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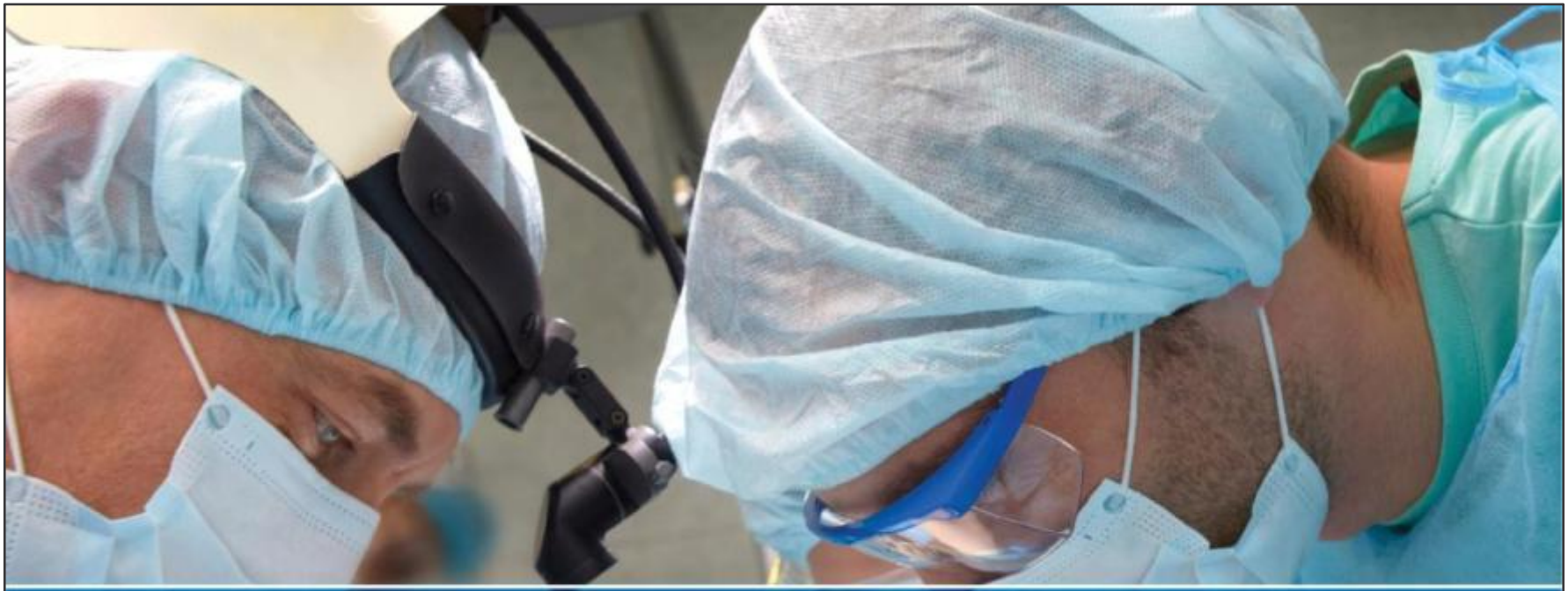


Update on the Revision of the Medical Devices Legislation

UNAMEC General Assembly, 13 November 2013

Valentina Ancona – Eucomed Manager Government Affairs and Public Policy

Outline

I. Where we stand: overall timeline

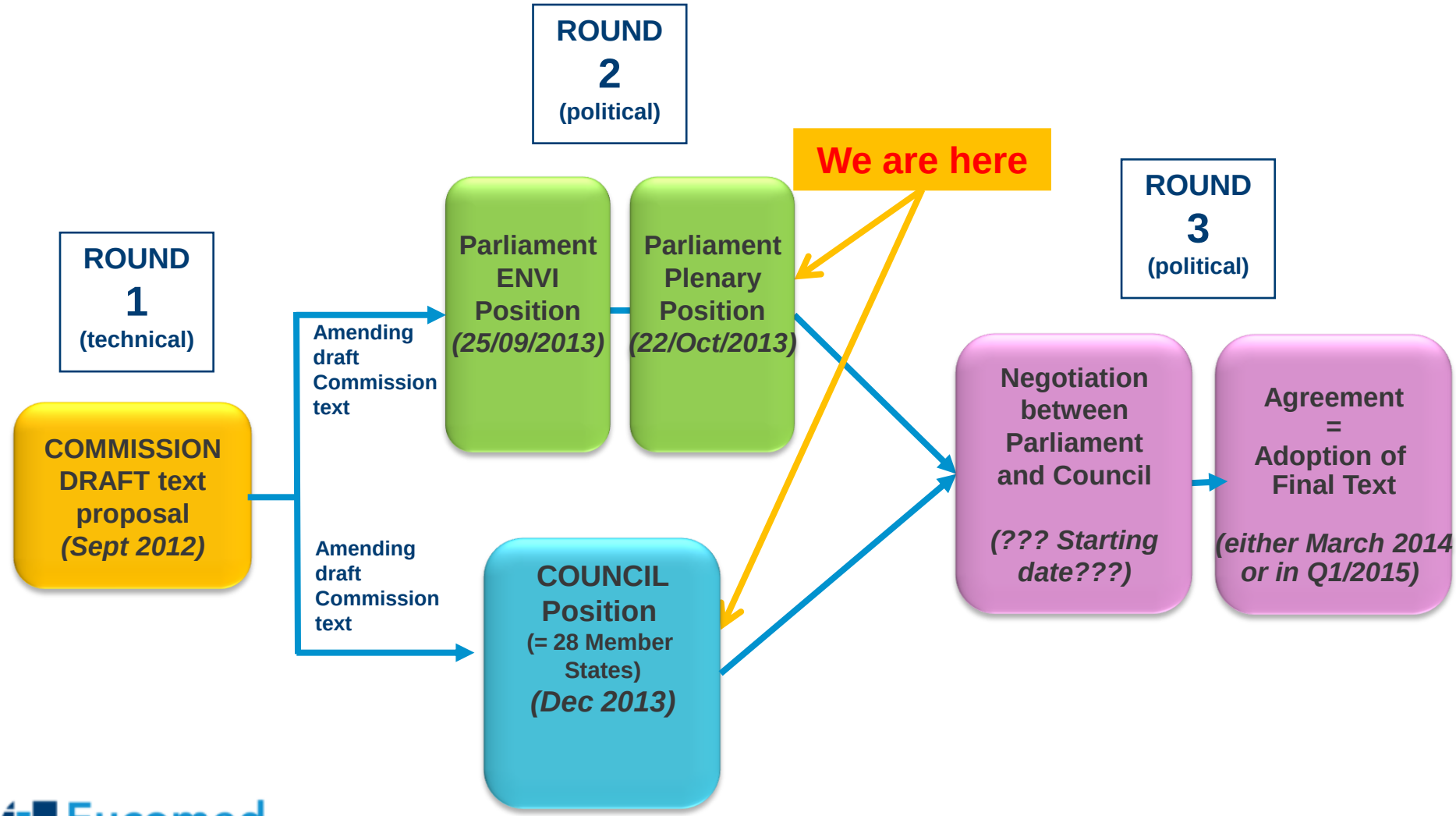
II. Overview of European Parliament plenary vote

- Positive elements
- Challenging elements

III. Procedures/timelines for adoption: short and long-term scenarios

IV. Action plan

I. Where we stand: overall timeline



II. Parliament plenary vote: positive elements

Overall, industry welcomes the majority of measures adopted by the European Parliament on 22 October 2013, *e.g.*:

- **Improving Notified Bodies:**
  - Specialisation
  - Qualification
  - Better control
- **Unannounced visits** of manufacturers
- Increasing **transparency and traceability**
- **Stricter post-market follow-up**
- Improved **stakeholders' engagement**

II. Parliament plenary vote: challenging elements 1/2

1. Key issues

a) Approval system:

- Positive elements:
  - ✓ Member States (MDCG) back in charge of scrutiny
  - ✓ Clinicians (ACMD) now better managed as a pool where experts are chosen from with advisory role to MDCG
  - ✓ Scope more targeted on a risk-based approach (high risk implantables + medium risk devices)
  - ✓ Complicated decision procedure streamlined (from comitology + EC decision to MDCG binding decision)
- Need for improvement:
  - ✓ Still case-by-case product scrutiny, not systematic (PIP/hip cannot be detected)
  - ✓ Still unnecessary length (can be integrated into NB's assessment)
  - ✓ EMA responsible for Special NBs, but no competence (better EC responsible)

b) Reprocessing:

- Positive elements:
  - ✓ Member States can ban reprocessing
  - ✓ Better standards for reprocessing
- Need for improvement:
  - ✓ Reprocessors exempted from undergoing conformity assessment procedure = safety at risk + no checks
  - ✓ Need to technically and scientifically prove that e.g., condoms and peacemakers cannot be reprocessed = global approach vs. EU approach
  - ✓ Safety jeopardized!!!!

II. Parliament plenary vote: challenging elements 2/2

c) **Clinical requirements:**

- Copy-paste requirements from pharma that cannot work for medical devices (use of Randomised Control Trials, reference to efficacy for devices, equivalence principle too narrow)

d) **Hazardous substances:**

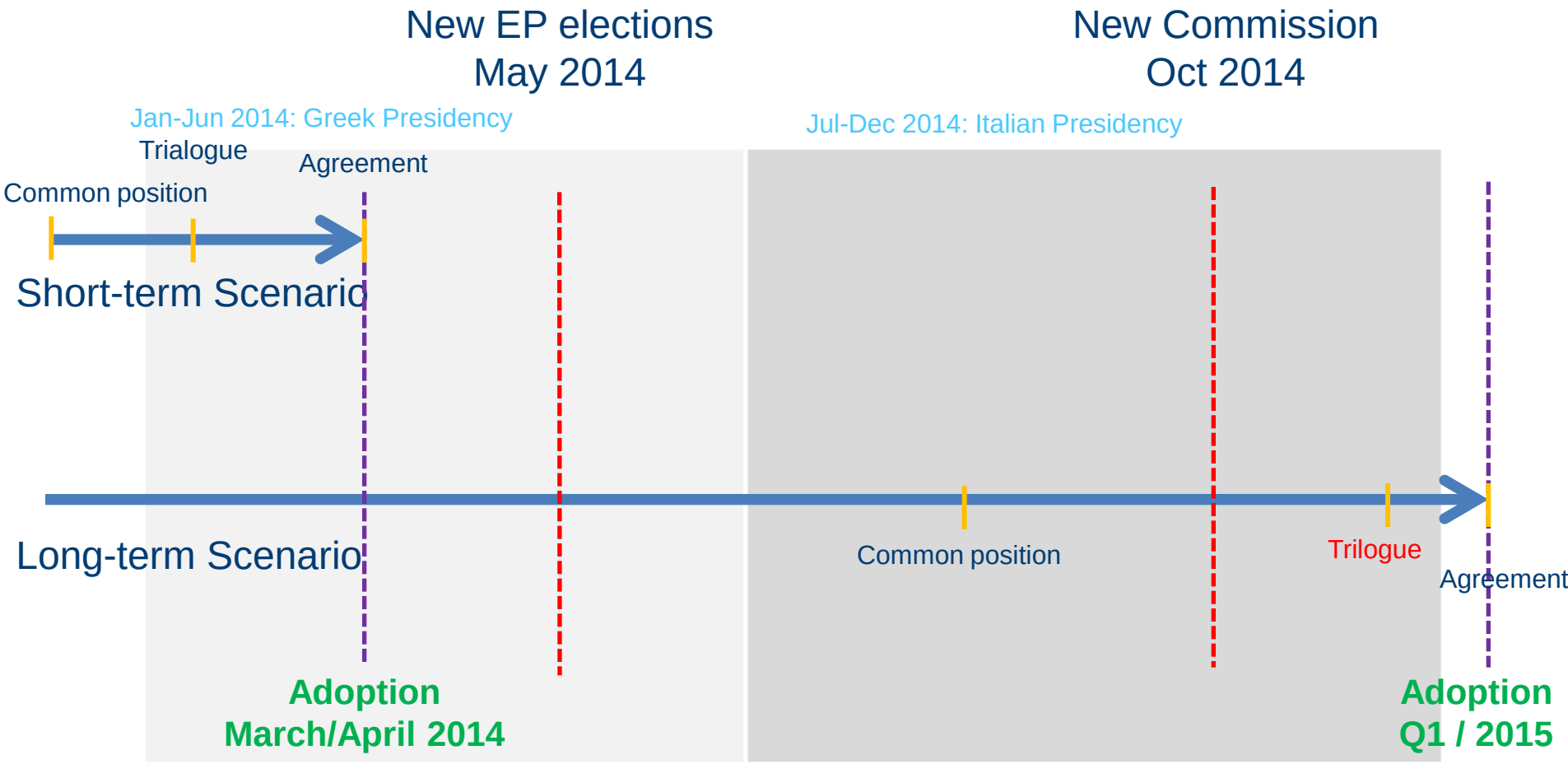
- “one-size-fits-all” ban on hazardous substances without taking into account the medical needs or the risk-benefit analysis of the device seen as inappropriate. Need of implementable approach

2. **Other issues:**

a) **Incidents reporting:** positive improvements but need to further define what and how to report

b) **Implant cards:** positive improvement but need technical adjustment to guarantee implementation

III. Procedure / Timelines



III. Reasoning for short & long-term scenarios

Short-term scenario
Political/dynamic/emotional

European Parliament:

a. Wants early adoption to show results for EP elections
b. Rapporteur not coming back – wants to create her legacy on MDD file
c. Rapporteur might use media to push Council to act
d. DRB+Liese+Commissioner = Pushing Trio

European Commission (Key driver !!!):

a. Commissioner wants early adoption – for re-election as Commissioner
b. COM behavior change since Comm. Mimica came into office (high political involvement)
c. May draft text for Council

Council:

a. Uninterested Member States might want to get this file closed
b. DE idea to 'split' the dossier
c. EPSCO gives political impetus (?)
d. Victim of Horse-trading – accelerate WG/subgroups to work

Long-term scenario
Factual/Process reasons

European Parliament:

a. DRB unhappy with outcome = looses interest

European Commission:

a. MDD not mentioned in their Work plan 2014

Council:

a. Interested in implementable, affordable outcome (no rushed- through result)
b. Regulation word-by-word
c. Council's focus is currently on the Clinical Trials Directive revision and Fees for Pharmacovigilance; some aspects (transparency) from CTD might be transferred to MDD
d. Weak presidencies (GR/IT/LV): overloaded, no focus on MDD
e. Short JT presidency
f. First see new regulation to work: Dalli Plan

Likeliness of each scenario: 50/50 ⟹ **Need to be ready for short-term scenario!**

III. 'Procedural' scenarios

External influence?

Timing: **Result:**

Scenario 1:

EP pushes → Commission 'normal' → Council continues line-by-line agreement → 'Slow' adoption → ?

Scenario 2:

EP pushes → Commission pushes → Council accepts

- 'organised' → 'Fast' adoption → Council strong; concessions from EP
- 'not-organised' → 'Fast' adoption → Council weak; EP strong

Commission pushes → Council reluctant → 'Slow' adoption → ?

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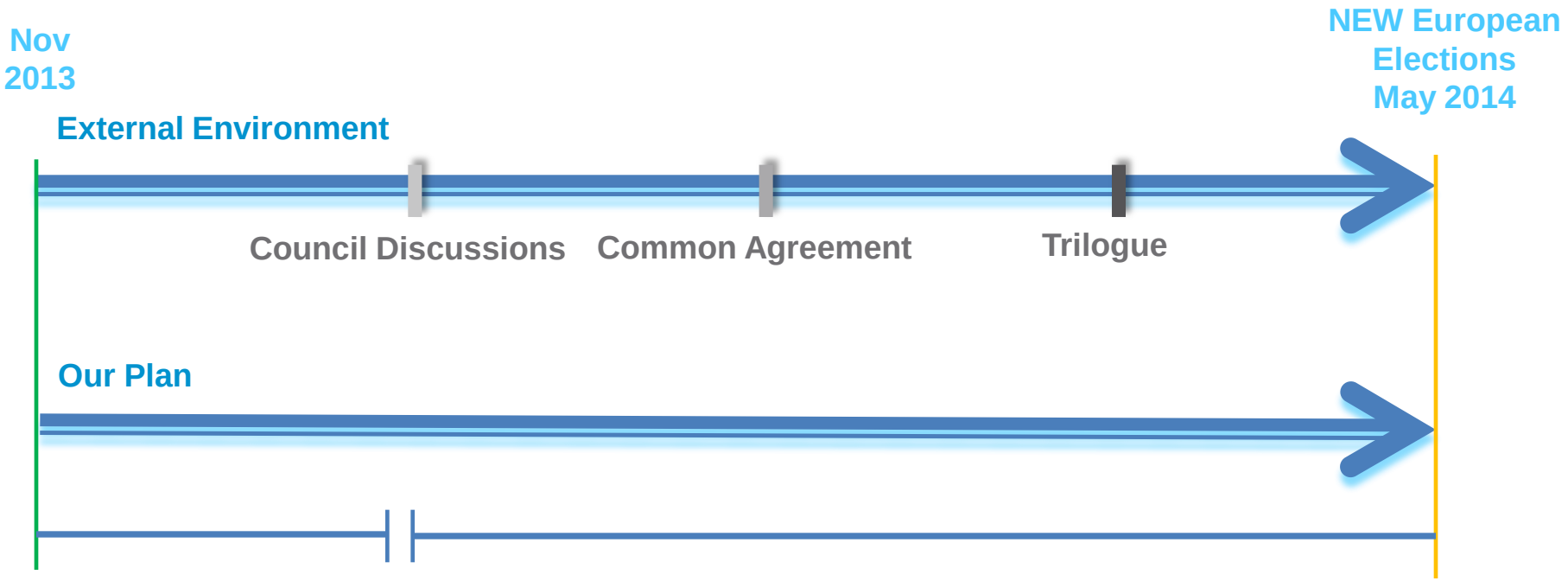
IV. Overview of Actions: ready for short-term scenario!



Nov 2013

Intelligence we need:

- **Crucial** role of NANs in gathering intelligence from their Governments (Q&As and key speaking points provided)

Dec 2013 onwards

Technical Advocacy:

- Supportive documents with technical argumentation to be provided to Council members

Merci/Dank u wel!

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Back-up slides

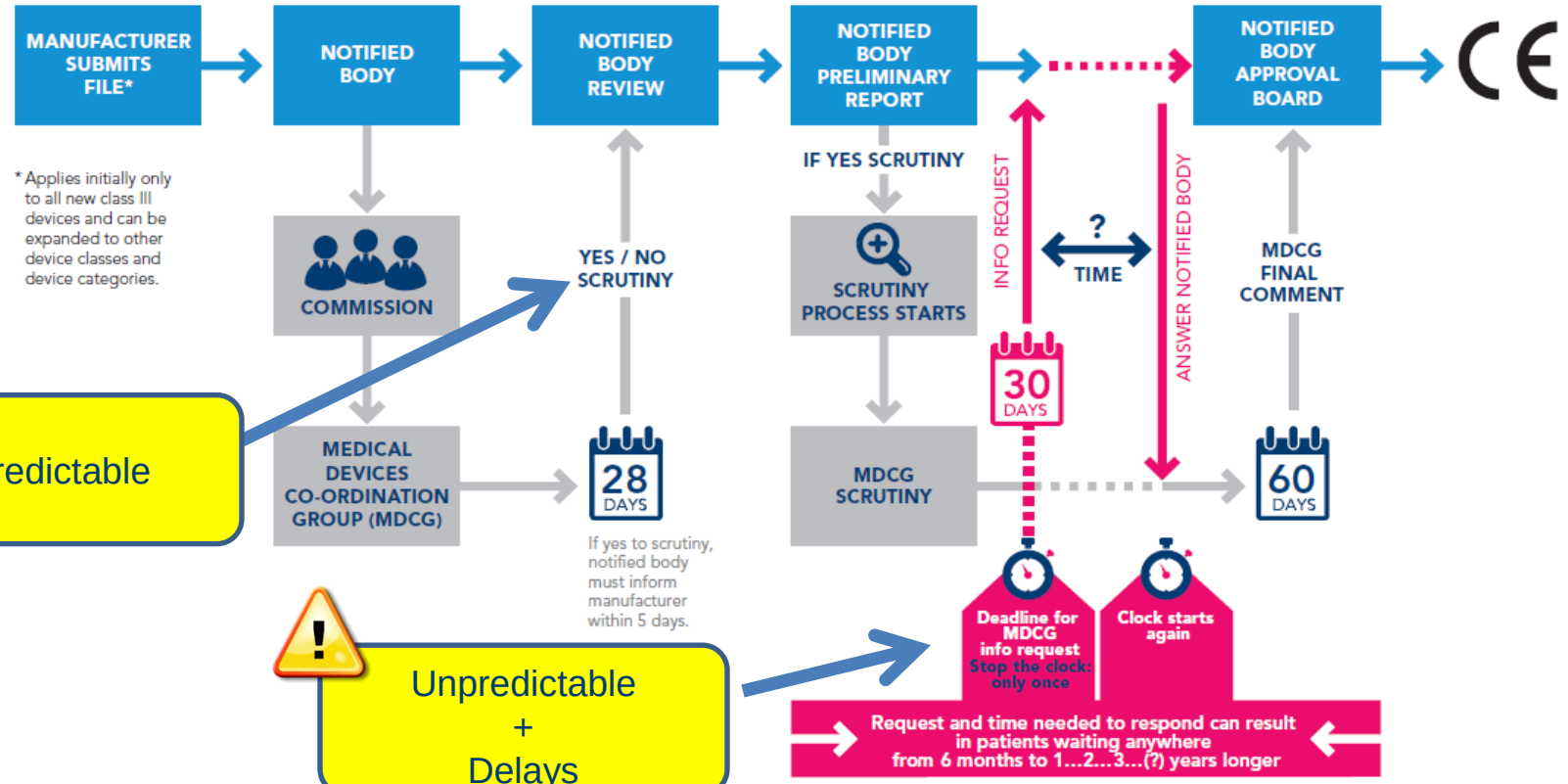
Scrutiny Procedure

- Scrutiny per Commission proposal
- Scrutiny per ENVI Committee
- Scrutiny per plenary European Parliament
- Scrutiny per Council ????
- Scrutiny by Industry: systematic scrutiny

Commission scrutiny…

- Random approach to safety
- Unpredictable process
- Unpredictable delays
- Net result: no improved safety and no market confidence = no patient benefit and innovation driven out of Europe

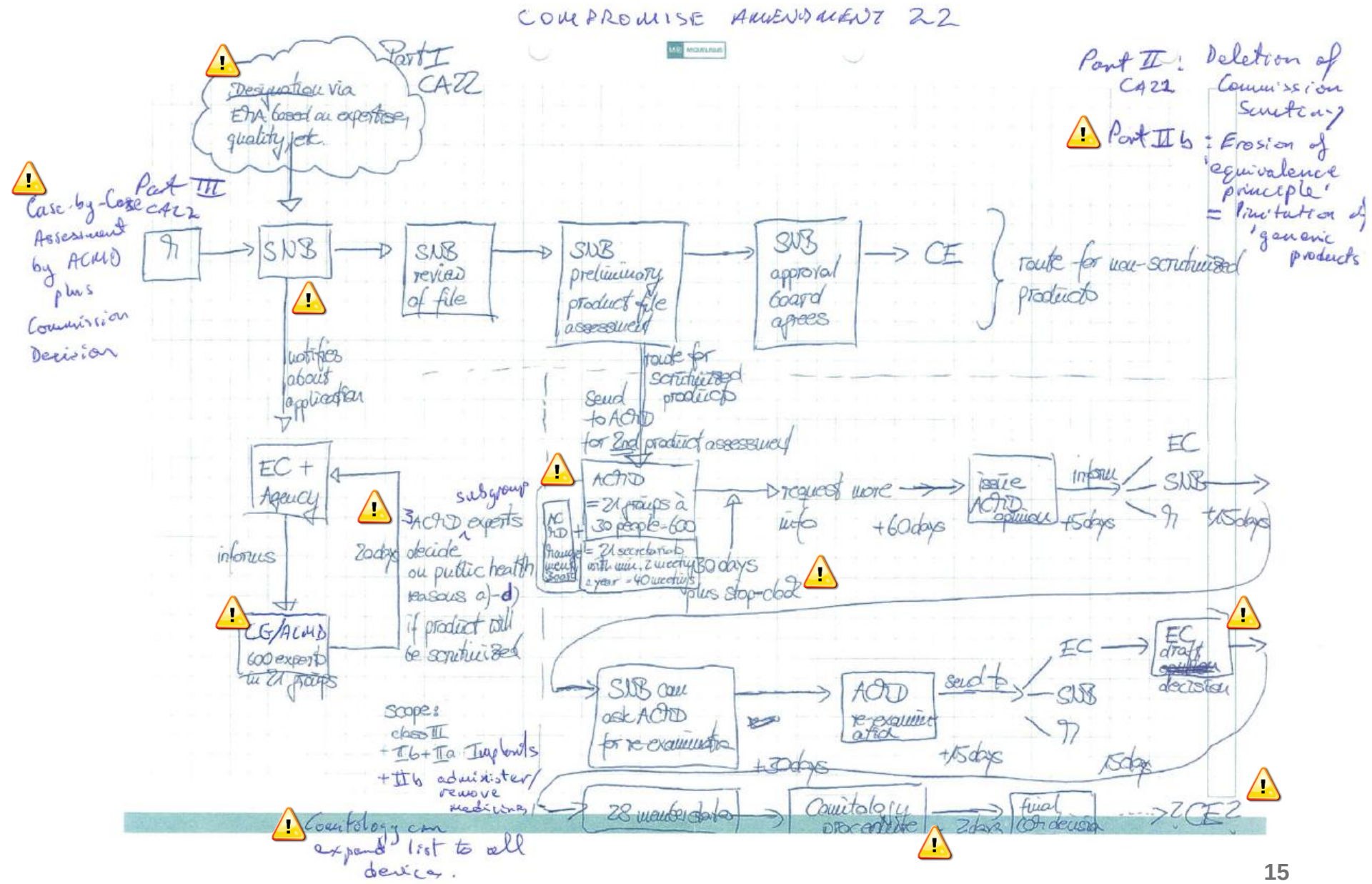
Proposed Scrutiny Procedure (Article 44, Page 66)
Medical Devices Directives revision proposal



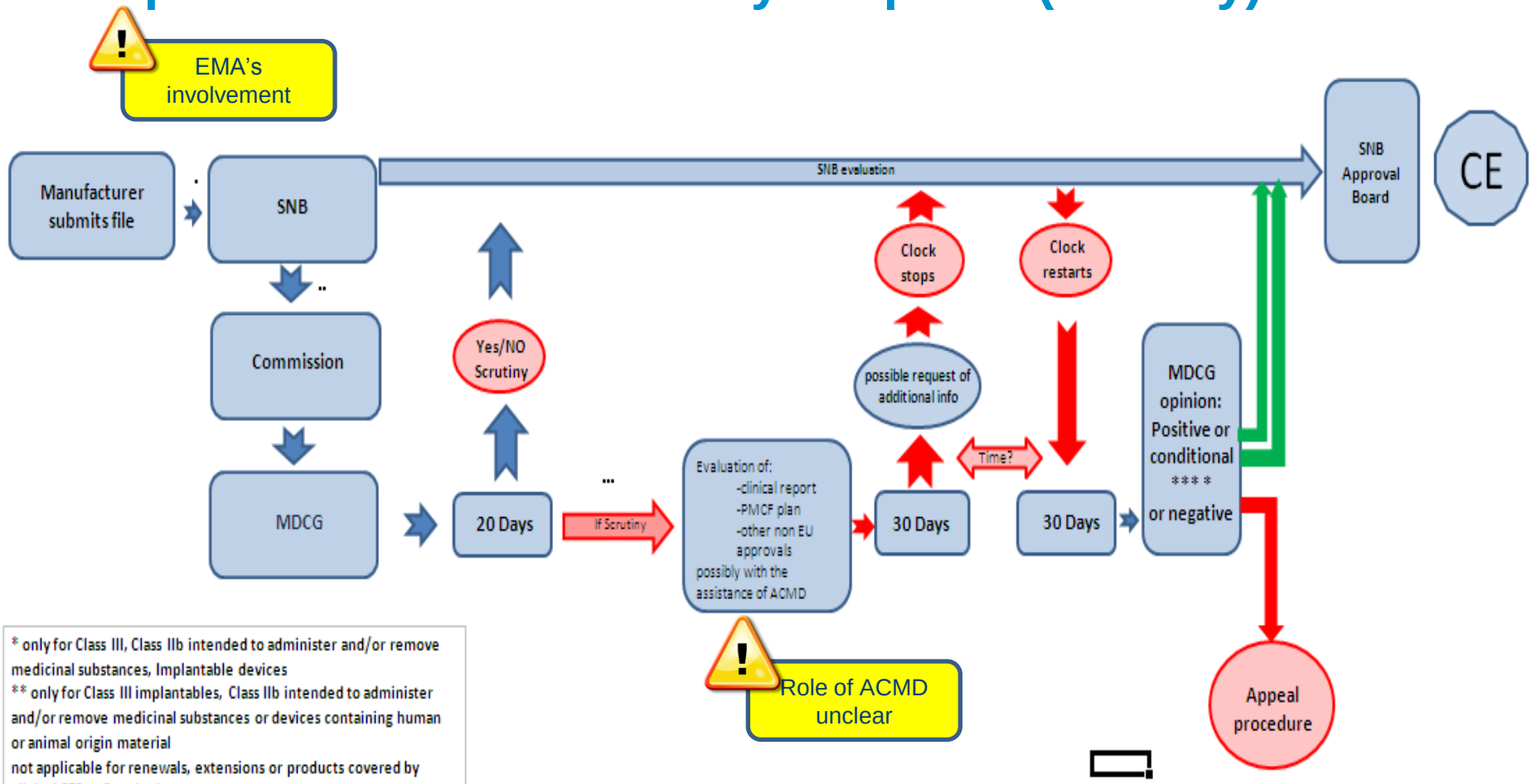
Unpredictable

Unpredictable + Delays

ENVI Committee Proposal



European Parliament Scrutiny Proposal (Plenary)



* only for Class III, Class IIb intended to administer and/or remove medicinal substances, Implantable devices

** only for Class III implantables, Class IIb intended to administer and/or remove medicinal substances or devices containing human or animal origin material

not applicable for renewals, extensions or products covered by clinical CTS or Standards

*** only if the device is novel and has a possible mayor impact on health, or there is a change in the risk-benefit profile for that group of devices or increase of incidents ratio with products of the same category

**** upon modification of the Clinical report or the PMCF plan only

Special Notified Bodies

- Only Special Notified Bodies (SNB) can deal with:
  - Implantable devices
  - Devices incorporating a medicinal substance with ancillary function
  - Class IIb devices intended to administer/remove medicinal product
  - Devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable
  - all other class III devices
- Special Notified Bodies (SNB) are designated by EMA

Scope of Scrutiny

- Smaller scope than what needs to go via a Special Notified Body:
  - Implantable devices: only class lll implantable devices
  - Devices incorporating a medicinal substance with ancillary function
  - Class llb devices intended to administer/remove medicinal product
  - Devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable
- Further reduction of scope:
  - Exclusion of certificate renewals and updates
  - Exclusion of devices for which a Common Technical Specification exists for clinical evaluation and Post Market Clinical Follow Up

Criteria for election of products for the scrutiny procedure

- Not all products in the scope will effectively go through the scrutiny procedure
- Selection depends on:
  - the novelty of the device with possible major clinical or health impact
  - an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure
  - an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices

    Comment: manufacturers that send many incident reports may be penalised!

Industry's ideas on improving the Commission scrutiny…

- Systematic approach to safety, especially clinical
- Predictable process
- MDCG monitor/scrutinise the system
- Net result: improved safety and market confidence = patient benefit and innovation remaining in Europe

Proposed Scrutiny Procedure (Article 44, Page 66)
Medical Devices Directives revision proposal

Eucomed Proposal = BETTER WAY = High Quality Systematic Approach

A. Measures to ensure **Notified Bodies** are doing a good and **consistent job**
   - More rigorous criteria for class III Notified Body designation and monitoring
   - Encourage further specialization of Notified Bodies
   - Undertake more regular audits of class III Notified Bodies

B. Measures to ensure that the **clinical evidence** for medical devices is being **properly reviewed by independent clinical experts**
   - MDCG to vet and maintain a list of clinical experts
   - Require Notified Bodies to engage only these vetted clinical experts
   - Require Notified Bodies to publicly disclose their internal and external technical experts
   - Allow manufacturers and authorities to use clinical experts for scientific advice