



Ministry of Health, Welfare and Sport

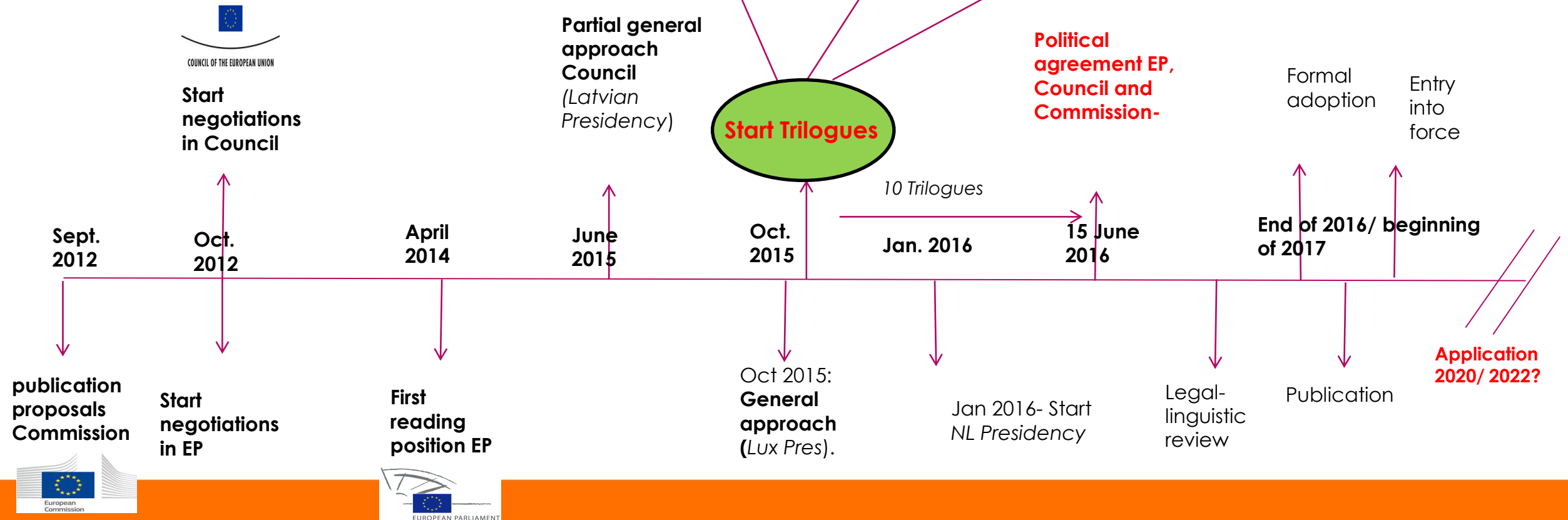


## **New EU-regulations Medical Devices and IVD's**

*Daniëlle van Mulukom- coördinator medical devices  
NL Presidency 2016- vice-chair working party  
medical devices EU 2016*



# B Legislative process





**EU**  
**2016**

Since 2012:

-8 Presidencies

-99 Council Working Parties (28 member states)

-10 Political Trilogues

-30 Technical Trilogues

MDD: 60 pages, MDR: 354 pages, IVDR: 310 pages



# B Decisive moments





It's a deal; new legislation for MD's and IVD's!





## Main changes

- 1 Scope (chapter I, annex XV)
- 2 Economic operators (chapter II)
- 3 Eudamed, UDI (chapter III)
- 4 Notified bodies (chapter IV)
- 5 Conformity assessment procedures (chapter V)
- 5 Clinical evidence (chapter VI etc.)
- 6 Authorities: cooperation MDCG, vigilance, surveillance (chapter VII+ VIII)





**IVD-negotiations....**





## Main political hurdles

- Genetic testing
- In-house
- Classification : rule 1, 4 and 5
- Clinical evidence
- PSUR + Trendreporting
- Near-patient testing
- Scope: indirect medical purpose
- Scrutiny
- Transitional provisions: Eudamed in place, expert lab's timely in place







## Main changes IVD-regulation

- Risk classification in 4 classes (GHTF)
- Reference labs
- Scrutiny class D devices without CS
- Genetic information, counselling and informed consent
- Companion diagnostics
- In-house testing
- Detailed requirements performance evaluations/ studies



Wanneer? 2022.....



**Wat nu.....wees voorbereid!**







## Links to documents:

<http://data.consilium.europa.eu/doc/document/ST-11662-2016-INIT/en/pdf>

<http://data.consilium.europa.eu/doc/document/ST-11663-2016-INIT/en/pdf>

## **Thank you for your attention!**

**Ms. D. van Mulukom** | MSc- Sr policy coordinator|

[Ministry of Health, Welfare and Sport](#) |

Department of Pharmaceutical Affairs and Medical Technology

Rijnstraat 50 | 2515 XP | The Hague | Postbus 20350 | 2500 EJ | The Hague |

' 0031(70) 3406542 | 0031 6-21160296 |20th floor|

\* [dm.v.mulukom@minvws.nl](mailto:dm.v.mulukom@minvws.nl) | [www.rijksoverheid.nl](http://www.rijksoverheid.nl) |



**Safer, more effective and innovative devices in the EU**

