

TERMS OF REFERENCE OF THE MEDICAL DEVICE COORDINATION GROUP

Background

Article 103(1) of Regulation (EU) 2017/745¹ establishes the Medical Device Coordination Group (hereinafter the “MDCG”). In accordance with Article 103(9) of Regulation (EU) 2017/745 and Article 98 of Regulation (EU) 2017/746², the MDCG carries out, with the support of the Commission, the tasks conferred on it under both Regulations. Article 105 of Regulation (EU) 2017/745 and Article 99 of Regulation (EU) 2017/746 define general tasks of the MDCG. Further specific tasks and roles of the MDCG are laid down in various provisions of the Regulations.

In view of its organisational structure and tasks, as laid down in Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the MDCG is subject to the horizontal rules on the creation and operation of Commission expert groups (hereinafter the “horizontal rules”).³

1. Tasks and roles⁴

MDCG provides advice to the Commission and assists the Commission and the Member States in ensuring a harmonised implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. Tasks and roles of the MDCG are laid down in each respective Regulation, in particular Article 105 of Regulation (EU) 2017/745 and Article 99 of Regulation (EU) 2017/746.

2. Membership⁵

Members of the MDCG are experts representing the competent authorities of the Member States. Member States shall ensure that their representatives provide a high level of expertise.

Each Member State appoints one member to the MDCG and one alternate, each with expertise in the field of medical devices, and one member and one alternate, each with expertise in the field of *in vitro* diagnostic medical devices.

A Member State may choose to appoint only one member and one alternate, each with expertise in both fields.

A Member State may also choose to appoint two members (one with expertise in the field of medical devices, and another with expertise in the field of *in vitro* diagnostic medical

¹ 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).

² 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).

³ Commission Decision C(2016) 3301.

⁴ Recital 82 and Article 105 of Regulation (EU) 2017/745 and recital 83 and Article 99 of Regulation (EU) 2017/746.

⁵ Article 103(2) of Regulation (EU) 2017/745.

devices), but one alternate (with expertise in both fields).

Finally, a Member State may choose to appoint one member (with expertise in both fields), but two alternates (one with expertise in the field of medical devices, and another with expertise in the field of *in vitro* diagnostic medical devices).

The members and their alternates are appointed for a term of three years which may be renewed. They remain in office until they are replaced or their appointment is renewed. When the appointment of a member or an alternate has been terminated before the end of the three year term, the Member State appoints a replacement for the remainder of that three year term.

3. Chairing⁶

The MDCG is chaired by a representative of DG GROW. The chair does not take part in votes of the MDCG.

The MDCG may decide to set up a coordination group to assist the Commission in activities related to management of the MDCG.

4. Working groups⁷

The MDCG may create permanent or *ad-hoc* sub-groups (hereinafter, working groups) to discuss specific topics, on the basis of terms of reference defined by the MDCG for each working group. *Ad hoc* working groups shall be dissolved as soon as their mandate is fulfilled.

Members to the working groups are appointed by Member States. Member States may appoint alternate members to the working groups, in accordance with the terms of reference of the working group.

In order to ensure timely and efficient exercise of its competences laid down in Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the MDCG may delegate certain tasks to a working group, in accordance with the terms of reference of the working group. MDCG can withdraw the delegation anytime.

The working groups are chaired by a representative of the Commission. Where appropriate, the working groups may be co-chaired by a member of the working group.

When necessary, Chairs or co-Chairs of the working groups that are not members of the MDCG may be invited to attend the MDCG meetings.

The working groups report to the MDCG.

5. Third countries, experts and other third parties⁸

Iceland, Liechtenstein, Norway, Switzerland and Turkey attend meetings of the MDCG and its working groups in the capacity of observers. In agreement with the Commission services, an observer status may be granted to candidate countries and to other non-EU countries where

⁶ Article 103(5) of Regulation (EU) 2017/745.

⁷ Article 103(2) of Regulation (EU) 2017/745.

⁸ Article 103(6) of Regulation (EU) 2017/745.

it is in the interest of the EU that such country is involved in the works of the MDCG, in particular based on an international agreement, an administrative arrangement or EU legislation. For that purpose, they may appoint observers and alternate observers.

Observer countries shall have the right to participate in the meetings of the MDCG and its working groups, take part in the discussions and provide expertise, however, they shall not have voting rights and they shall not participate in the formulation of positions of the MDCG or, as appropriate, a working group.

The Chair of the MDCG or, as appropriate, of a working group, acting on request of the MDCG or, as appropriate, of a working group, may invite, on a case-by-case basis, experts and other third parties with a specific competence in a subject on the agenda to participate in the meetings or their parts or to provide written contributions. The Chair of a working group shall inform the MDCG about any such invited experts or other third parties, indicating the meeting and the reason for the invitation to that meeting.

6. Stakeholders⁹

Organisations representing the interests of the medical device industry, other economic operators, healthcare professionals, conformity assessment bodies, hospitals, laboratories, patients and consumers at Union level (hereinafter, the stakeholders) may be given an observer status in the MDCG and/or a working group either by a direct invitation by the Chair, or following a call for applications, as appropriate.

Following an invitation from the Chair of the MDCG, stakeholders with an observer status may be invited to attend an open information session of the MDCG or a part thereof.

Stakeholders attending sessions of the MDCG or its working groups may be permitted by the Chair to take part in the discussions and provide expertise, however they shall not have voting rights and they shall not participate in the formulation of positions of the MDCG or, as appropriate, a working group.

The Chair of the MDCG, or, as appropriate, the Chair of a working group, acting on his own initiative or on a proposal of a member, may invite, on a case-by-case basis, a stakeholder without the observer status to attend an open session of the MDCG or the working group or parts thereof, or to provide a written contribution.

7. Operation

The MDCG and its working groups meet either in physical meetings or for audio or videoconferences. Physical meetings of the MDCG and its working groups are, in principle, organised on the Commission's premises. The frequency and type of the meeting is decided based on needs, as appropriate.

As far as possible, and unless otherwise specified in these Terms of Reference or the Rules of Procedure, the MDCG or its working groups act by consensus. In the event of a vote, the outcome of the vote is decided by simple majority of all appointed members. The members that have voted against or abstained have the right to have their position and the grounds on which it is based recorded in the overall position.

⁹ Article 103(7) of Regulation (EU) 2017/745.

In agreement with the Chair, the MDCG or any of its working groups may, by simple majority of all appointed members, decide that a meeting or its part shall be public.

Minutes on the discussion on each point on the agenda and on the positions delivered by the MDCG or a working group shall be meaningful and complete. Minutes are drafted by the secretariat under the responsibility of the Chair of the MDCG, or, as appropriate, the Chair of the working group.

The Commission services provide technical, scientific and logistic support for the MDCG and any of its working groups.

The MDCG and its working groups shall act in compliance with the horizontal rules.¹⁰

8. Conflicts of interest¹¹

Members of the MDCG and the working groups, and their alternates may not have financial or other interests in the medical device industry, whether direct or indirect, which could affect their impartiality. They shall act in the public interest and in an independent manner. For this purpose, the members and their alternates must make a declaration of interests in accordance with the Rules of Procedure. Such declaration of interests shall be also made by the representatives of non-EU countries referred to in point 5.

Prior to a meeting or when providing a written contribution, experts and other third parties referred to in point 5 must declare any interests they may have in the issue in question, in accordance with the Rules of Procedure.

9. Rules of Procedure¹²

The MDCG adopts its Rules of Procedure on the basis of the standard rules of procedure for expert groups, in compliance with the horizontal rules.¹³

The Rules of Procedure may, in particular, lay down procedures for the following:

- the adoption of opinions or recommendations or other positions, including in cases of urgency;
- the implementation of Article 107 of Regulation (EU) 2017/745 regarding conflict of interests;
- the functioning of working groups.

The MDCG may review the Rules of Procedure as necessary. In any case, the MDCG will assess the need to revise the Rules by 2 years from the day of their adoption.

10. Professional secrecy and handling of classified information

The members, their alternates, representatives of non-EU countries, experts and other third parties referred to in point 5 participating in the works of the MDCG and its subgroups are subject to the obligation of professional secrecy, which by virtue of the Treaties and the rules

¹⁰ Article 13(1) of Commission Decision C(2016) 3301.

¹¹ Article 107 of Regulation (EU) 2017/745.

¹² Article 103(8) of Regulation (EU) 2017/745.

¹³ Article 17 of Commission Decision C(2016) 3301.

implementing them applies to all members of the institutions and their staff, as well as to the Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443¹⁴ and 2015/444¹⁵. If they fail to respect these obligations, the Commission services may take all appropriate measures.

11. Transparency

The MDCG and its working groups are registered on the Register of expert groups.

The following data on the composition of the MDCG and its working groups are published on the Register:

- a) the names of the members and their alternates, and their affiliation;
- b) the declarations of interests of the members and their alternates;
- c) the names of observers and any appointed alternate observers referred to in point 5 first paragraph, and their affiliation;
- d) the declarations of interests of observers and any appointed alternate observers referred to in point 5 first paragraph;
- e) the names of observers referred to in point 6.

The secretariat makes available all relevant documents, including the agendas, the minutes and the participants' 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. Access to dedicated websites is not subject to user registration or any other restriction.

In particular, the secretariat publishes the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication can be made only where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001¹⁶.

12. Travel and subsistence expenses

Members and observers to the MDCG and its working groups are not remunerated for the services they provide.

Travel expenses incurred by members or their alternates are reimbursed in accordance with the provisions in force in the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources. The reimbursement of travel expenses is limited to one person per Member State.

¹⁴ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

¹⁵ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

¹⁶ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43). These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.