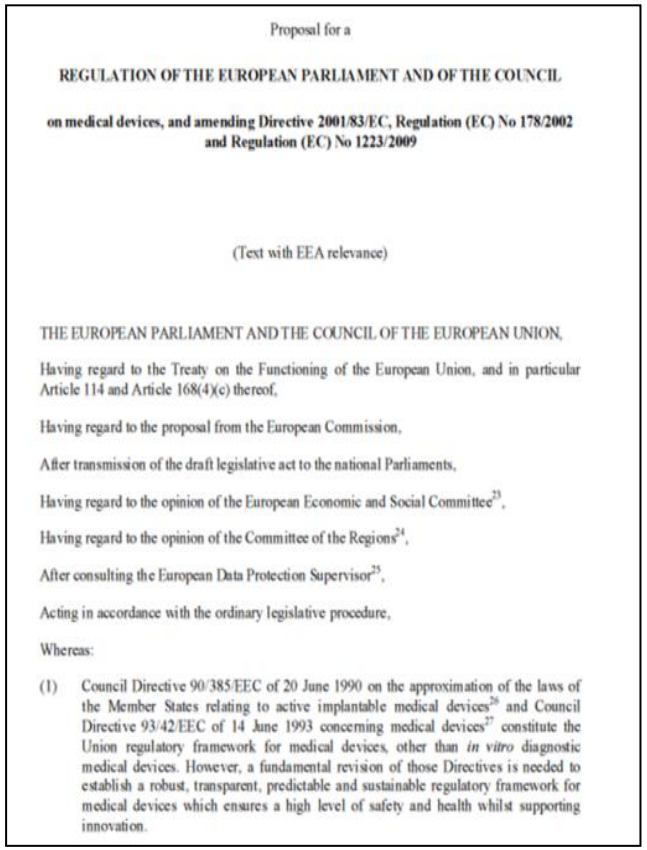
- IVD EU Reg.
- MD EU Reg.
- Reg 765/2008

MS PT:

CH Rev.:

- HMG oder MPG ?
- MepV's
- HFG & VO's
- ……
- MRA ?!
- …

Structure overview summary of proposed regulation



Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[23],

Having regard to the opinion of the Committee of the Regions[24],

After consulting the European Data Protection Supervisor[25],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[26] and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[27] constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

10 Chapters

1 – Scope & definitions

2 – Making available of medical devices, MAID

3 – Identification & traceability

4 – Notified Bodies

5 – Classification, conformity assessment

6 – Clinical evaluation & investigation

7 – Vigilance and market surveillance

8 – Governance

9 – Confidentiality

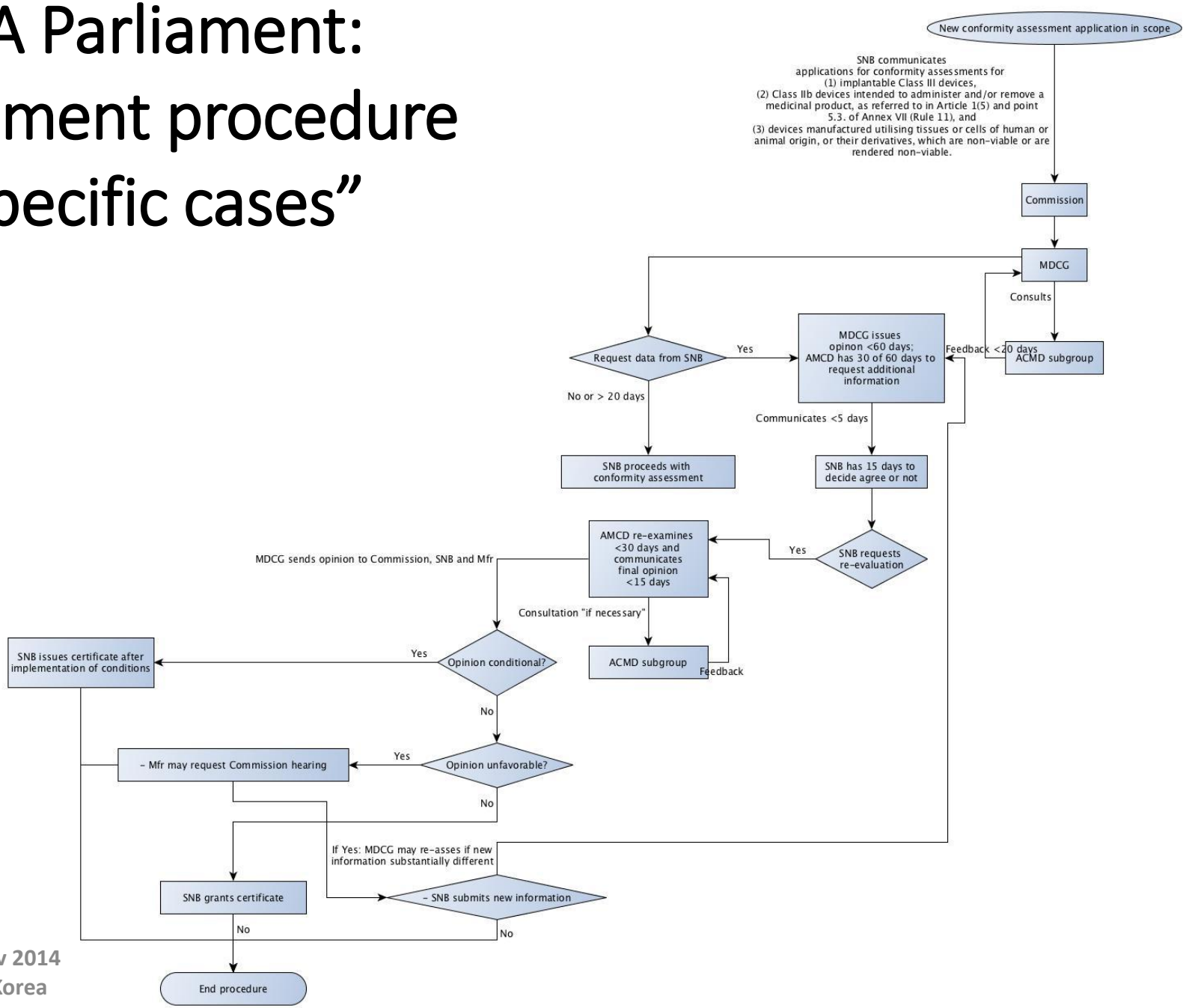
10 – Final Provisions

Structure overview summary of proposed regulation

16 Annexes

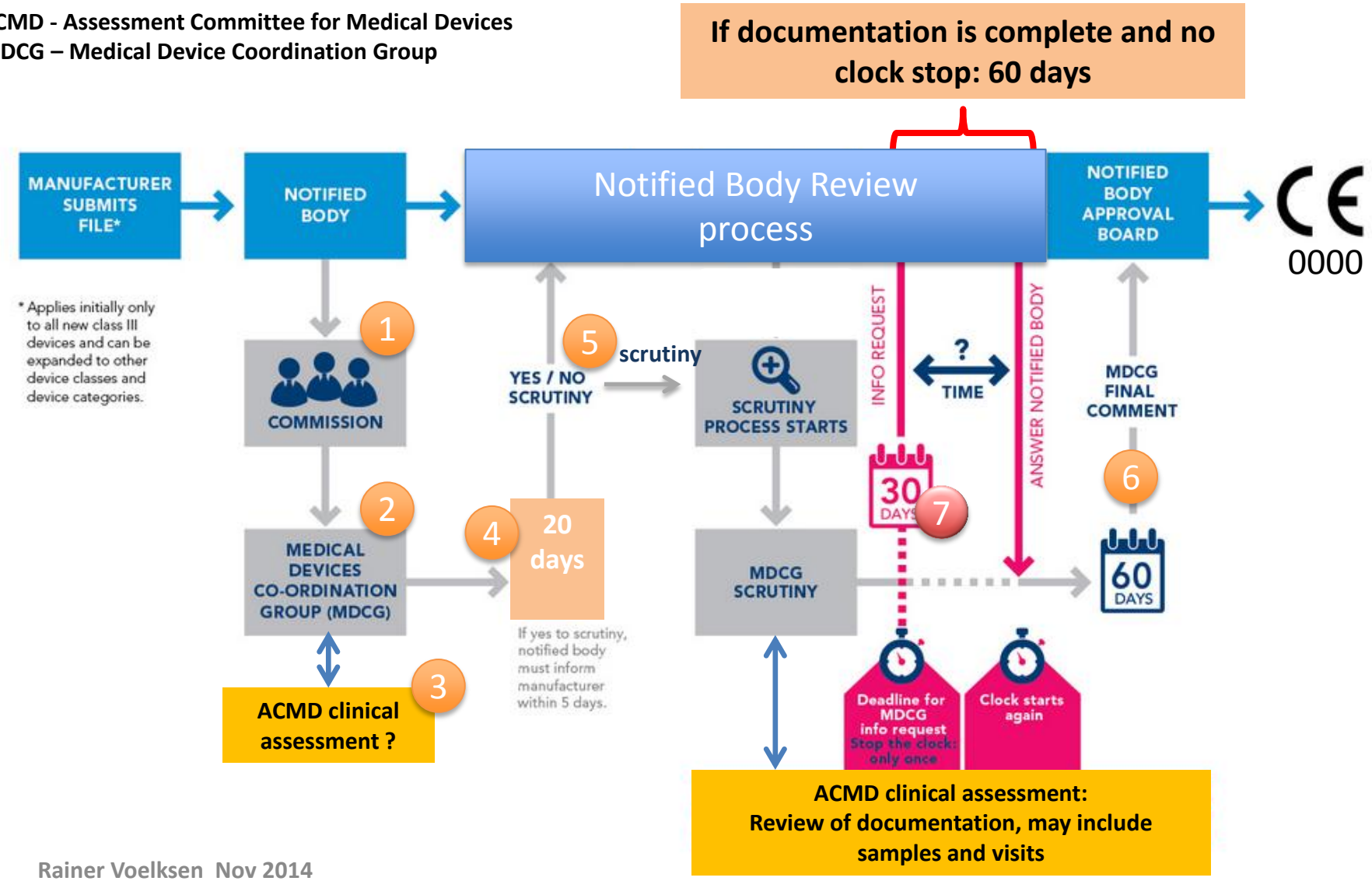
I – General safety & performance req.
II – Technical Documentation
III – EU Declaration of Conformity
IV – CE marking
V – Device & Operator registration, UDI
VI – Requirements for NB
VII – Classification criteria & rules
VIII – Full quality assurance and design examination
IX – Type examination
X – Production Quality Assurance / Product Verification
XI – Custom made devices
XII – Content of certificates
XIII – Clinical evaluation / PMCF
XIV – Clinical investigations
XV – Products without medical claim covered
XVI – Correlation table Directives vs. Regulation

PMA Parliament: “Assessment procedure in specific cases”

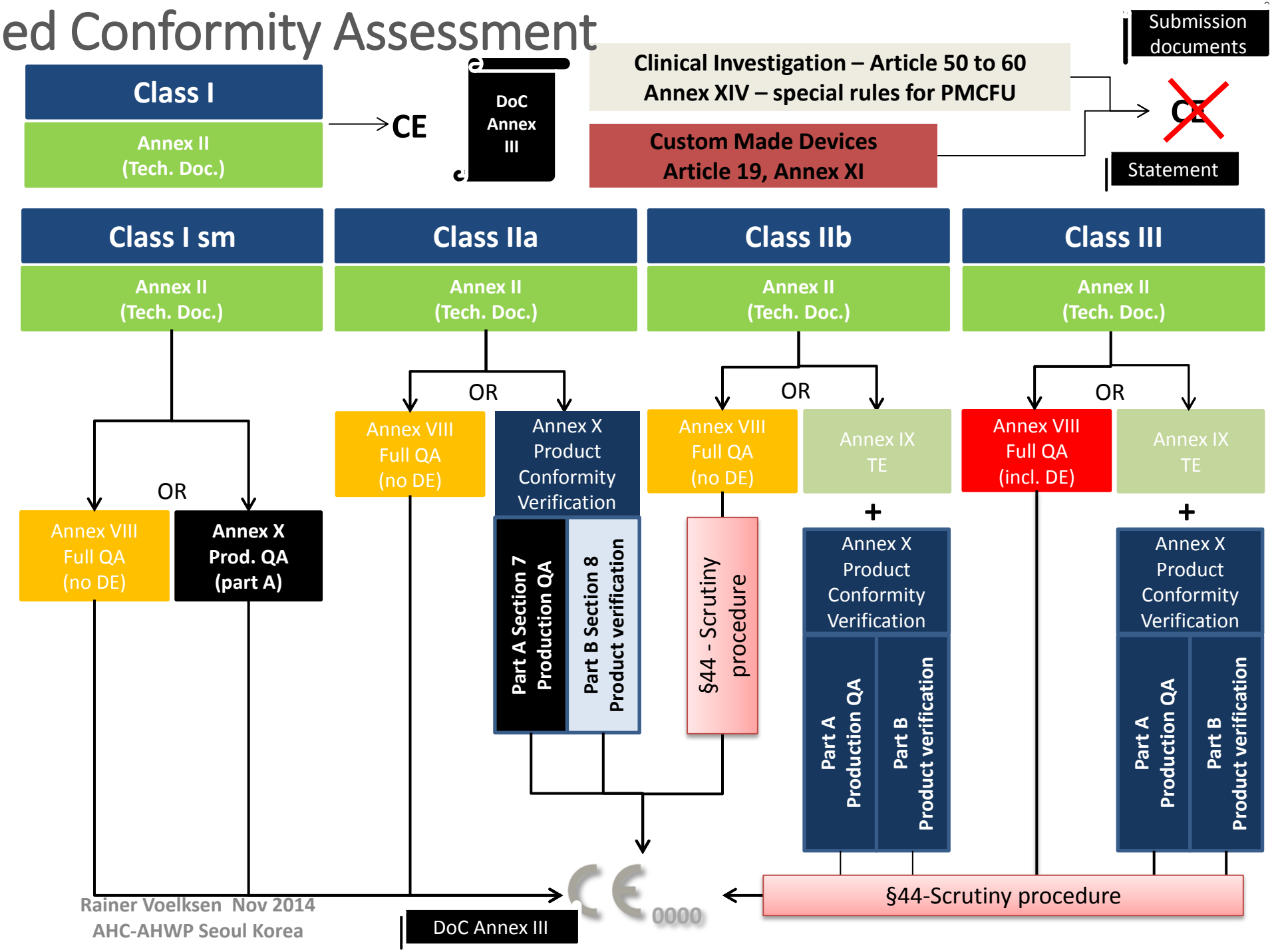


Scrutiny mechanism for certain conformity assessments

ACMD - Assessment Committee for Medical Devices
MDCG – Medical Device Coordination Group

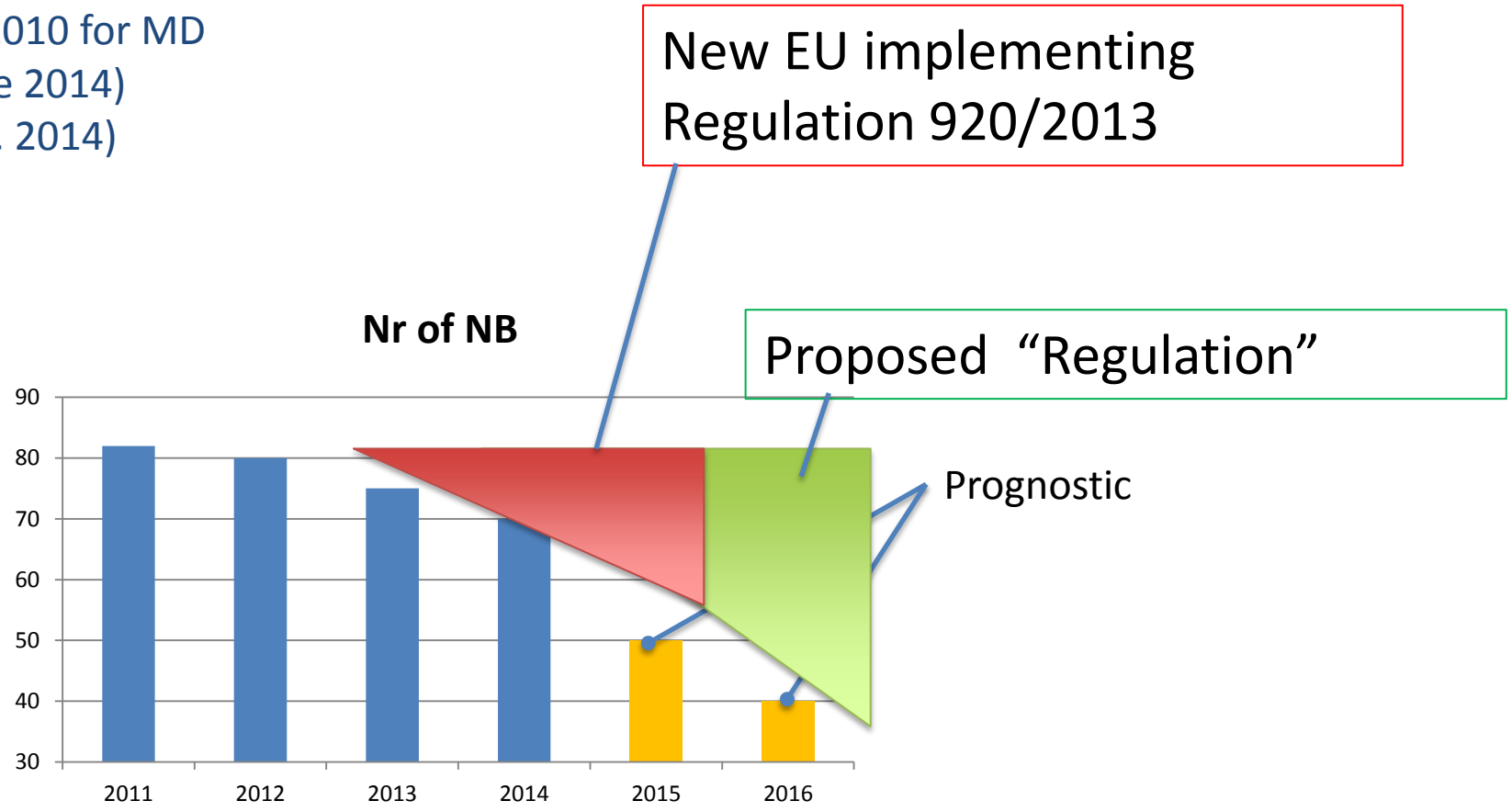


Proposed Conformity Assessment



“Nando” list of Notified Bodies

- 82 NB before 2010 for MD
- 75 NB (21 June 2014)
- 70 NB (11 Oct. 2014)



Experience with the 2012 “immediate measures”

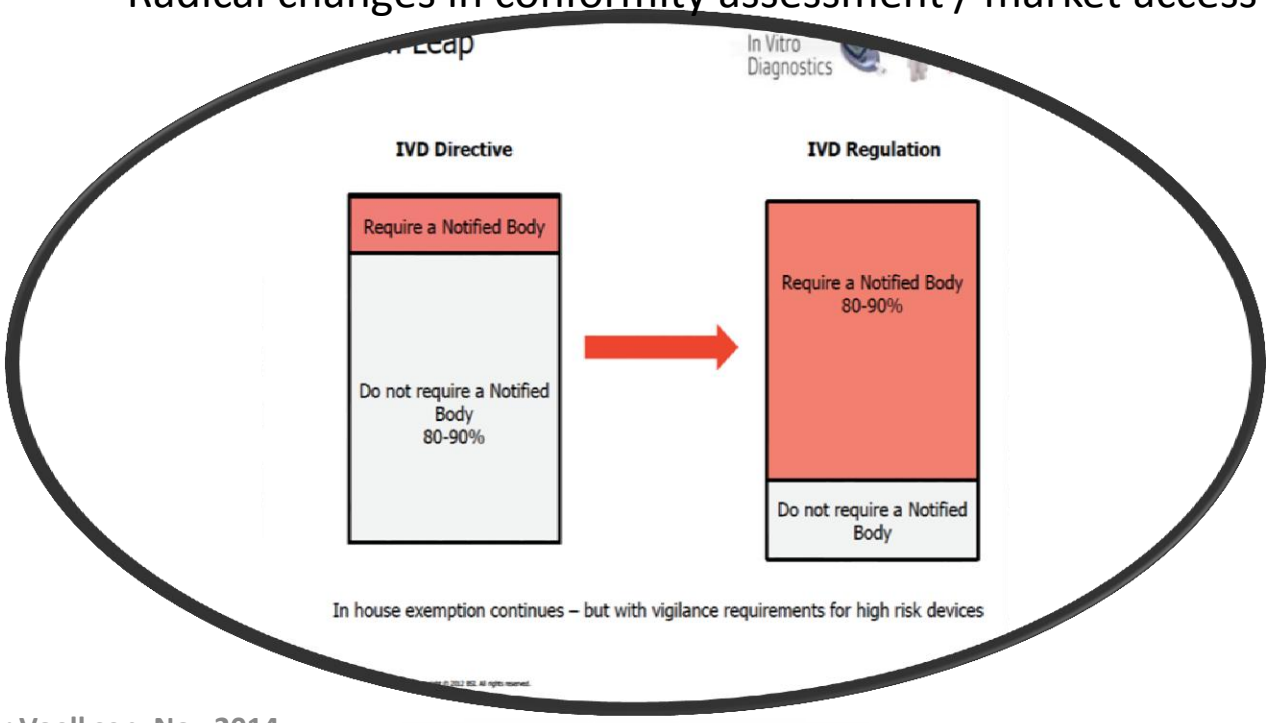
- EU Implementing Regulation 920/2013 from Sept. 2013, effective since January 2014: assessment of NB with multi-national audit team plus EU –Food and Veterinary Office (Inspectorate)
- Monthly tcons/F2F meetings between all Member States in regards to Vigilance
- Strong collaboration and information exchange between all Member States in the area of clinical trials
- Strong new committee of the Member States
- Each “approval”, verification, notification only valid in one Member State
- Publication in July 2014 of the “experience under the immediate measures” by the EU Commission

Process

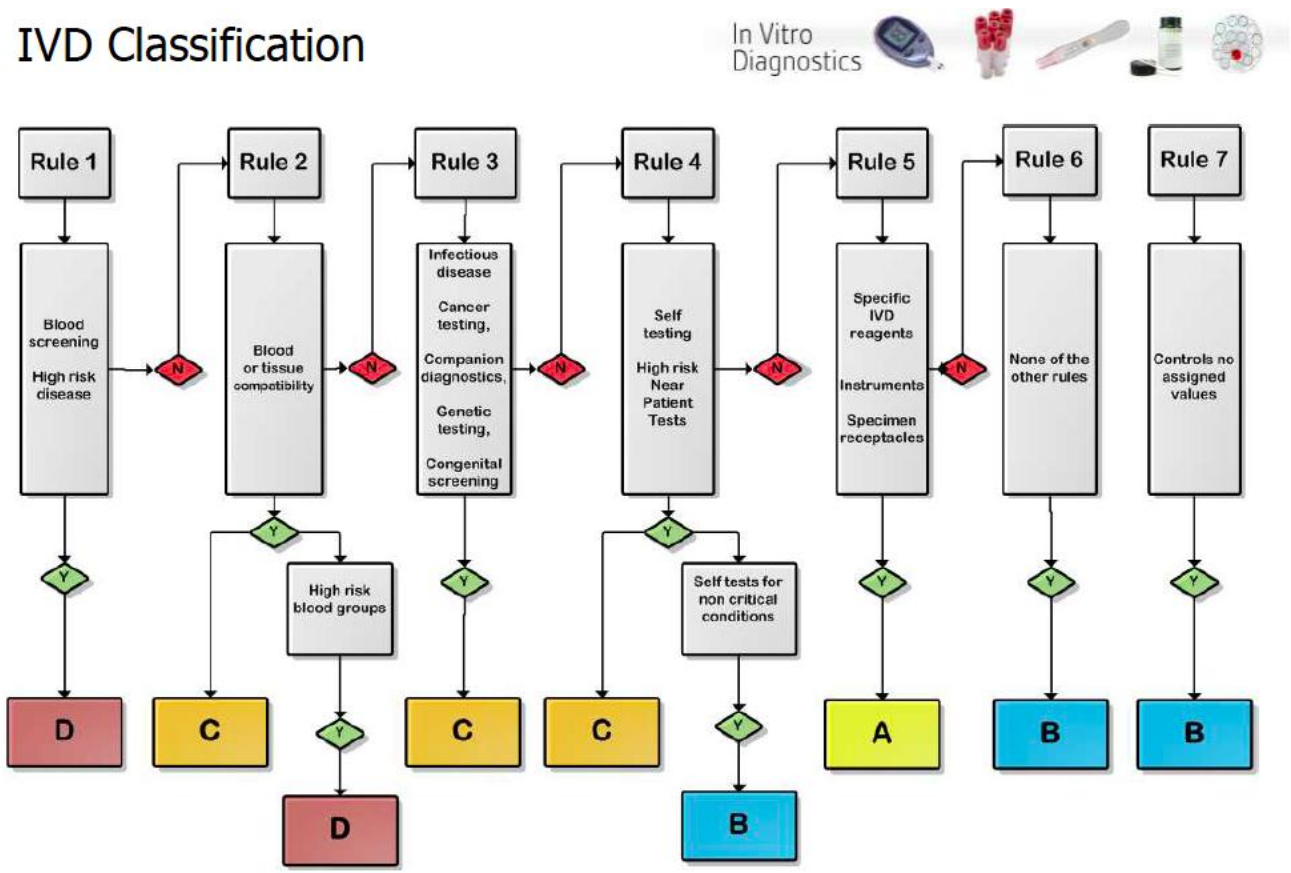

Ordinary legislative procedure
How it works
Complete text
Treaty
Glossary
Share
#4 2nd reading in Parliament
Parliament examines Council's position and approves it, in which case the act is approved; or rejects it, in which case the act will not enter into force and the whole procedure is ended; or proposes amendments and returns the proposal to Council for a 2nd reading.
The legislative proposal is adopted
The vast majority of proposals are adopted at this stage
The legislative proposal is not adopted
The legislative proposal is adopted
The legislative proposal is adopted
#5 2nd reading in Council
Council examines Parliament's 2nd reading position and either approves all of Parliament's amendments meaning the act is adopted, or does not approve all amendments, leading to the convening of the Conciliation Committee.

IVDs: the quantum leap

- IVDs neglected in political discussion, but immense changes in the works
  - IVDs for ‘indirect medical purpose’ (“life style tests”) likely to be regulated
  - Genetic testing practice requirements
  - Radical changes in conformity assessment / market access



Proposed IVD Classification



Quo vadis,
Medical Devices Regulation?

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OUTLOOK

- Final system should be safe, thought-through and implementable
- Equal implementation and interpretation throughout all Member States
- Less and more competent Notified Bodies
- Better classification for IVD
- More clinical trials required for more products
- Stronger and more effective collaboration between all Member States
- Stronger EU “Body” / “Committee” with mandatory decisions
- **Safe products for all patients**

Thank you – any questions?

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