EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Directorate D – Consumer, Environmental and Health Technologies
Unit D4. – Health Technology and Cosmetics

Brussels, 20 November 2018

Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 11 October 2018

1) Opening, adoption of the agenda

This was an extraordinary session of the MDCG, with the purpose of discussing the pending corrigendum to MDR/IVDR.

2) Corrigendum to MDR/IVDR

The scope of the corrigendum under preparation by the Council and the process for its adoption was outlined and discussed.

The basis for a technical discussion was a document circulated by the Commission ahead of the meeting, presenting a set of possible revisions to the text of the two Regulations, aimed at correcting identified mistakes or inconsistencies of the text.

The proposed changes – with only a few technical adjustments - were generally agreed by consensus with only a reservation at this stage of the Danish delegation for changes related to alignment of UDI registration and alignment of grace-period for certain Class I devices. Agreement was also reached on two previous points arising from previous meetings, notably on Annex IX, point 3 of MDR and Annex IX, points 2.3, 3 (title) and 3.5 of IVDR.

For two additional proposed changes discussed in the meeting – notably 1) correction of alleged inconsistencies in the provisions containing procedures for substantial modifications of clinical investigations in both Regulations 2) possible alignment of the Annex VII section 4.5.3 of the IVDR the MDCG requested additional time for review. COM agreed to organise a written consultation on those two points following the meeting.

A summary of all points agreed as a result of the discussion undertaken as from the 17 July meeting, will be sent to the MDCG in the view of its 30 November meeting.

3) AOB

a) Annex XVI products (next steps)

The draft text of an Implementing Act for Annex XVI products and the Q&A documents were sent to Member States on 25 September. Following the request of some delegations, the Commission decided to run a new round of consultation before proceeding with an informal consultation of stakeholders before the end of the year. Member States are requested to provide feedback by Monday, 22 October. Proposal will be collected and discussed in an operational meeting. Unfortunately, due to shortage of room availability, only a half-day meeting on Thursday 29 November can be confirmed so far. The

Commission will try to get availability also for the morning the same day and a formal invitation will be sent in due course. In order to ensure that sufficient time will be dedicated to the discussion, a teleconference will be organised before 29 November.

b) MDCG working groups – call to stakeholders (state of play)

The call will be published in the next days and stakeholders will have four weeks to apply.

c) Selection of nomenclature (state of play)

The Commission indicated that the inputs provided by the interested providers are currently being examined by the task-force and a report is also being drafted. Based on the report, a discussion is expected to take place on this point at the MDCG meeting on 30 November, in the view of possible MDCG views.

List of participants

No	MDCG Member/ Observer	Institution/Organisation
1.	AT	Federal Ministry of Health and Women's Affairs
2.	BE	Federal Agency for Medicines and Health Products (AFMPS)
3.	HR	Agency for Medicinal Products and Medical Devices (HALMED)
4.	CZ	Ministry of Health
5.	DK	Danish Medicines Agency
6.	EE	Estonian Health Board
7.	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
8.	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
9.	IE	Health Products Regulatory Authority (HPRA)
10	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
11	LT	State Healthcare Accreditation Agency
12	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
13	NO	Ministry of Health and Care Services
14	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
15	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
16	SI	Agency for Medicinal Products and Medical Device (JAZMP)
17	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
18	SE	Medical Products Agency (MPA)
19	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission: DG GROW D4