EDMA Workshop on EU Health Technology Assessment Network Strategy: how will EDMA respond to the synergy HTA-Regulatory?

02 February 2015, 09h30-17h30

DIAMANT MEETING CENTRE
Bd. A. Reyerslaan 80, 1030 Brussels

THIS WORKSHOP IS FREE OF CHARGE AND OPEN TO:

- EDMA Corporate Associate Members (CAMs)
- National Association Members (NAMs) affiliated to EDMA

Please distribute this invitation within your company or among your members.
The number of people per company is not limited.

EU Health Technology Assessment Network (HTAN), the strategic cooperation of Ministries of Health or competent authorities responsible for Health Technology Assessment (HTA), has been set up under Article 15 of the Directive on the application of patients' rights in cross-border healthcare 2011/24.

HTAN has adopted its strategy on 29 October 2014 and within its vision it states that **stronger synergies and closer interaction between developers of health technologies, regulators, HTA bodies** and decision makers shall be explored through the EU cooperation.
For medical devices and IVDs, **synergies** shall be explored in relation to the legislation and its implementation, including **conformity assessment procedures with Notified Bodies.**

This workshop is aimed at both presenting and sharing information between members on HTAN Strategy and its drive to imbricate regulation and HTA processes, to reflect together on the implications for IVD industry, such as the **risk of increase hurdle to access** (both in terms of increased investment required to obtain clinical data for CE Marking and increased lag time to reach the market) if HTA standards were in place, develop EDMA talking points and outreach plan.

9:30 -10:00 - Registration and Coffee

10:00 - 10:15 - Welcome
Markus Ott (Bayer) – Co-Chair Policy & Value of EDMA HTA TF
Yves Verboven-EDMA Market Access & Economic Policies Director

10:15 - 10:25 – Introduction and objectives
Yves Verboven-EDMA Market Access & Economic Policies Director
Victoria Wurcel-EDMA HTA & Economic Policies Manager

10:25 – 11:00 - New role of HTA on the Market Access Pathways for IVDs
Yves Verboven-EDMA Market Access & Economic Policies Director

11:00 – 11:35 - Clinical Evidence for IVDs (regulatory)
Jesus Rueda-EDMA Director International Affairs

11:35 – 12:05 - Clinical Utility for IVDs (HTA) - What could happen if HTAN input on regulation?
Victoria Wurcel-EDMA HTA & Economic Policies Manager

12:05 – 13:15 - Roundtable discussion: Members view on Industry Position Synergy Regulation- HTA
Benny Ons (BD) - Chair of EDMA Regulatory Affairs Committee and Labeling Task Force, Chair of EDMA Clinical Evidence Task Force
Dagmar Kownatka (Roche) - Chair of EDMA Public Affairs Committee
Markus Ott (Bayer) – Co-Chair Policy & Value of EDMA HTA TF
Luc Van Hove (Biocartis)-Co-Chair of EDMA Clinical Evidence Task Force
Members input

13:15 - Lunch

14:15 – 14:45 – Questions and answers

14:45 – 15:10 – HTA at EU Level & Synergy drive
Yves Verboven-EDMA Market Access & Economic Policies Director

15:10 – 16:00 –Core messages and talking points- Response to HTAN
Members input
Yves Verboven-EDMA Market Access & Economic Policies Director
Victoria Wurcel-EDMA HTA & Economic Policies Manager

16:00 – 17:20 - Roundtable discussion: outreach plan
Benny Ons (BD) - Chair of EDMA Regulatory Affairs Committee and Labeling Task Force, Chair of EDMA Clinical Evidence Task Force
Dagmar Kownatka (Roche) - Chair of EDMA Public Affairs Committee
Markus Ott (Bayer) – Co-Chair Policy & Value of EDMA HTA TF
Luc Van Hove (Biocartis)-Co-Chair of EDMA Clinical Evidence Task Force
Members input

17:20 – 17:30 – Conclusions and closing remarks
Markus Ott (Bayer) – Co-Chair Policy & Value of EDMA HTA TF