



**DENTAL STAKEHOLDER CONFERENCE  
23 FEBRUARY 2017  
MEETING MINUTES**

**1. Opening address by D. Deschietere and F. Wijckmans**

D. Deschietere opened the meeting by welcoming all participating associations and Mr. Kohler and Piscoi from the European Commission.

F. Wijckmans shortly introduced contrast and the practice areas in which contrast is providing legal advice.

**2. Introduction of the organisations (ADDE, CED, FEPPD, FIDE)**

D. Deschietere (president ADDE) explained the working of ADDE and its members, the ADDE business plan, the ADDE mission statement and key policy topics.

M. Landi (president CED) informed about the working of CED, its members and working groups and referred to CED's policy statements, publications and most important policy issues.

P. Zammit (Secretary-General) explained the working of FEPPD, the interests of its members and informed about the most important policy issues for dental technicians.

A. Gamberini (president FIDE) discussed the working of FIDE and its members, the FIDE activities and main issues of the dental industry.

The slides used by ADDE, CED and FIDE are part of the slide presentation attached.

**3. Implications of the new MDR for the dental sector + debate on the implications of the MDR for the dental sector**

P. Piscoi (EU Commission, Legal Officer) gave a short presentation on the state-of-play and next steps of the new EU medical Device Regulation (see slide presentation attached).

M. Kohler provided more detailed information on the implementation of the MDR and practicalities. He referred to a couple of novelties of the MDR:

- Direct applicability of the MDR: There is no need to transpose the MDR into national legislation, as the MDR will be directly applicable within all member states.
- Parallel trade: M. Kohler referred to a recent case of the European Court of Justice (ECJ) on parallel trade of in-vitro medical devices. The ECJ ruled that parallel traders are not required to conduct an assessment of the conformity of alterations when they translated the labelling

of an in-vitro medical device into the official language of the member state into which the device is imported. The device was already bearing a CE mark and had been subject to a conformity assessment when being placed on the market by the manufacturer.

- Clarification procedure: M. Kohler referred to the possibility for national competent authorities and the Commission to clarify classification issues of medical devices.

Next a debate between the representatives of the different associations and the Commission officials started on the definition of manufacturer in the context of 3D printing.

P. Piscoi informed the participating associations that there would be a call for stakeholders becoming part of the medical device coordination group after the official publication of the MDR. He invited the participating organisation to join this coordination group as one common group.

#### Possible follow-up?

The participating associations confirmed that they would report back to their respective boards to see if there was interest in the creation of a joint platform of the dental sector with regard to the MDR. It was clearly emphasized during the meeting that such joint platform would focus on information sharing and would not entail any decision-making.

#### **4. Debate on import of dental products into the EU, market surveillance activities and free movement of dental professionals and import of dental products**

F. Wijckmans chaired the debate on import of dental products, market surveillance and free movement of dental professionals.

The participating associations discussed the activities of the MHRA (UK Medicines and Healthcare products Regulatory Agency) and its advertising campaigns as an example of possible action that could be taken against counterfeited products.

#### Possible follow-up?

ADDE, FEPPD and FIDE concluded that a collective initiative by the three associations on parallel trade and market surveillance should be further explored.

#### **5. Closing remarks**

D. Deschietere closed the meeting and thanked all participants for their presence. He invited the different organisations to keep contact and to explore possible common initiatives of the dental sector as a whole.