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Update on ongoing trilogue negotiations between the Council, Parliament and Commission on the proposal for a Regulation on medical devices

The Luxembourg Presidency (July 2015 – December 2015) reported at the end of its term on the status of the ongoing trilogue negotiations on the proposals for a Regulation on medical devices ("**MDR**") and for a Regulation on in vitro medical devices between the Council of the European Union ("**Council**"), the European Parliament ("**Parliament**") and the European Commission ("**Commission**") (see attachment).

From this report it appears that five informal trilogue meetings were held on 13 October 2015, 28 October 2015, 10 November 2015, 18 November 2015 and 3 December 2015 between the Council, Parliament and the Commission.

In order to ensure that the discussions would take place in an efficient manner, taking into account the size of the proposals, it was decided to divide the proposals into the following four thematic blocks:

- Block I: Chapter I (Scope), Chapter II (Obligations of economic operators) except Article 15 of the draft Regulation on Medical Devices, Chapter V, section I (Classification), and the related annexes.

  The general obligations of distributors in Article 12 of the MDR are contained in Block I.

- Block II: Chapter III (Identification and traceability), Chapter VI (Clinical evaluation for medical devices and performance evaluation for IVDs), Chapter IX (Confidentiality and data protection), Chapter X (Final provisions, including transitional measures), and the related annexes.

- Block III: IVD-specific issues, notably rules on IVDs for self-testing and genetic testing as well as classification rules and parts of the provisions on performance evaluation.

- Block IV: Chapter IV (Notified bodies), Chapter V. section II (Conformity assessment), Chapter VII (Surveillance of the market), Chapter VIII (Cooperation between Member States, notably the Medical Device Coordination Group), and the related annexes.

Negotiations on the four blocks have been opened during the informal trialogue meetings.

The main political issues covered in the informal trialogue meetings were identified and concern: (i) aesthetic devices, (ii) in-house products, (iii) liability insurance, (iv) implant card, (v) classification rules, (vi) use of cancerogenic, mutagenic and reprotoxic substances and endocrine disrupting substances, (vii) reprocessing of single-use devices, (viii) traceability, (ix) transitional measures (in particular regarding validity of certificates), (x) prescription rules, (xi) devices for genetic tests, (xii) companion diagnostics, (xiii) genetic counselling, (xiv) self-testing and near-patient testing and (xv) the scrutiny procedure for high-risk devices.

The Luxembourg Presidency concluded that "*While it is noted that nothing is agreed until everything is agreed, the Presidency deems that there is an emerging agreement on Chapters I, II and III in both proposals, except for Article 15 (reprocessing) in the medical device proposal. The Presidency is, now that discussions on all blocks have been opened, convinced that the ground has been laid for an agreement between the Institutions.*"

It can therefore be expected that an agreement will be reached under the Dutch Presidency (January 2016 – June 2016) in the coming months.

We hope this information is useful to you.

Please do not hesitate to contact us should you have any further questions.

Best regards,

Sarah