EUROMCONTACT
PRESS RELEASE
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In a seminar organised on 22nd March 2017 in Brussels by Euromcontact, participants discussed the impact of the new Medical Devices Regulation on the contact lens sector. Industry representatives also hold an exchange on strategies to best plan for the implementation of the MDR. The seminar took place shortly after the formal adoption of the MDR by the European Health Council (EPSCO) at its March Council, while the ENVI Committee of the European Parliament adopted the text on 21st March 2017 ahead of formal plenary adoption in spring 2017.

More than 40 industry participants attended the seminar, from global manufacturing companies to SMEs and from across the EU. The seminar featured three presentations from the European Commission, including a key speech by Salvatore D'Acunto, Head of Unit of Health technologies and Cosmetics of Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, on the main aspects of the MDR. Commission also presented the new provisions applying for custom made lenses and clarified the transition periods. Commission also gave some indications on how the non-corrective lenses, falling under Annex XVI of the MDR for devices with non-medical purposes, will be dealt with in the future. Medtech Europe stressed the priorities and challenges for the industry implementation of the MDR while Mr. Ghislain, Deputy Director for the Division for Science and European Dimension at ANSM provided a perspective from a competent authority's point of view on the new requirements for pre-market authorisation. Mr. Junker, Vice-President of Team NB stressed the impact of MDR on the technical file for manufacturers.

In the afternoon session, Mr. Junker explained the impact of the MDR on Notified Bodies (NB) and the impact on the relations between NB and manufacturers, while Mr. Malonne, Director General of DG Post Authorisation at FAMHP, provided the perspective of the Belgium competent authorities on the post-market surveillance measures expected from manufacturers. An industry expert gave a presentation on the Eudamed-UDI and the specific cases for contact lenses. The last panel discussions featured practical experiences of manufacturers planning the changes in-house to be able to comply with MDR.

Antonieta Lucas, Chair of the Euromcontact Regulatory Affairs stressed: "*Over the last years, Euromcontact has been engaging with the European Commission and Member States in the negotiations on MDR, especially on non-corrective contact lenses, but also on labelling issues and on UDI; we are pleased to see that this collaboration continues today. Some of our membership, especially the SMEs, stressed today that meeting the new requirements of MDR will be a great challenge. We welcome the openness of the Commission to exchange on this very specific issue of SMEs. There are still lots of unknown with respect to the implementation of the MDR and we look forward to continuing our exchanges with the Commission for a smooth implementation in the contact lens sector*."

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EUROMCONTACT is the voice of European contact lens and lens care industry to the European Institutions, media, stakeholders and the public. EUROMCONTACT is the European Federation of National Associations and International Companies of Contact Lens and Lens Care Manufacturers. EUROMCONTACT members include National Associations of Manufacturers, representing Netherlands, Germany, Italy, Spain, Switzerland and the United Kingdom; the global companies Alcon, AMO Ltd., Bausch & Lomb, CooperVision, Johnson & Johnson Vision Care, Mark'ennovy, Menicon and the European Federation for the Contact Lens Industry EFCLIN.

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