Impacts of the new IVD Regulation – a Notified Body's perspective

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IVDR status

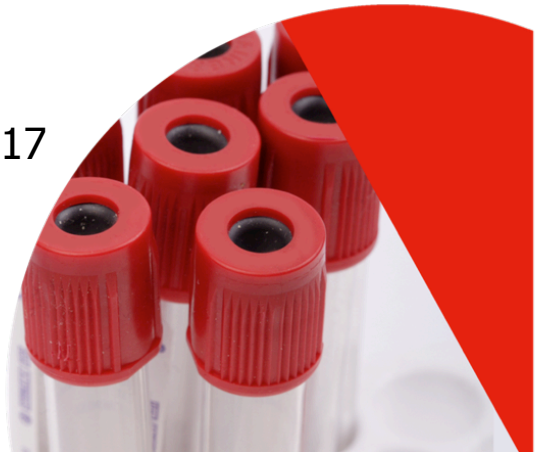
Medical devices: deal reached on new EU rules

25/05/2016 | 20:15 | Press release | 283/16 | Health

On 25 May 2016, the EU agreed new rules on medical devices and in vitro diagnostic medical devices.

The Netherlands presidency of the Council and representatives of the European Parliament reached a political agreement. It is still subject to the approval by the Council's Permanent Representatives Committee and of the Parliament's ENVI committee.

- Political agreement reached between Council & Parliament
- Consolidated draft text issued 27-Jun-2016
- Post-trilogue technical amendments 26-Oct-2016
- Formal adoption of text by Council and Parliament expected Q1 2017
- Publication in the Official Journal of the EU – expected Q2 2017



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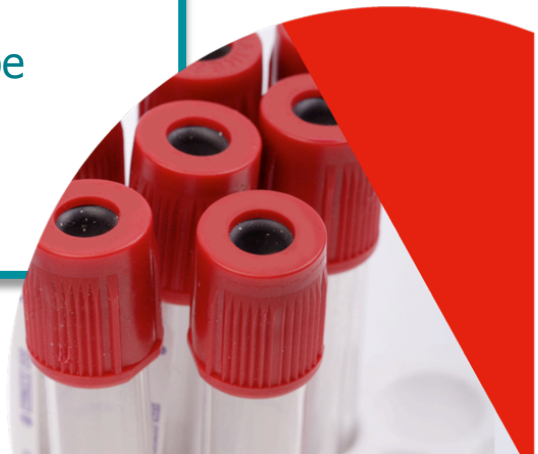
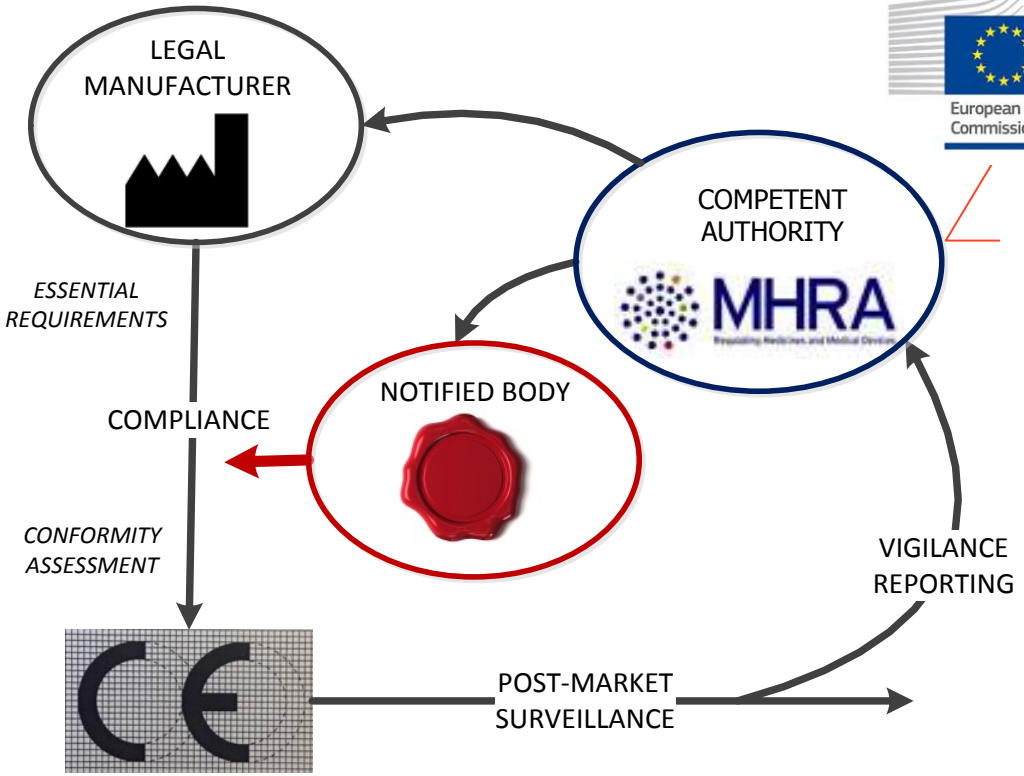
Alignment of the MDR and IVDR

- '…There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices,
- whereas the horizontal aspects common to both sectors should be aligned.'



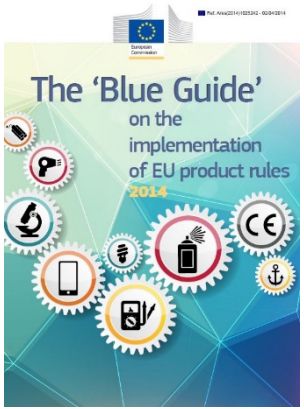
New Approach directives

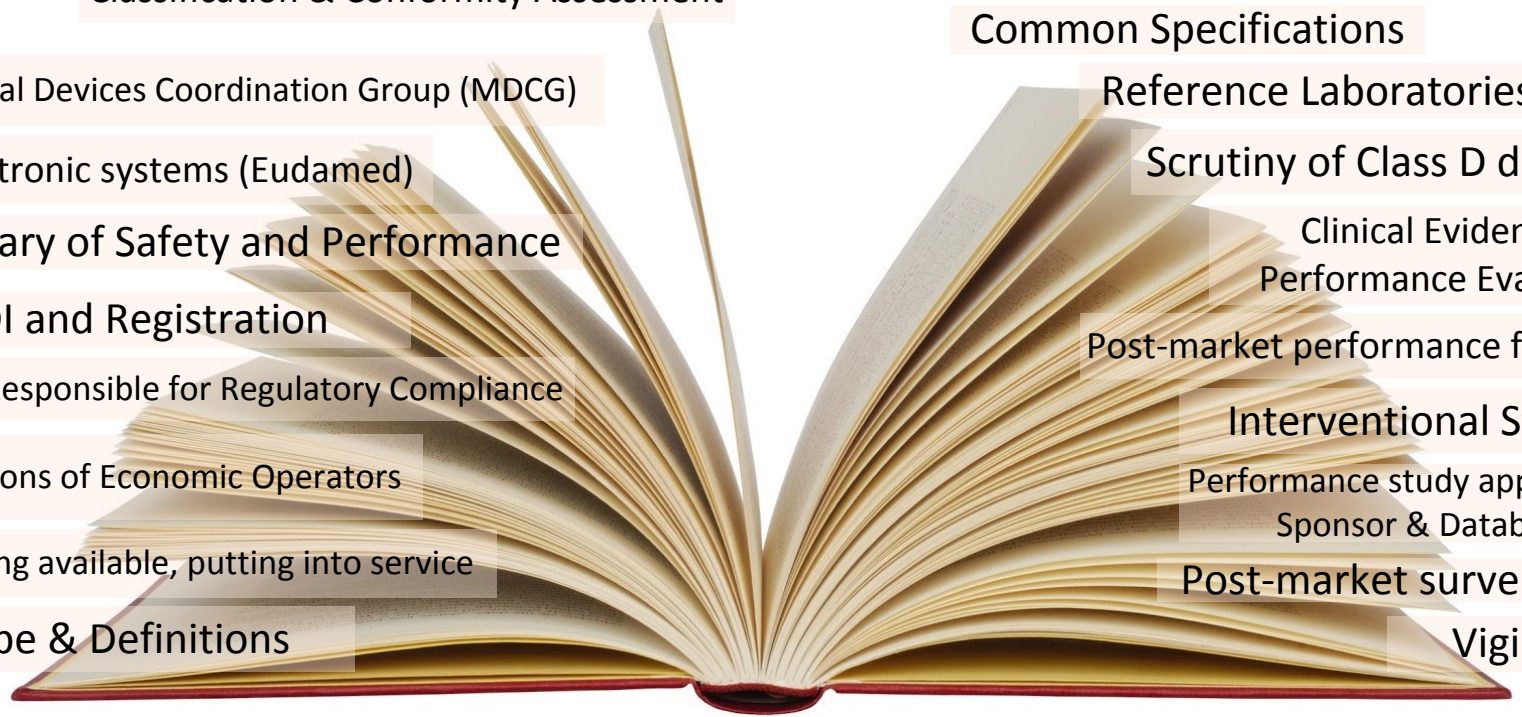


European Commission

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

EUROPEAN PARLIAMENT





New wave of transparency

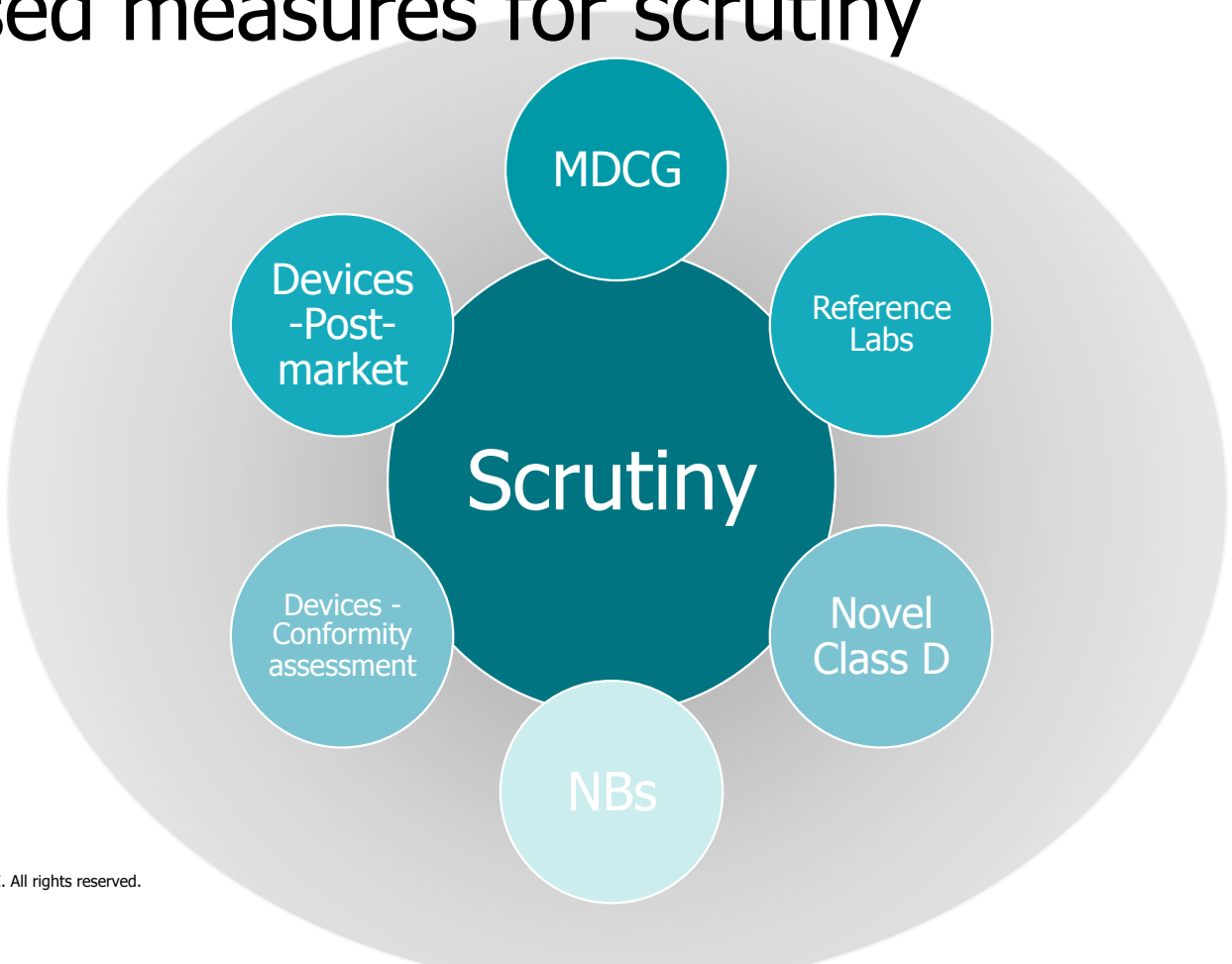
Eudamed

Device Registration &
Economic operators

Competent Authorities
exchange

Audits of Notified Bodies
& Certifications issued

Increased measures for scrutiny



Conformity assessment

Re-classification of IVDs will mean 80-90 % will need NB involvement
Compared to 10-20% currently

Review of **technical documentation** under the IVDR will be at the same depth for all devices, but sampling will be proportionate to risk

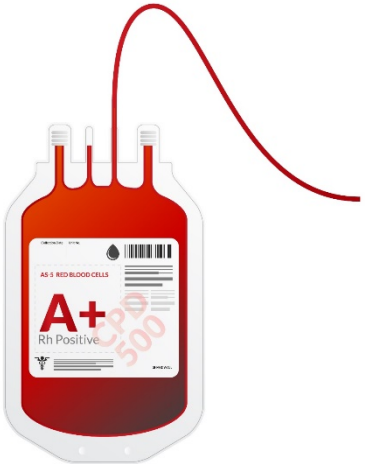
Reviews will have more emphasis on ***risk***, ***clinical evidence*** and ***post-market surveillance***

- D — High Population, High Patient risk
- C — Low Population, High Patient risk
- B — Medium-low patient
- A — Low patient risk

Directive to a Regulation…

There is no 'grandfathering'

- Therefore, all IVDs will need to undergo a new conformity assessment according to the new Regulation

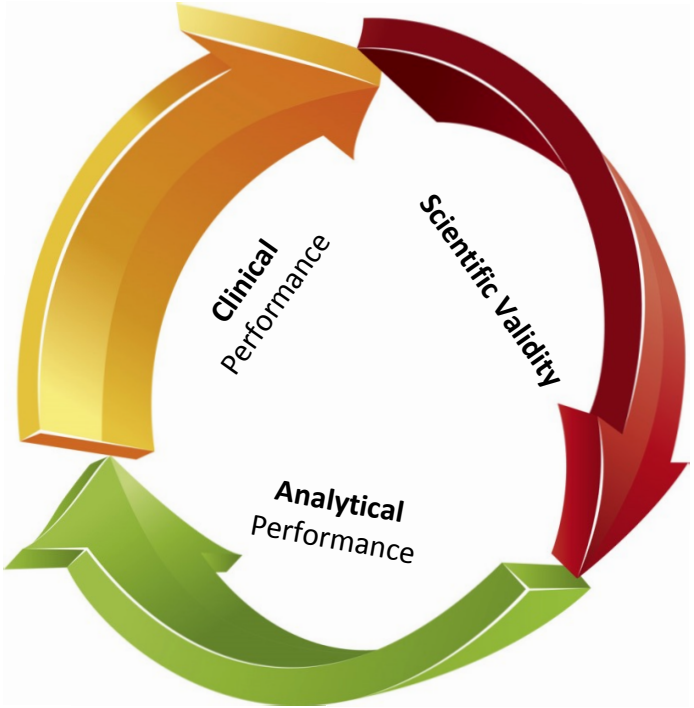


- For existing Annex II list A devices – these will be Class D (IVDR)
  - Involvement of EU Reference Laboratories for conformity assessment

Now you have a CE mark…

Post-market obligations defined

- Vigilance requirements
  - Incident Reporting
  - Trending
- Post-market Surveillance Plan & Post-market Surveillance
  - Post-market surveillance Report (Class A & B); or
  - Periodic Safety Update Reports (Class C & D)
- Post-market Performance Follow-up (PMPF)
- For Class C & D devices, updates to the Summary of Safety and Performance



***Clinical Evidence* through-out the device lifetime**

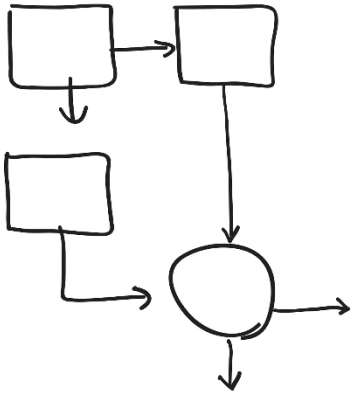
What now…

Notified bodies

- Preparing for designation
- NBOG codes
- Developing our teams & breadth
- Implementation and training

- *Talking to manufacturers*

Manufacturers



- Project Plan according to the current text
- Engage with your/a Notified Body

- *Use the Transition Period effectively!*

Other Economic Operators

- Authorised Representatives, Importers and Distributors need to plan to meet new obligations

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