The European Association
Medical Devices - Notified
Bodies

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Informative meeting of the Dutch EU 2016 presidency on MD/IVD
On December 10th 2015
REPORT

Place: Permanent Representation of the Netherlands to the EU,
Avenue de Cortenbergh 4-10, Brussels
Time: 14.00 to 15.30
Programme :

- Opening and Welcome
  Marcel van Raaij - Director of the Pharmaceuticals and Medical Technology Department of the Dutch Health Ministry
- State of play trilogues MD/IVD
  Ricco Buitink - Health Attaché
  Daniëlle van Mulukom- Project manager EU presidency Medical Devices
- Closure
  Marcel van Raaij - Director of the Pharmaceuticals and Medical Technology Department of the Dutch Health Ministry

1 Opening and Welcome

Welcome by Marcel van Raaij Director of the Paharmaceuticals and Medical Technology Departement of the Dutch ministery of halth, Welfare and sport

The meeting is organized in 3 steps:

- presentation of the state of play
- questions and answers in face-to face
- Wrap up meeting with summary of the most frequent questions and requests

The presidency team will be available in the room for the 2nd step.

2 State of play trilogues MD/IVD

Ricco Bui Health attaché
Danielle van Mulukom: Project manager NL EU presidency MD

2.1 How does it really work?

It is a methodology for negotiations between Council and the EPs in order to reach an agreement on a legislative file. The Commission is part of the negotiations and that the reason why it is called trilogues. Although Commission is only present as a facilitator.

Trilogues are both made of political and technical meetings.

From DG Grow: Carlo Pettnelli + Salvatore D'acunto + Mincheva
From EP: G. La Via + G. Willmott + Piechia + Mc Guinness (7 shadow)
From Council: DPR W. Kingma

2.2 State of play negotiations

Under Luxembourg Presidency, there has been 5 political trilogues (1st on October 13th) and 7 technical meetings.
Netherlands representative was invited by the Luxembourg presidency to attend all meetings in order to prepare their presidency in a more effective way.
Today about 25 to 33 % of the text had been covered through technical meetings.

2.3 Expectations and forecasts

Forecasts of the Netherlands presidency is 3 to 5 political meetings and 10 to 15 technical meetings.
It is needed in order to get both tracks (political and technical) in balance.
Possible agreement and vote on June 2016?

Core next regulations from 65 to 389 pages
There are stricter requirements on

- market authorized procedure
- Manufacturers - Importers - Distributors
- Notified Bodies
- Market surveillance
- Clinical Investigation
- Cooperation coordination MS, COM

Political issues:
Today there are still a solid package of issues and when there is no agreement on everything there is no agreement at all.
The main issues are

- Genetic testing
- CMR substances
- Reprocessing (very different positions, MSs could still agree or not on the process and put or not additional requirements on this process)
- Liability insurance (Council is not convince on the need which will add additional costs on Manufacturers and at the end of the day on patients)
- Scrutiny / special NBs at the start all 3 wanted it but now it is asked only by Eps and one of the reasons is that it has to take place in the pre-market phase and thus will add time before the product is put on the market
- Validity of certificates: not yet agreed
- Classification rules (still in discussions: 6(reusable materials), 19 (nanomaterials), 21 (ingested products) MD & 1 classification in class D, 4, 5 IVD)
- Chapter 6 in both regulations
- Clinical investigations / performance studies IVD

The outcome is definitively more regulations for all the stakeholders.
The Luxembourg decided to divide the 2 regulations in 4 bocks each for the meetings.

After the presentation took place bilateral interactions.

There will perhaps be a similar meeting during the next 6 months.

3 Wrap up

Mr. van Raaij tanks the participants for the interactions and their interests for this meeting.

The main questions were on:

- the transition period
- How participant can reach NL representatives
  The answer is : send positions papers and if possible by emails.

It is noticed that their work is to work from the Council proposal.

There is 2 other items which are pointed out namely:

- authorization on high risk devices
- importance on info to patients.