

## Comments of the Commission on a request for information from the European Ombudsman

- Complaint by M [REDACTED], ref. 2132/2022/OAM

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### I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

The complaint in question was put forward by M [REDACTED], a [REDACTED]  
[REDACTED]  
[REDACTED]. Since September 2022, M [REDACTED] has repeatedly contacted the Commission with regards to the publication of meeting documents of the Commission's Medical Device Coordination Group (MDCG) and its subgroups.

### II. THE COMPLAINT

The complaint relates to the alleged Commission's breach of MDCG Rules of Procedures, specifically point 15(3) under which the secretariat (in accordance with Article 26 of Commission Decision C(2016)3301) shall make available all relevant documents, including the agendas, the minutes and the participant's submissions, either on the Register of expert groups or via a link from the Register to a dedicated website, where this information can be found. The complainant argues that although the agenda and minutes are published by the secretariat, the Commission fails to publish any further relevant documents of the group's meetings, such as draft versions of guidance documents that are still under discussion in the MDCG or one of its subgroups.

### III. THE COMMISSION'S COMMENTS TO THE COMPLAINANT'S ARGUMENTS

#### MDCG governance

The MDCG is registered in the Register of Commission expert groups and other similar entities<sup>1</sup> ('the Register of expert groups') as a consultative body to the Commission<sup>2</sup>, which was established by the Union legislator through Article 103(1) of Regulation (EU) 2017/745<sup>3</sup> (MDR).

The MDCG has the mission to provide advice to the Commission and assist the Commission and the Member States in ensuring a harmonised implementation of medical devices Regulations (EU) 2017/745 (MDR) and 2017/746<sup>4</sup> (IVDR), including through its contributions to the development of guidance documents and standards<sup>5</sup>. The MDCG thereby plays an essential role in ensuring a coherent implementation of the medical devices Regulations. It consists of officially nominated representatives of national

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<sup>1</sup> [Register of Commission expert groups and other similar entities \(europa.eu\)](https://european-council.europa.eu/media/en/press-communications/infographic/infographic-register-expert-groups-and-other-similar-entities-2017-2022.pdf).

<sup>2</sup> An 'other similar entity' in the sense of Article 2(2) of Commission Decision C(2016)3301.

<sup>3</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1.

<sup>4</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176.

<sup>5</sup> MDR Article 105 sets out the tasks of the MDCG

competent authorities, responsible for the implementation of the relevant legislative framework.

Since its establishment in 2017, MDCG has established 13 (thirteen) technical subgroups in line with the Commission Decision for Expert Groups<sup>6</sup>. Subgroups are responsible for facilitating the implementation of the legislation in specific areas such as vigilance, clinical evaluations and investigations, market surveillance, new technologies etc. The involvement of stakeholders and transparency is a vital element of the MDCG governance and working methods. Stakeholders' associations who have expressed interest through dedicated calls of expression of interest (also published on the Register of expert groups) have been nominated in the past years as observers in the MDCG and 11 of the 13 subgroups. All organisations appointed as observers and participating in the MDCG and its subgroups are registered in the Commission Transparency Register and have fulfilled a list of selection criteria (e.g. ability to represent the relevant stakeholder's interests at the European level). Stakeholder associations appointed as observers are invited to technical discussions in subgroups and to MDCG plenary meetings where they have the opportunity to exchange their views and present their positions both to MDCG members and the Commission.

## **On the publication of documents concerning the work of the MDCG**

- **MDCG documents proactively published**

**Agendas and minutes** are prepared ahead of and after MDCG plenary meetings and meetings of all 13 MDCG subgroups; they are regularly published ahead of and after the respective meetings on the Registry of the Commission expert groups<sup>7</sup>. The minutes are published once the meetings have been concluded and participants have been consulted.

**Meeting documents that are endorsed by the MDCG** are the main output of the MDCG's work. Since its establishment, the MDCG has produced and published over 100 documents in the form of guidance documents, Q&A documents, templates, instructions, notices, position papers, frequently asked questions documents, application forms or explanatory notes to support the harmonised implementation of the two Regulations. The Commission regularly publishes the final documents following official MDCG endorsement and provides a link to endorsed documents on the Commission's dedicated website<sup>8</sup> and on the Register<sup>9</sup>.

As relevant group of national experts, the MDCG is also consulted with regard to **draft delegated acts** developed in accordance with the MDR or IVDR<sup>10</sup>. Unless duly justified on grounds of urgency, the draft delegated acts are usually subject to a 4 week public consultation period via the Have Your Say webpages<sup>11</sup> and are therefore in the public domain before they are formally submitted to MDCG for consultation and adopted by the

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<sup>6</sup> [Register of Commission Documents - C\(2016\)3301 \(europa.eu\)](#)

<sup>7</sup> [Register of Commission Documents - C\(2016\)3301 \(europa.eu\)](#)

<sup>8</sup> [Guidance - MDCG endorsed documents and other guidance \(europa.eu\)](#)

<sup>9</sup> [Register of Commission Expert Groups and Other Similar Entities – MDCG](#)

<sup>10</sup> See Common Understanding on Delegated Acts, Annex to the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1).

<sup>11</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives?frontEndType=DEL\\_ACT](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives?frontEndType=DEL_ACT)

Commission followed by their publication on the interinstitutional register of delegated acts<sup>12</sup>.

- **MDCG documents not proactively published**

**Preliminary/draft versions of documents prior to their endorsement by the MDCG.**

These are documents drawn up by the members of MDCG group or its sub-groups for internal discussions of the MDCG and with the Commission services, which relate to a matter where endorsement has not yet taken place by the MDCG and which, if disclosed, could create confusion, prolong decision making or otherwise undermine the decision-making process relating to the outputs of the MDCG. As pointed out in previous correspondence with the Ombudsman<sup>13</sup>, exceptions to publication are possible only where it is deemed that disclosure of a document would undermine the protection of any public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001.

We note that in accordance with case T-93/11<sup>14</sup> documents exchanged within the framework of an advisory committee (including with working groups and organisations invited as experts) do not become public documents in accordance with the rules of Regulation (EC) No 1049/2001, but they may still be subject to the relevant exceptions to public access if applicable.

Such documents, in this case documents which have not been formally endorsed by the MDCG and have not yet gone through the appropriate consultation processes, contain preliminary views, which are often subject to amendments after the consultation process. Disclosure of those versions at a premature stage could indeed undermine the protection of the decision-making process, as it would reveal preliminary views and policy options, which are at a given stage under consideration. The participants in those expert groups (including Commission services and experts) should be encouraged to engage in constructive discussions and be free to explore all possible options in preparation of the group's output (such as opinions/recommendations/reports) free from external pressure.

In addition, the work carried out by expert groups is a collective one, which very often leads to conclusions being reached by consensus, in a spirit of mutual trust. Experts should be able to contribute freely to the work of expert groups and to express their views in a flexible way, in light of the specific circumstances.

This interest would be significantly compromised should all versions of preliminary drafts be made accessible to the public by default and without ad hoc assessment and this would ultimately be detrimental to the decision-making process of this expert group.

**Meeting documents that are not intended to be endorsed by the MDCG**, such as PowerPoints, background information or other working documents on individual agenda points prepared by the Commission services, MDCG members or observers are currently not published on the Commission's expert group Register website. These documents as well as any documents used in MDCG meetings are circulated to the nominated participants (if applicable also to observers) of the MDCG and its subgroups through the dedicated system CIRCABC. It is acknowledged that these documents should also be made available on the Register in accordance with Art 26(2) of Commission Decision

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<sup>12</sup> [Delegated acts - Register of delegated acts \(europa.eu\)](#)

<sup>13</sup> See for example the Commission's reply to the European Ombudsman's recommendation in her strategic inquiry OI/6/2014/NF concerning the composition of Commission expert groups

<sup>14</sup> Case T-93/11 *Stichting Corporate Europe Observatory v Commission* [2013] ECLI:EU:T:2013:308

C(2016) 3301 (horizontal rules of expert groups), provided that the publication of those documents would not undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001.

Background notes are sometimes distributed to meeting participants prior to the meeting to allow for better preparation of the meetings. It should be noted that some of these background notes include parts of draft versions of MDCG documents that require MDCG endorsement or documents supporting discussions thereof, all of which relate to a matter for which the MDCG has not yet made a decision and which, if disclosed, could seriously undermine the decision-making process of the MDCG.

#### **On the Commission's revision of its current practices concerning MDCG**

As outlined by the European Commission in its email exchanges with M [REDACTED], some of the above practices, which concern specifically MDCG, are currently being revisited.

Pursuant to Article 26(2) of the horizontal rules on expert groups, the European Commission will be making available, if necessary in a redacted format, PowerPoints and other background information used to inform the discussions of the MDCG plenary meetings and meetings of its 13 subgroups, unless their disclosure would undermine the protection of any public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001 or the documents include parts of draft versions of MDCG documents that require MDCG endorsement or documents supporting discussions thereof.

Further, as outlined in Article 4(4) of Regulation (EC) No 1049/2001, for the publication of third-party documents, the European Commission will consult the third parties involved with a view to assessing whether publication of the document would undermine the protection of a public or private interest (Article 4(1) and Article 4(2) of Regulation (EC) No 1049/2001). Lastly, the Commission notes that a Member State may request the Commission not to disclose a document originating from that Member State without its prior agreement (Article 4(5) of Regulation (EC) No 1049/2001).

#### **IV. Conclusions**

The European Commission ensures very extensive stakeholder involvement in the work of the MDCG and proactively publishes the agendas and minutes of all MDCG and subgroups meetings for the sake of transparency of the expert group, as laid out in its Rules and Procedures.

The Commission also provides full and easy access to the many documents formally endorsed by the MDCG, but does not proactively publish those documents that are still under discussion within the group.

The Commission commits to also provide in the future access or - where relevant - partial access to presentations and other background information related to the work of the MDCG, unless this would undermine the protection of a public or private interest protected under Article 4 of Regulation (EC) No 1049/2001 or, in the case of a document originating from a Member State, the Member State concerned has requested the Commission not to disclose the document.

*For the Commission*

*Stella KYRIAKIDES*

*Member of the Commission*

