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|  | EUROPEAN COMMISSION  Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  Consumer, Environmental and Health Technologies  **Health Technology and Cosmetics** |

Brussels,

GROW/D4/OT/PP

28/03/2019

Note to the File

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| Subject: | Borderline and Classification Working Group Teleconference | |
|  | Open session – 28 March 2019 10:00-11:00 | |
| *Participants:* | *BE, DE, AT, GR, HR, CY, DK, FI, NO, LV, IT, FR, SE, SI, PT, ES, UK, PL* |
|  | *NB-MED, TEAM NB, APPLIA, BioMed Alliance, AESGP, COCIR, ECOO, EUCOPE, EUROM VI, FIDE, MedPharmPlast* |
|  | *DG GROW D4: PP, OT; DG SANTE: B5, F; EMA* |

1. **Agenda and adoption of minutes of the open session on 06/12/2018.**

The minutes of the open session of the meeting on 06/12/2018 were approved. The agenda was approved.

1. **Transition to MDCG Working Group status, welcome to new stakeholder participants**

The Chair explained that the BCWG is now a Working Group under the MDCG. The MDCG, or the Medical Device Coordination Group, is the high-level group of Competent Authority representatives in charge of the medical devices sector, chaired by the Commission. The Terms of Reference of the BCWG can be found on the [Commission website](http://ec.europa.eu/growth/sectors/medical-devices/new-regulations/dialogue-interested-parties_en). Following a call for interest earlier this year, new stakeholder observers joined the group and the Chair welcomed them to the teleconference.

The Chair reiterated the following rules for stakeholders, which are essential to ensure adequate management of the teleconferences: not more than one connection per stakeholder association is permitted, and stakeholders should include the name of the association they represent when they connect. Stakeholders not respecting these rules will be disconnected from the teleconference.

1. **Progress of task forces**

Two task forces are currently in place at the BCWG. One is working on a new guidance document on the basis of MEDDEV 2.1/3 rev 3 (mainly borderline with medicines). This task force consists of three streams: main text, definitions, herbal products. The second task force is working on classification guidance on the basis of MEDDEV 2.4/1 rev 9.

1. **MEDDEV 2.1/3 rev 3**

The stream leaders gave short updates on the status of each stream:

* **Main**: a first draft document has been circulated among the regulators in which some new elements from the Regulation have been reflected. Further discussion among regulators is to take place. Structure and coverage of matters such as tissues and cells and ancillary human blood products, and substance-based devices are being discussed. EUROM VI stressed the need for clear examples. AESGP insisted on the need to coordinate between the different streams to ensure a consistent approach.
* **Definitions**: COM informed the group that it has received the EMA opinion on the draft texts and will forward it to the regulators in the stream shortly. A workshop, ideally a face-to-face one-day meeting but possibly a teleconference, may be organised with MS and stakeholders to discuss example products under these definitions.
* **Herbal products**: PT informed the group that following public consultation comments are being processed and further feedback on this topic will be provided in the next weeks. AESGP and EUROM VI insisted on a common approach for this topic and the general qualification guidance. PT and UK noted that it is intended to have the same approach and to highlight that herbal substances may in some cases have ancillary medicinal action. The text will be revised to improve clarity.

1. **ToR MEDDEV 2.4/1 rev. 9**

DE informed the group that intense drafting and discussion is ongoing with the last teleconference on 20 March. A consolidated draft may be ready by the end of April/beginning of May. Special attention is being given to Rules 11, 14, 19 and 21 and examples used throughout the document.

APPLIA enquired whether classification of Annex XVI products is being explicitly considered. COM clarified that the same classification rules under MDR will apply to those products but the discussion is premature as common specifications for those products are still in preparation.

AESGP raised the possibility of a workshop with stakeholders also for this guidance document. This will be considered by the regulators.

**For all streams:**

New stakeholder associations were invited to express interest in joining one or more of the above streams. Should they wish to do so, they were requested to send names of contacts to COM at [GROW-D4-BCWG@ec.europa.eu](mailto:GROW-D4-BCWG@ec.europa.eu) by **12 April 2019**.

1. **Non-viable human tissues and cells**

This complex topic has been previously discussed at several meetings and teleconferences. A preliminary document aiming to capture questions on this matter was presented. COM underlined that the document is intended for internal discussion in the group and not for application in practice, and that the current views expressed are strictly tentative and pending internal consultation. A 1-month period (until **30 April 2019**) was agreed for submission of written comments on the document to [GROW-D4-BCWG@ec.europa.eu](mailto:GROW-D4-BCWG@ec.europa.eu).

1. **AOB**

The next coordination teleconference will take place in June 2019.

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