EUROPEAN COMMISSION

RULES OF PROCEDURE OF THE EUROPEAN COMMISSION EXPERT PANELS ON MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC DEVICES (EXPAMED)

Expamed document D 3.2

March 2022 (draft Version 4)

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1. INTRODUCTION AND BACKGROUND

1. The new Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices ("MDR") and on *in vitro* diagnostic medical devices ("IVDR"), respectively, require the designation of expert panels. MDR Article 106(1) outlines that panels must be designated for the assessment of clinical evaluation of medical devices in relevant medical fields in relation to MDR Article 54 and for the assessment of performance evaluation of *in vitro* diagnostic medical devices in relation to IVDR Article 48. Both articles refer to expert consultation procedures in the context of conformity assessment by notified bodies concerning specific high-risk medical devices fulfilling specific criteria stipulated in MDR including novelty and resulting clinical/health impact (clinical evaluation consultation procedure, CECP – see also Article 106(9)) and specific novel class D *in vitro* diagnostic medical devices (performance evaluation consultation procedure, PECP).

2. The expert panel advice furnished in the context of these two consultation procedures also constitutes, where applicable, one information source of the 'mechanism for scrutiny' as outlined in MDR Article 55 and IVDR Article 50, aimed at ensuring close monitoring of these specific high-risk medical devices and class D *in vitro* diagnostic devices. According to this mechanism, Member State competent authorities and, where applicable, the Commission, may request scientific advice in relation to any device falling under said mechanism in case there are reasonable concerns.

3. MDR Article 106(2) stipulates that expert panels may be designated in areas where the Commission, in consultation with the MDCG[1], has identified a need for the provision of consistent scientific, technical and/or clinical advice in relation to the implementation of the MDR. MDR Article 106(10) and 11 stipulate possible tasks of expert panels in addition to those described in Article 106(9) (see paragraph 1 above). Tasks include (a) contribution to common specifications, guidance, standards; (b) advice under Article 61(2) to manufacturers concerning intended clinical development strategies and proposals for clinical investigation; (c) advice to Member States, notified bodies and manufacturers on, inter alia, criteria of conformity assessment.

4. The Commission Implementing Decision (EC) 2019/1396 of 10 September 2019 (hereinafter the "Decision") lays down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices.

5. In accordance with Article 1(1) of the Decision, expert panels were designated in the following areas ("thematic expert panels") to fulfil the tasks referred to in paragraphs 9 and 10 of MDR Article 106:

   (1) Orthopaedics, traumatology, rehabilitation, rheumatology

   (2) Circulatory system

   (3) Neurology

[1] MDCG is the 'Medical Devices Coordination Group' (see MDR Article 103 and 105). The MDCG is composed of representatives of Member States and the Commission.

(4) Respiratory system, anaesthesiology, intensive care
(5) Endocrinology and diabetes
(6) General and plastic surgery; dentistry
(7) Obstetrics and gynaecology, including reproductive medicine
(8) Gastroenterology and hepatology
(9) Nephrology and urology
(10) Ophthalmology
(11) *In-vitro* diagnostic medical devices (IVD)

An additional expert panel was designated under Article 1(2) of the Decision to be in charge of the decision referred to in point (c) of Section 5.1. of MDR Annex IX to Regulation (EU) 2017/745 (hereinafter the "Screening Panel").

6. In accordance with Article 2(1) of the Decision, the Commission appoints advisors to these expert panels following a call for expression of interest and consultation with the MDCG, based on eligibility and selection criteria stipulated in the call (hereinafter the "advisors").

7. In accordance with Article 2(3) of the Decision, the Commission, following consultation with the MDCG, includes advisors who satisfy the criteria stipulated in the call but who were not appointed to an expert panel in a central list of available advisors (hereinafter the "central list").

8. In accordance with Article 2(5) of the Decision, due to the workload of a certain expert panel or the need to provide the required expertise to a certain expert panel, additional advisors may be appointed to that expert panel from the central list.

9. In accordance with Article 2(6) of the Decision, due to the workload of a certain expert panel or the need to provide the required expertise to a certain expert panel, advisors on the central list or in another expert panel may be assigned to that expert panel for specific tasks and for a limited period of time.

10. Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices assigns the European Medicines Agency to provide the secretariat of the expert panels and to provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in MDR Article 106(9) and (10).

2. OBJECTIVE AND SCOPE OF THIS DOCUMENT

In accordance with Article 9(1) of the Decision, rules of procedure are adopted by the Coordination Committee (hereinafter the "Committee") on proposal by and in agreement with the Commission. In accordance with Article 9(2) of the Decision, the rules of procedure for the expert panels provide for, inter alia:

a) procedures for carrying out the tasks of the expert panels;
b) rules ensuring the application of the principles laid down in Articles 12 to 15 of

the Decision: expertise, independence, impartiality and objectivity, commitment, confidentiality and transparency.

3. PRINCIPLES

The expert panels must perform their tasks in compliance with the principles of

- **Expertise**: advisors need to have up-to-date clinical, scientific or technical expertise – MDR Article 106(3); and
- **Independence, impartiality and objectivity**: advisors must not have interests which could affect their impartiality (MDR Article 107) and must act objectively, i.e. solely on the basis of scientific, clinical or technical considerations; and
- **Commitment**: advisors need to commit to all principles and commit to provide their advice to the best of their ability; and
- **Confidentiality**: advisors must not divulge any information of confidential nature acquired as part of their work in the expert panels and, in particular, not divulge any commercially confidential information and trade secrets.

3.1 Expertise

Expert panels consist of advisors appointed on the basis of their up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission seeks to achieve gender balance when selecting and appointing advisors.

3.2 Independence, impartiality and objectivity

1. Advisors are appointed or assigned in their personal capacity. They must not delegate their responsibilities to any other person.

2. Advisors must not have financial or other interests in the medical device industry or in a notified body or any other organisation or sector, which could affect their independence, impartiality and objectivity. They must make a declaration of interests indicating any interest, which may compromise or may reasonably be perceived to compromise their independence, impartiality and objectivity, including any relevant circumstances relating to their close family members.

3. Declarations of interests are submitted in writing and by using the appropriate declaration of interest (DOI) electronic form in accordance with the instructions for filling out the form provided by the Secretariat. The DOIs will enable the Secretariat to apply the *'European Commission policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices'*.

4. To this end, advisors must ensure that the Secretariat has up-to-date versions of their DOIs at any point in time during their term. Advisors must update their DOIs following the instructions provided in the *'Procedural guidance on inclusion of declared interests in the European Commission's electronic declaration of interests form for the*

expert panels on medical devices and in vitro diagnostic medical devices':

a) prior to the appointment to an expert panel or prior to inclusion on the central list;

b) whenever a change of circumstances so requires;

c) prior to commencement of a specific task in the expert panel – however only in case circumstances have changed.

5. The Secretariat, in response to its obligation under MDR 106(3) third paragraph, will analyse the up-to-date DOIs of advisors of a panel or sub-group in relation to each scientific request. In case there are conflicts of interests of advisors in relation to a specific request and a specific role within a panel or sub-group, the Secretariat will inform the Chair about possible restrictions and exclusions from that particular role as outlined in the *'European Commission policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices'*. The policy is made available by the Secretariat to expert panel members.

6. In addition, advisors not excluded from participation in specific tasks by the Secretariat based on conflict of interests identified by the Secretariat, must signal any potential conflict of interest in relation to a specific task that was not or could not have been identified by the Secretariat for whatever reason. In such cases, advisors should inform as soon as possible both, the Secretariat and the Chair of the panel or, in case a panel is structured in sub-groups, the Chair of the sub-group.

7. Each time when forwarding a new request for advice to a panel / sub-group, the Secretariat will remind advisors not excluded from participation in specific tasks, to identify possible COIs that were not identified by the Secretariat (see 6). Absence of communications by experts is understood as *confirmation* that there are no COI in relation to the specific request for advice and, further, that the DOI furnished to the Secretariat are indeed up-to-date (see 4).

8. Advisors must act solely on the basis of scientific, clinical or technical considerations.

3.3 Confidentiality

1. Advisors must not divulge any information of confidential nature acquired as part of their work in the expert panels or as result of other activities governed by the Decision.

2. Advisors must sign a declaration of confidentiality. The Secretariat will publish the template of declaration of confidentiality on the Medical Devices - Expert Panels website (https://ec.europa.eu/health/md_expertpanels/overview_en). This will be accompanied by a statement that all advisors have signed the declaration.

3. Advisors must comply with the rules on security regarding the protection of the European Union classified information (EUCI) and sensitive non-classified information, laid down in Commission Decisions (EU, Euratom) 2015/444 and 2015/443 respectively.

4. Advisors must comply with the *'Handling instructions and security measures for the Commission Expert Panels on medical devices and in vitro diagnostic medical devices'* provided by the Secretariat with regard to sensitive non-classified information received from third parties, such as notified bodies, manufacturers and device developers and which may contain commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights.

3.4 Commitment

1. Advisors must act in the public interest and observe the principles outlined in Section 3.
2. Advisors must sign a declaration of commitment. The Secretariat will publish the template of declaration of commitment on the Medical Devices - Expert Panels website. This will be accompanied by a statement that all advisors have signed this declaration.
3. Advisors must respond to requests and other communications from the Secretariat or the Chair of their respective expert panel or sub-group without undue delay.

3.5 Transparency

1. The Commission must provide relevant information on the panels' operations and outcomes in agreement with transparency requirements and ensuring consideration of confidentiality in regard to personal data (MDR Article 110) and commercially confidential information and trade secrets (MDR Article 109).
2. As concerns the expert panel composition, the following information must be published on the Medical Devices - Expert Panels website:
   a) the name of advisors appointed or assigned to expert panels or included in the 'central list of available experts' (see MDR 106(6));
   b) the curriculum vitae (CV) and declarations of interests, confidentiality and commitment of advisors appointed or assigned to the expert panels (see also 3.2, 3.3 and 3.4);
   c) the rules of procedure of the expert panels;
   d) scientific opinions, views, advice and guidance in accordance with the second subparagraph of MDR Article 106 (12).
3. The Secretariat collects and processes personal data in compliance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies and agencies and on the free movement of such data[2].
4. Exceptions to publication are only foreseen where it is deemed that disclosure of these documents or parts thereof would undermine the protection of the public

[2] https://ec.europa.eu/dpo-register/detail/DPO-3084-2

interest, privacy and the integrity of the individual as defined in Article 4 of Regulation (EC) 1049/2001 and the MDR Article 109 on confidentiality.

3.6 Timelines

1. Advisors must dedicate the necessary effort in order to complete the assigned tasks to the best of their ability and within of the timelines outlined by the MDR and IVDR (see 6.1 and 6.2), as well as by the respective mandates in case of provision of the type of advice outlined under 6.3.

2. In particular:

   a) Decisions of the Screening Panel in response to a Clinical Evaluation Consultation Procedure (CECP) must be delivered within 21 calendar days from when the Screening Panel receives the documents from the Secretariat via the electronic platform for document exchange. In case there is no intention to provide a scientific opinion, the decision should be communicated as soon as possible (MDR Annex IX, Section 5.1. (d)) and in any event within the 21 days timeline. In case there is intention to provide a scientific opinion, the decision should be made as soon as feasible in order to provide the thematic expert panel with a maximum of time for developing the scientific opinion. In both cases, the decision must be delivered by upload of the completed decision template on the relevant space on the electronic platform for document exchange.

   b) Scientific opinions of a thematic expert panel in response to a Clinical Evaluation Consultation Procedure (CECP) must be delivered within 60 calendar days of receipt of the documents referred to in point (a), i.e. from the date when the Screening Panel received the documents from the Secretariat. Scientific opinions must be delivered by upload of the completed scientific opinion template on the relevant space on the electronic platform for document exchange.

   c) Views of the thematic expert panel on IVD in response to a Performance Evaluation Consultation Procedure (PECP) must be delivered within 60 calendar days from the date when the panel received the documents from the Secretariat. Views must be delivered by upload of the completed view template on the relevant space on the electronic platform for document exchange.

   d) In case, the above advice was not delivered within these timelines, advisors will not be reimbursed and the notified body can proceed with certification procedure of the device in question.

   e) Advice according to MDR Article 106(10), (11) and MDR Article 55(3) as well as IVDR Article 50(3) must be delivered within the timelines outlined in the mandate. Extensions of deadlines can be requested by the Chair or Vice-Chair. Such extensions can be granted by the Secretariat in duly justified cases.

4. ORGANISATION OF THE EXPERT PANELS

4.1 Coordination Committee

1. The Committee is composed of the Chairs and Vice-Chairs of all expert panels. Depending on need, Representatives of the medical fields of the Screening Panel will be invited to participate in the meetings of the Coordination Committee.
2. The Committee acts at the request of the Secretariat, operates in agreement with these rules of procedure and is chaired by the Secretariat.
3. The Committee must support the efficient and uniform operation of the expert panels by, *inter alia*:
   a) ensuring effective exchange of information between panels;
   b) adopting and reviewing the rules of procedure in agreement with Article 9(3) of the Decision;
   c) adopting and regularly reviewing the necessary internal guidance and methodologies to be used by the expert panels, to ensure that these consider the latest scientific developments and state-of-the-art practice;
4. The Committee should meet at least once a year, if possible physically. Only attendance of either the Chair or Vice-Chair of every panel is required. Equally, where Representatives of the Screening Panel are invited, attendance of either the Representative or Vice-Representative of a given medical field is required.

4.2 Screening Panel

1. The Screening Panel is composed of advisors allocated to specific medical fields. The fields correspond to those for which thematic expert panels have been designated (see 1.4 (1)-(10)).
2. Where necessary due to the workload, advisors on the central list or in another panel may be assigned to the Screening Panel for specific tasks.
3. The Screening Panel acts at the request and under the supervision of the Secretariat, as well as in accordance with the '*Commission guidance for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure (2020/C 259/02)*'.
4. Screening Panel members are in charge of deciding whether or not there is intention to provide a scientific opinion on the clinical evaluation assessment report (CEAR) of the notified body (MDR Annex IX Section 5.1. point (c) and point (d)).
5. The advisors of each of the medical fields of the Screening Panel (see 1 above) will elect one Representative and Vice-Representative for possible participation in the Coordination Committee meeting (see 5.1).
6. Furthermore, the elected Representatives/Vice Representatives will elect two advisors amongst themselves as Screening Panel Chair and Vice-Chair for participation in the Coordination Committee.

4.3 Thematic expert panels

1. Thematic expert panels are those listed under section 1.4. of these rules of procedure (panels 1-10 for specific medical fields relevant for medical devices and panel 11 panel for *in vitro* diagnostic medical devices).
2. Each expert panel is composed of advisors. Where it is necessary due to workload or a specific need for expertise, advisors from the central list or from another panel may be assigned to an expert panel for specific tasks.
3. Each thematic expert panel acts at the request of the Secretariat.
4. Thematic expert panels listed under section 1.5. (1-10) are in charge of the tasks specified in MDR Article 106 paragraphs (9), (10), (11), Article 54(1), Article 55(3) and Article 61(2).
5. The thematic expert panel listed under section 1.5. (11) - the IVD panel - is in charge of the task of IVDR Article 48(6), Article 50(3) as well as specific tasks listed under 106(10) where relevant for *in vitro* diagnostic medical devices.

4.4 Expert panel sub-groups

1. Following a proposal of and in agreement with the Secretariat, thematic expert panels can be structured into sub-groups on a permanent or ad hoc basis.
2. Sub-groups must operate in compliance with the present rules of procedure.
3. In case a thematic expert panel is structured in sub-groups, all scientific requests will be processed by the sub-groups of that panel. Each sub-group of an expert panel acts at the request of the Secretariat. Expert panel sub-groups are entrusted with specific tasks by the Secretariat and perform them autonomously.
4. Each sub-group elects a Chair and Vice-Chair (see point 5.3 on elections), unless a sub-group is chaired by the Chair or the Vice-Chair of the thematic expert panel (see 5.3.4.g).
5. The Chairs and Vice-Chairs of a sub-group regularly report their activities to the Chair / Vice-Chair of the thematic expert panel in order to support their contributions to the Coordination Committee.
6. Sub-groups of expert panels should not have any overlapping responsibilities with other sub-groups or their parent expert panel.

4.5 Secretariat

1. The European Medicines Agency on behalf of the Commission provides the Secretariat for the expert panels, for the Screening Panel and for the Coordination Committee.
2. The Secretariat coordinates the overall functioning of all panels and Coordination Committee and provides technical and administrative support. In particular, the Secretariat will:

   a) Identify, manage and prevent potential conflicts of interests;

b) supervise the consistent application of the criteria set out in point (c) of MDR Annex IX Section 5.1. by the Screening Panel in accordance with the *Commission guidance* (2020/C 259/02);

c) supervise the work of the expert panels, i.e. monitor compliance with these rules of procedure including adherence to timelines, relevant guidance, working instructions and use of templates;

d) publish scientific opinions and views delivered in accordance with MDR Article 106(9) and (11), ensuring consideration of aspects of confidentiality (second subparagraph of MDR Article 106 (12));

e) respond to requests from expert panels for additional expertise;

f) chair the Coordination Committee.

3. In emergency or other duly justified cases, the Secretariat may temporarily chair thematic expert panels or sub-groups. In such cases, members of the Secretariat have no decision-making rights.

5. ROLES AND RESPONSIBILITIES IN THE EXPERT PANELS

5.1 Elections of Screening Panel Representatives and Vice-Representatives and Screening Panel Chair and Vice-Chair

1. At the beginning of the term, each medical field of the Screening Panel elects a Representative and a Vice-Representative for possible participation in the Coordination Committee (see 4.1). The Screening Panel Representatives/Vice Representatives will, amongst themselves, elect two of the Representatives as Chair and Vice-Chair of the Screening Panel (see 8 below).

2. The Representative and Vice-Representative of a given medical field will, depending on need, participate in meetings of the Coordination Committee in order to support the Screening Panel Chair and the Chairs of thematic panels in regard to information exchange on scientific aspects of the screening step and to support dialogue, where needed, with the Chair and Vice-Chair of the corresponding thematic expert panel.

3. The Representatives and Vice-Representatives are elected by secret ballot and in writing by the members of each medical field.

4. The election procedure is organised by the Secretariat.

5. The procedure is as follows:

a) The Secretariat sends an e-mail to all advisors of each medical field of the Screening Panel asking them to express their interest to stand for election as Representative or Vice-Representative of the respective medical field of the Screening Panel.

b) The advisors willing to put forward their candidacy send an e-mail to the Secretariat outlining briefly their motivation, attaching their CV as well as an up-to-date DOI form, in case their interests have been changed since their last submitted DOI form. By submitting their candidature, advisors agree to represent the respective medical field in regard to the tasks of the Screening Panel at the

Coordination Committee.

c) The Secretariat assesses the up-to-date DOI forms of the candidates and makes a list of all the candidates, indicating the number of interests declared and whether these are direct or indirect.

d) The Secretariat sends this list to the advisors of respective medical field, providing also the following information:
   i) the motivation statement of each candidate
   ii) the up-to-date CV of each candidate using preferably the Europass format
   iii) the up-to-date DOI form of each candidate

e) Each advisor within a given medical field of the Screening Panel has one (1) vote. Advisors cannot vote for themselves. Abstentions from voting are generally strongly discouraged, unless in duly justified cases (e.g. sickness, candidates of run-off elections). Any vote not in agreement with above rule or cast after the deadline set by the Secretariat will not be considered.

f) The candidate receiving a simple majority of the votes of the advisors allocated to the respective medical field is elected as Representative. The candidate receiving the second highest number of votes is elected as Vice-Representative. In case of equal number of votes for a given position, a run-off election between the candidates with equal votes will be held. In case this does not resolve the situation, the Secretariat will seek an agreement by direct interaction with the candidates.

g) In case the advisors of a medical field do not succeed in electing a Representative or Vice-Representative due to lack of candidatures, the advisors of the respective medical field should determine, facilitated by the Secretariat and on an ad hoc basis, at least one advisor who will represent the medical field at a Coordination Committee meeting.

h) Candidates may withdraw their candidature at any time during the procedure.

6. In case a given medical field of the Screening Panel consists of less than three advisors, no elections will be held for the position of Representative and Vice-Representative. Instead, the Secretariat will seek an agreement concerning these positions by direct interaction with the advisors allocated to the respective medical field.

7. The names of the Representative and the Vice-Representative of each medical field of the Screening Panel will be made public.

8. The elections of the Chair and Vice-Chair of the Screening Panel will adhere to the following procedure:

a) The Secretariat sends an e-mail to all Representatives and Vice Representatives asking them to express their interest to stand for election as Chair or Vice-Chair of the Screening Panel.

b) The advisors willing to put forward their candidacy send an e-mail to the Secretariat. By submitting their candidature, advisors agree to participate in the

Coordination Committee meetings and to collaborate with the other Representatives of the Screening Panel.

c) The Secretariat sends a list of the candidates to the Representatives and Vice-Representatives.

d) Each Representative and Vice-Representative has one (1) vote. Advisors cannot vote for themselves. Abstentions from voting are generally strongly discouraged, unless in duly justified cases (e.g. sickness, candidates of run-off elections). Any vote not in agreement with above rules or cast after the deadline set by the Secretariat will not be considered.

e) The candidate receiving a simple majority of the votes is elected as Chair of the Screening Panel. The candidate receiving the second highest number of votes is elected as Vice-Chair. In case of equal number of votes for a given position, a run-off election between the candidates with equal votes will be held. In case this does not resolve the situation, the Secretariat will seek an agreement by direct interaction with the candidates.

5.2 Replacement of Screening Panel Representative and Vice-Representative and Screening Panel Chair and Vice-Chair

1. The term of office of both Representative and Vice-Representative is a maximum of three years, and in any case not exceeding the term of appointment (see 5.10). The term is renewable. Replacement of the Representative or Vice-Representative during the three-year term is for the remainder of that term and follows the procedure described in point 5.1.5.

2. The term of office of both Screening Panel Chair and Vice-Chair is a maximum of three years, and in any case not exceeding the term of appointment (see 5.10). The term is renewable. Replacement of the Screening Panel Chair or Vice-Chair during the three-year term is for the remainder of that term and follows the procedure described in point 5.1.8.

5.3 Election of Chair and Vice-Chair of thematic panels and sub-groups

1. At the beginning of the term, each thematic expert panel and sub-group elects a Chair and a Vice-Chair (for sub-groups, see however bullet 4.g. below). In case of ad hoc sub-groups, the Chair will be determined by simple majority of the experts assigned to the sub-group following the procedure under point 4. below, with the exception that no Vice-Chair will be elected and that no election will be held in case the thematic panel Chair or Vice-Chair happen to be assigned to the ad hoc sub-group and, in such cases, act as Chair of the ad hoc sub-group.

2. The Chairs and Vice-Chairs are elected by secret ballot and in writing by the members of each thematic expert panel or sub-group.

3. The election procedure is organised by the Secretariat.

4. The procedure is as follows:

a) The Secretariat sends an e-mail to all advisors of each thematic expert panel (and

sub-group where applicable) asking them to express their interest to stand for election as Chair or Vice-chair of the panel (or sub-group).

b) The advisors willing to put forward their candidacy for Chair or Vice-chair of the thematic expert panel (or sub-group) send an e-mail to the Secretariat outlining briefly their motivation, attaching their CV as well as an up-to-date declaration of interest (DOI) form, in case their interests have been changed since their last submitted DOI form. By submitting their candidature, advisors agree to accept the tasks described in point 5.5 on responsibilities of Chair and Vice-Chair.

c) The Secretariat assesses the up-to-date DOI forms of the candidates and makes a list of all the candidates for the role of the Chair/Vice-chair, indicating the number of interests declared and whether these are direct or indirect.

d) The Secretariat sends this list to the members of the thematic expert panel (or sub-group) providing also the following information:

   i) the motivation statement of each candidate

   ii) the up-to-date CV of each candidate using the Europass format

   iii) the up-to-date DOI form of each candidate

e) Each member of the thematic expert panel (or sub-group) has one (1) vote. Panel members cannot vote for themselves. Abstentions from voting are generally strongly discouraged, unless in duly justified cases (e.g. sickness, candidates of run-off elections). Any vote not in agreement with above rule or cast after the deadline set by the Secretariat will not be considered.

f) The candidate receiving a simple majority of the votes of the members of the thematic expert panel is elected as Chair. The candidate receiving the second highest number of votes is elected as Vice-Chair. In case of equal number of votes for a given position, a run-off election between the candidates with equal votes will be held. In case this does not resolve the situation, the Secretariat will seek an agreement by direct contact with the candidates.

g) An elected Chair of a thematic expert panel structured in sub-groups is requested to act as Chair of the sub-group that he/she was allocated to prior to the elections. In such cases, no elections for the Chair position will be held in the respective sub-group. Equally, an elected Vice-Chair of a thematic expert panel structured in sub-groups is requested to act as Chair of the sub-group that he/she was allocated to prior to the elections, unless the Vice-Chair and Chair have been allocated to the same sub-group. In such cases, the Vice-Chair of the panel will be requested to act as Vice-Chair of the respective sub-group. Sub-group elections will be held according to the outcome of above procedures.

h) Candidates may withdraw their candidature at any time during the procedure.

5. In case a thematic expert panel or sub-group consists of less than three members, no elections will be held for the position of Chair and Vice-Chair. Instead, the Secretariat will seek an agreement concerning these positions by direct interaction with the panel members. If no agreement can be reached, the default procedure is that described under 5.4.6. or 5.4.7., respectively.

6. The names of the Chair and the Vice-Chair of each thematic expert panel and sub-group (with the exception ad hoc sub-group for PECP) will be made public on the Medical Devices - Expert Panels website (https://ec.europa.eu/health/md_expertpanels/overview_en).

5.4 Replacement of Chair and Vice-Chair

1. The term of office of both Chair and Vice-Chair is a maximum of three years, and in any case not exceeding the term of appointment (see 5.10). The term is renewable. Replacement of the Chair or Vice-Chair during the three-year term follows the procedure in point 5.3.4 and is for the remainder of that term.
2. If the Chair is not in a position to fulfil his/her function, he/she is replaced by the Vice-Chair or, failing that (apart for a COI shared by both Chair and Vice-Chair, see point 3 below), another member elected by the members in agreement with the procedure 5.3.4.
3. In case the Chair and Vice-Chair share the same COI in relation to a specific dossier and both cannot fulfil their responsibilities, the Rapporteur will, for that given dossier, address the Chair's responsibilities.
4. In case a thematic expert panel consists of less than three members, the two members will represent their panel as Chair and Vice-Chair at the Coordination Committee, whilst acting solely as Rapporteur and Co-Rapporteur in relation to a specific dossier or request for advice.
5. If not replacing the Chair, the Vice-Chair can take any task within the thematic expert panel or /sub-group.
6. In case a thematic expert panel or sub-group does not succeed in electing a Chair and/or Vice-Chair due to lack of candidatures, the functions of Chair and Vice-Chair will be executed by the Rapporteur and Co-Rapporteur assigned to a specific request for advice (and for that specific request only). Furthermore, in such cases the panel should determine, facilitated by the Secretariat and on an ad hoc basis, at least one panel member who will represent the panel at a Coordination Committee meeting.
7. In case a sub-group does not succeed in electing a Chair and/or Vice-Chair due to lack of candidatures, the functions of Chair and Vice-Chair will be executed by the Rapporteur and Co-Rapporteur assigned to a specific request for advice (and for that specific request only).

5.5 Responsibilities of Chair and Vice-Chair of thematic panels and sub-groups

1. The thematic expert panel Chair will represent the panel in the Coordination Committee. The Vice-Chair of the thematic expert panel will replace the Chair in case of unavailability. In case of panels with sub-groups, the Chair or Vice-Chair of the thematic expert panel will represent all panel's sub-groups at the Coordination Committee.
2. The Chair of a thematic expert panel or sub-group, in cooperation with the Vice-Chair of the panel or sub-group and supported by the Secretariat, is responsible for the

efficient operation of the panel (in case there are no sub-groups) or of the sub-group.

3. Further to point 2, the Chair of a thematic expert panel (in case there are no sub-groups) or of a sub-group has the following responsibilities:

   a) Planning and coordinating the work of the expert panel in agreement with and supported by the Secretariat;

   b) Organising the work in view of timely completion of tasks, in particular by:

      - assigning Rapporteurs and Co-Rapporteurs to a specific request, duly considering the proposals from the Secretariat based on an analysis of possible conflicts of interests,
      - assigning reviewing members to support the Rapporteur and Co-Rapporteur in regard to specific aspects of the draft opinion / view,
      - striving for an even workload distribution,
      - initiating written procedures as described in point 6.5 and by proposing teleconferences if needed;

   c) Informing the Secretariat in case additional advisors with specific expertise are needed;

   d) Ensuring that at the beginning of each task or meeting potential conflicts of interests are declared;

   e) Supporting and implementing measures identified by the Secretariat based on the advisors' DOIs and aimed at the management and prevention of conflicts of interests;

   f) Informing the Secretariat in case an advisor does not or is not able to participate sufficiently in the work of the panel or sub-group for whatever reason;

   g) Chairing the discussions during teleconferences and summarising the conclusions drawn by the panel or sub-group;

   h) Building consensus among expert panel members, coordinating voting if needed and facilitating the adoption of scientific opinions, views;

   i) Deciding, following requests by reviewing members in this regard, whether a presentation of a draft opinion by the Rapporteur is required in view of building consensus;

   j) Ensuring that scientific opinions and views are based on the evaluation of all available information, are properly documented, clearly explained and scientifically justified;

4. The Vice-Chair of a panel or sub-group substitutes the Chair in regard to the tasks under point 3 in case of Chair's unavailability.

5.6 Responsibilities of Rapporteur and Co-Rapporteur

1. All procedures handled by the Screening Panel (where applicable) or a thematic

expert panel are based on the four-eye-principle. Requests must be handled by at least two advisors, a Rapporteur and a Co-Rapporteur.

2. In the Screening Panel, the Rapporteur and Co-Rapporteur are responsible for taking the decision whether or not there is an intention to provide a scientific opinion on the clinical evaluation assessment report (CEAR) of the notified body (MDR Annex IX Section 5.1. (e)). The decision must be taken in accordance with point 3.6.2.a. of these rules of procedure.

3. In a thematic expert panel, the Rapporteur and Co-Rapporteur are responsible for preparing the draft scientific opinion or view. The scientific opinion or view must be delivered in accordance with points 3.6.2 b or 3.6.2 c of these rules of procedure. Rapporteur and Co-Rapporteur may collaborate with specific reviewing members assigned by the Chair on the basis of, for instance, their specific expertise, to support the drafting of specific parts of the scientific opinion (or view).

4. The Rapporteur and Co-Rapporteur must collaborate and coordinate their work when making the decision (Screening Panel) or during the preparation of a scientific opinion (thematic expert panel). When preparing the draft opinion or view, the Rapporteur and Co-Rapporteur are encouraged to exchange views by phone calls and/or electronic means provided by the Secretariat.

5. The Rapporteur of a thematic expert panel or sub-group is responsible for communicating with the Chair of the panel or respective sub-group as well as the Secretariat on matters related to a given task.

6. The Rapporteur is responsible for sending the draft documents to the Chair, who is responsible for coordinating consultation of the draft with the expert panel or sub-group and adoption (preferably by consensus), involving all reviewing members of the expert panel or sub-group (see point 5.3.4.g). In case no consensus can be found, the Rapporteur and Co-Rapporteur will describe the divergent positions in the scientific opinion. Reviewing members may request that the Rapporteur presents the draft scientific opinion during a meeting of the expert panel or sub-group.

7. The Rapporteur is responsible for the delivery of the scientific opinion (or view) by uploading it on the electronic platform for document exchange within the deadline. The delivery can also be made by the Co-Rapporteur or any other panel member should the Rapporteur not be able to do so.

8. If, under specific circumstances, the Rapporteur is not able to fulfil his/her function, he/she is replaced by the Co-Rapporteur. A new Co-Rapporteur will be proposed by the Secretariat and assigned by the Chair from the remaining members of the expert panel or sub-group without DOI restrictions.

5.7 Responsibilities of reviewing members

1. All members of a thematic expert panel or sub-group who have not been excluded from participating in deliberations and decision-making in relation to a specific task on the basis of the application of the COI policy by the Secretariat are considered ‘reviewing members’.

2. Reviewing members have the duty to:

a) Carefully read all documents related to a specific request for advice,

b) Support the Rapporteur and Co-Rapporteur in drafting specific parts of the scientific opinion, if so assigned by the Chair (see 5.4.3.),

c) Provide input to the deliberations during final consultation on the scientific opinion within the thematic expert panel / sub-group,

d) Express their agreement / disagreement with the final draft scientific opinion when requested by the Chair in view of consensus decision making and participate in voting, in case no consensus can be found in the thematic expert panel or sub-group,

e) Explain and justify their standpoint in case they do not agree with the scientific opinion / view. Such standpoints will be recorded in the final scientific opinion prepared by the Rapporteur and Co-Rapporteur.

5.8 Temporary members of the panels

1. In well-justified cases and for a limited period of time, the Secretariat may, on request of the Chair, assign advisors from the central list of available experts or from another thematic expert panel to support work on a specific task in another expert panel or sub-group.

2. In such cases, the Secretariat will propose advisors with requested expertise and without conflicting interests from the central list of available experts or another panel for approval by the requesting Chair.

5.9 Presentation by the requesting notified body

1. As specified in MDR Annex IX, Section 5.1. (b), a thematic expert panel or sub-group may, in agreement with the Secretariat, request that the notified body presents its conclusions as presented in its clinical evaluation assessment report (CEAR).

2. In such cases, the Chair should make a request to the Secretariat, which will facilitate such presentation.

5.10 Term of office and renewal of term

1. Advisors are appointed as members of the Screening Panel or a thematic expert panel for a term of three years, with the possibility of renewal.

2. Where an advisor no longer complies with the conditions set out in Articles 12 and 15 of the Decision or in Article 339 of the Treaty on the Functioning of the European Union, resigns or is no longer capable of contributing effectively to the panel's work, the Commission may terminate the appointment of that advisor.

3. The Chair must inform the Secretariat where an advisor no longer complies with the conditions set out in the Decision, or is no longer capable of contributing effectively to the expert panel's work.

4. Where an advisor resigns or where an advisor’s appointment is terminated during his or her term of office, a replacement for that advisor may be appointed by the

Commission for the remainder of the term from the central list.

5. Advisors' terms can be renewed where the principles and conditions set out in the Decision and the call for expression of interest continue to be satisfied.

6. Before the end of their term, the Secretariat will request all advisors to indicate whether or not they are interested and available to serve another term.

6. OPERATIONS OF EXPERT PANELS, SUB-GROUPS AND COORDINATION COMMITTEE

6.1 Consultations on clinical evaluations in the context of conformity assessment

6.1.1 Screening decision in the context of the clinical evaluation consultation procedure (CECP)

1. Obligatory consultations of expert panels on clinical evaluations in the context of MDR of certain high-risk devices will be requested by notified bodies through Eudamed or alternative means (i.e. the electronic platform for document exchange) until Eudamed is fully available.

2. The documents required for such consultations will be submitted by notified bodies to the Secretariat through the electronic platform for document exchange.

3. The Secretariat checks the completeness of the incoming clinical evaluation consultation procedure (CECP) documentation as well as compliance with the marking instructions made available to notified bodies by the Commission.

4. The Secretariat having regard to the expertise of the Screening Panel members and an even workload distribution, assigns each consultation request to a Rapporteur and Co- Rapporteur after having checked their up-to-date DOIs.

5. The Secretariat provides access of the Rapporteur and Co-rapporteur to the dossier folder in the electronic platform for document exchange. The Secretariat provides, where available, the Rapporteur and Co-Rapporteur with information relating to the decision criteria two and/or three (MDR Annex IX Section 5.1. (c)) as well as information from stakeholders. The Secretariat communicates the timeline for delivering the decision. Rapporteur and Co-Rapporteur should, in terms of practical procedure, work in agreement with the navigation guide for the screening step provided by the Secretariat.

6. The Rapporteur and Co-Rapporteur, under supervision of the Secretariat, will need to make the decision referred to in points (c), (d) and (e) of Section 5.1. of MDR Annex IX, i.e. whether or not there is intention to provide a scientific opinion on the CEAR of the notified body. The decision must be taken in accordance with the Commission guidance (2020/C 259/02) for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure', which is made available by the Secretariat. The decision must be taken latest within 21 calendar days of receipt of the documents from the Secretariat.

7. The Rapporteur and Co-Rapporteur collaborate in analysing the documentation relating to the consultation. They will strive for consensus when deciding whether

there is an intention to provide a scientific opinion or not.

8. Following their assessment under supervision of the Secretariat, the Rapporteur and Co-Rapporteur will need to agree whether or not there is intention to provide a scientific opinion (MDR Annex IX Section 5.1. (e)). They need to summarise the reasons for their decision in the corresponding template. In case there is intention to provide a scientific opinion, they should indicate the most appropriate thematic expert panel or sub-group for the development of the scientific opinion. The Rapporteur or Co-Rapporteur need to upload the relevant template on the appropriate space in the electronic platform for document exchange. In the absence of Eudamed, this upload replaces the notification under MDR Annex IX Section 5.1. point (e).

9. If the Rapporteur and Co-Rapporteur cannot reach an agreement, they will inform the Secretariat as soon as possible. The Secretariat will try to resolve the disagreement. If the disagreement is not solved, the decision of intention to provide a scientific opinion will be the default outcome. In such cases, the Rapporteur and Co-Rapporteur summarise their divergent positions in the corresponding template. They should indicate the most appropriate thematic expert panel or sub-group for the development of the scientific opinion.

10. The Secretariat checks the relevant section of the template for completeness in regard to appropriate documentation of the decision and checks that the decision criteria were properly applied and adhered to in agreement with MDR Annex IX Section 5.1. (c) and the relevant Commission guidance document.

11. The Secretariat communicates the decision of the Screening Panel to the notified body.

12. In case there is no intention to provide a scientific opinion, the respective consultation is closed and the notified body can proceed with the certification.

13. In case the screening step identified an intention to provide a scientific opinion, the Secretariat, taking account of the suggestion of the Screening Panel, allocates the CECP dossier to the appropriate thematic expert panel or sub-group where applicable (see 6.1.2).

14. In case the screening advisors do not deliver a decision through upload (point 8 above) within the 21 days timeline, the advisors will not be remunerated and any decision provided after this timeline cannot be considered. The consultation will be closed and the Secretariat will inform the notified body that it can proceed with the certification procedure of the device in question.

6.1.2 Development of scientific opinions in the context of the clinical evaluation consultation procedure (CECP)

1. The Secretariat identifies panel advisors without dossier-specific conflicts of interest after having checked their up-to-date DOIs.

2. The Secretariat informs the relevant Chair of the allocation of the dossier by communicating the request number. The Secretariat proposes a Rapporteur and Co-Rapporteur and informs the Chair about restrictions and exclusions of panel members for that task, where applicable.

3. The Secretariat provides dossier access rights in the electronic platform for document exchange to thematic expert panel (or sub-group) members and communicates the deadline for delivery of the scientific opinion. The Chair of the relevant expert panel or sub-group assigns the dossier to the proposed Rapporteur and Co-Rapporteur (after having checked their availability), taking into account their expertise and an even workload distribution. The Chair informs the Secretariat of the assignment by e-mail, referencing the request number communicated by the Secretariat. All advisors involved should, in terms of practical procedure, work in agreement with the navigation guide for the opinion step provided by the Secretariat.

4. The Rapporteur and Co-Rapporteur collaborate in drafting the scientific opinion according to the responsibilities described in paragraph 5.6. Rapporteur and Co-Rapporteur must collaborate with the Chair, the Vice-Chair and other reviewing members (if applicable, see 5.7.2. b)) and adhere to the template provided by the Secretariat.

5. The draft scientific opinion must be made available for comments and adoption by the thematic expert panel (or sub-group) members at least 14 calendar days before the deadline.

6. The thematic expert panel (or sub-group) must adopt its opinion within 60 calendar days from when the Screening Panel received the documents from the Secretariat, in accordance with point 3.6.2. on timelines. Delivery of the scientific opinion is through upload of the relevant template on appropriate section of the electronic platform for document exchange.

7. In case the thematic expert panel (or its sub-group) does not deliver its scientific opinion within 60 days, the advisors will not be remunerated, the consultation is closed and, hence, any opinion provided after this timeline cannot be considered. In such cases the Secretariat will inform the notified body that it can proceed with the certification procedure of the device in question (MDR Annex IX Section 5.1. (f)).

8. The thematic expert panel must strive for consensus when adopting opinions relating to the CECP. Adoption takes place in accordance with paragraph 6.6 on decision making.

6.2 Consultations on performance evaluations in the context of conformity assessment

1. Obligatory consultations of expert panels on performance evaluation in the context of the IVDR of certain class D devices will be requested by notified bodies through Eudamed or alternative means (i.e. the electronic platform for document exchange) until Eudamed is fully available.

2. To this end, notified bodies will provide the manufacturer's Performance Evaluation Report (PER) to the Secretariat through Eudamed or alternative means (i.e. the electronic platform for document exchange) until Eudamed is fully available.

3. The Secretariat checks the completeness of the performance evaluation consultation procedure (PECP) dossier as well as compliance with the marking instructions made

available to notified bodies by the Commission.

4. The Secretariat defines an *ad hoc* sub-group and identifies panel members without COI after having checked their up-to-date DOIs and informs the Chair about possible restrictions and temporary exclusions of panel members.

5. On the basis of a proposal by the Secretariat concerning possible Rapporteurs and Co-Rapporteurs, the Chair of the relevant thematic expert panel/sub-group assigns the dossier to a Rapporteur and Co-Rapporteur (after having checked their availability), taking into account the expertise of its members and an even workload distribution. The Chair informs the Secretariat of the assignment by e-mail, referencing the request number communicated by the Secretariat.

6. The Secretariat provides dossier access rights in the electronic platform for document exchange to panel members and communicates the deadline for delivery of the opinion. All advisors involved should, in terms of practical procedure, work in agreement with the navigation guide for the PECP provided by the Secretariat.

7. The Rapporteur and Co-Rapporteur collaborate in drafting the view in response to a request. See also paragraph 5.6 on Rapporteur and Co-Rapporteur. Rapporteur and Co-Rapporteur must collaborate with the Chair, the Vice-Chair and other reviewing members (if applicable, see 5.7.2. b)) and adhere to the template provided by the Secretariat.

8. The draft view must be made available to the Chair, Vice-Chair and reviewing panel members at least 14 calendar days before the deadline for comments and adoption.

9. The expert panel must adopt its view within 60 calendar days from the receipt of the documents, in accordance with point 3.6.2. of these rules of procedure. Delivery of the opinion is through upload of the relevant template on appropriate section of the electronic platform for document exchange.

10. The expert panel must strive for consensus when adopting views on performance evaluations. Adoption must take place in accordance with paragraph 6.6 on decision making.

6.3 Other requests for expert panel advice

1. In regard to advice other than the consultation procedures outlined under paragraphs 6.1 and 6.2 of these rules of procedure, the Secretariat prepares, in collaboration with the party that requests the advice, a draft mandate for the thematic expert panel (or sub-group). The draft mandate will outline:

   a) the legal basis for the request,

   b) the scientific context and background information,

   c) relevant medical field and areas of competence required for providing the requested advice as well as indication of the appropriate panel and, where applicable, of a specific thematic panel or panel sub-group best suited to address the request for advice,

   d) the scope of the advice,

e) the timelines for providing the advice,

f) any consultation or collaboration with other scientific bodies deemed necessary for the preparation of the advice.

2. The Secretariat forwards the draft mandate to the Chair of the appropriate thematic expert panel, together with a list of panel members without conflict of interests after having checked their up-to-date DOIs. The Secretariat informs the Chair about possible temporary exclusions and restrictions of panel members, thereby establishing who amongst the panel's advisors will be involved in the particular advice.

3. The Secretariat ensures electronic access to the draft mandate and, where applicable, other available documents.

4. The panel advisors without COI support the Chair and the Secretariat in regard to amending the draft mandate in regard to any of the aspects outlined in point 1, where necessary. The Chair may request the involvement of additional advisors to be involved by temporary assignment form other thematic expert panels (or sub-groups) or from the central list.

5. The final mandate will be approved by the Secretariat and, subsequently, adopted by simple majority by all panel members without conflicts of interests.

6. The Chair of the relevant thematic expert panel/subgroup assigns the dossier to a Rapporteur and Co-Rapporteur (after having checked their availability), the expertise of its members and an even workload distribution. The Chair informs the Secretariat of this assignment.

7. The Rapporteur and Co-Rapporteur collaborate in drafting the scientific advice using the corresponding templates and in agreement with the adopted mandate. See also paragraph 5.6 on Rapporteur and Co-Rapporteur.

8. The draft opinion must be made available to the Chair, Vice-Chair and remaining panel members before the deadline for the draft advice specified in the mandate.

9. The thematic expert panel (or sub-group) must finalise the scientific advice within the deadline for adoption specified in the mandate. The advice is adopted by simple majority of those panel members assigned to the request (see paragraph 6.6 of these rules of procedure on decision making).

6.4 Stakeholder input

1. When preparing their scientific opinions, expert panels must take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals. In case such information is available, the Secretariat will provide it to the relevant expert panels.

6.5 Written procedure and sharing of relevant documentation

1. The timelines required by the MDR and IVDR for the expert panel consultations outlined under 6.1 and 6.2 require that the advice is prepared and finalised exclusively by remote involving written procedure for adoption.

2. Scientific and clinical advice (see 6.3) other than the consultations outlined under 6.1

and 6.2 may also be delivered via written procedure.

3. The Secretariat communicates with the relevant thematic expert panels/sub-groups via e-mail and provides advisors with access to the documentation on the electronic platform for document exchange. Advisors without conflicts of interests must actively download the documentation from the platform. Download is understood as acknowledgement of the handling instructions concerning commercially sensitive information as provided to the panels by the Secretariat. Advisors excluded by the Secretariat from work on a specific dossier on the basis of their conflicts of interests are not entitled to download or read the relevant documentation.

4. If necessary, the Chair can convene a teleconference at any point in time. For other requests as described under paragraph 6.3, the Chair may alternatively include the item in the agenda for the next physical meeting of the panel / sub-group.

6.6 Decision making

1. The Secretariat determines, where applicable, which advisors of a thematic expert panel or sub-group are excluded from work and decision making on a specific request for scientific opinion, view or advice based on the assessment of their up-to-date DOIs and conflicts of interest identified by panel members. All remaining members are entitled to participate in the deliberations and the decision-making process.

2. The Chair of the panel is responsible for managing and facilitating the decision-making process. In justified circumstances (e.g. to resolve contentious issues), the Chair can request the Secretariat to organise a tele- or videoconference to facilitate decision-making.

3. The Chair must ensure that the expert panel or sub-group uses its best endeavours to reach consensus when adopting scientific opinions or views in regard to the consultation procedures outlined under 6.1 and 6.2.

4. If consensus cannot be reached, the expert panel or sub-group will take a decision by voting. The outcome is decided by simple majority of expert panel or sub-group members with voting rights (i.e. Chair, Vice-Chair, Rapporteur, Co-Rapporteur and reviewing members). A vote is achieved by simple majority. In cases of a vote being split, the vote of the Chair will be counted twice.

5. When adopting scientific opinions or views, any divergent positions and the grounds on which they are based must be mentioned in the respective document.

6.7 Communication

1. E-mail is the preferred means of communication on general and organisational matters between the Secretariat and advisors.

2. To organise the work, the Chair communicates with the thematic expert panel / sub-group members preferentially through e-mail. In justified cases and upon request by the Chair, the Secretariat can arrange tele- and videoconferences (see also 6.6.2).

3. When exchanging draft scientific opinions and messages relating to confidential information, advisors must use exclusively the dedicated electronic means provided by the Secretariat. Advisors that, on the basis of COI, have been excluded by the

Secretariat from participation in the deliberations and decision-making of a panel or sub-group must not be put in copy when exchanging draft scientific opinions or views about them.

4. Any communication of a thematic expert panel or sub-group Chair with the Coordination Committee should be through the Secretariat.

5. Any communication of a thematic expert panel or sub-group Chair with other panel or sub-group Chairs should be through the Secretariat.

6. In case of communications between thematic expert panel Chairs/Vice-Chairs with Screening Panel Representatives/Vice-Representatives in the context of the work of the Coordination Committee, the Secretariat (acting as Chair of the Coordination Committee) must be put in copy.

7. During the course of their mandate, advisors should respond to requests or other communications related to the expert panels' work in a timely manner, preferably within 3 working days.

6.8 Handling of sensitive non-classified information and exchange of draft scientific opinions

1. The documentation received from notified bodies in the context of the consultation procedures outlined under 6.1 and 6.2 as well as information from manufacturers / device developers in regard to request for advice under MDR Article 61(2) is considered 'sensitive non-classified' information. This information will be received already labelled with the appropriate markings made by the respective third party. Advisors must handle such information in accordance with the *'Handling instructions and security measures for the Commission Expert Panels on medical devices and in vitro medical devices'* and, further, observing specific guidance provided for by the Secretariat (navigation guides on CECP screening step, CECP opinion step and PECP).

2. When preparing scientific opinions and exchanging these (see 6.7.7.) by electronic means, advisors must observe principles of data security and confidentiality as provided by the Secretariat in relevant internal guidance.

6.9 Physical meetings

1. Physical meetings are organised by the Secretariat and held on Commission or European Medicines Agency premises. In case physical meetings cannot be held for whatever reason, online meetings will be organised (see section 6.10).

2. Meetings of the Coordination Committee will be convened in support of its specific roles.

3. Meetings of thematic expert panels or sub-groups will be restricted to the type of advice outlined under section 6.3 on other requests for panel advice. The Chair of a panel or sub-group may request the organisation of a meeting.

4. Joint meetings of more than one thematic expert panel or sub-group may be convened to discuss matters falling within their respective areas of responsibility in relation to advice outlined under section 6.3.

5. Depending on need, meetings of the Screening Panel and/or members of its medical fields will be convened in view of the specific roles of this panel.

6. The Secretariat and the Chair(s) of the Screening Panel / thematic expert panels / sub-groups and Representatives of medical fields in case of the Screening Panel collaborate in drawing up the meeting agenda. The Secretariat provides the draft agenda to the members of the expert panel(s) or sub-group(s).

7. The Secretariat will provide the invitation to the meeting and the first draft agenda, preferably no later than 30 calendar days before the date of the meeting. The Secretariat will provide the working documents, preferably no later than 14 calendar days before the date of the meeting. In urgent or exceptional cases, the documentation may be provided up to 5 calendar days before the date of the meeting.

8. At each physical meeting, the Secretariat draws up an attendance list to be signed by the participants. The agenda will be adopted by the participating advisors at the beginning of the meeting.

9. Minutes of physical meetings are drafted by the Secretariat in collaboration with the Chair or, in case of the Coordination Committee, are drafted by the Secretariat in its function as Chair of the Committee. The minutes will outline:
    - The list of participants.
    - Key discussion points in regard to the agenda items including divergent positions.
    - Decisions and conclusions reached as well as agreed follow-up actions.

6.10 Online meetings

1. Online meetings via appropriate videoconference platforms are organised by the Secretariat.

2. The Secretariat is responsible for drafting the minutes of teleconferences organised by the Secretariat in collaboration with the Chair. In case of online meetings of the Coordination Committee, the Secretariat will draft the minutes in its function as Chair of the Committee.

6.11 Reimbursement of advisors

1. Only the Chair, Vice-Chair, Rapporteur, Co-Rapporteur and all advisors established by the Secretariat as reviewing members in relation to a specific request are entitled to remuneration. Advisors are remunerated in agreement with the latest version of the Decision and only for scientific opinions, views and advice that have been finalised within the applicable timelines.

7. ANNEXES

Annex 1 - Declaration of interest (DOI) form

Available at: ***https://ec.europa.eu/docsroom/documents/42201***

Annex 2 - Declaration of confidentiality

European Commission expert panels on medical devices
and *in vitro* diagnostic medical devices – *Declaration of confidentiality*

Name: ……..

I hereby declare that:

1. I am aware of my obligation to respect confidentiality and not to divulge information acquired as a result of my work in the expert panels for medical devices and *in vitro* diagnostic devices (or one of its sub-groups). I will respect the confidential nature of the scientific opinions expressed by members of the expert panel meetings or external experts during discussions in expert panels or other working groups. I will not disclose such information even after my participation in the work of the expert panels has ceased.
2. I am aware of the Commission's security rules for protecting European Union classified information and sensitive non-classified information, as laid down in Commission Decisions (EU, Euratom) 2015/443 and 2015/444. Should I receive confidential information or restricted information in the course and context of my duties for an expert panel, I will treat them strictly confidential and use them exclusively for the purpose for which it was made available. I will handle the information in accordance with the provided handling instructions and not divulge them to any third party.

The above implies that the undersigned:

- Will not divulge, publish or otherwise make available to any third party information received from the expert panel, without prior written consent of the Secretariat, even after completion of a specific event or assignment. The duty of confidentiality exists vis-à-vis any third party, including employees, employers or affiliates or the general public;
- Will not use information received from expert panels for a personal benefit or that of any third party;
- Will ensure safe storage of the confidential or restricted information (in accordance with the corresponding handling instructions), by applying appropriate security measures if the information is managed electronically and not retain the information for longer than needed for the completion of an assignment within the expert panels.

Date:

Signature:

Annex 3 - Declaration of commitment

European Commission expert panels on medical devices and *in vitro* diagnostic medical devices – Declaration of commitment

Name: ……..

1. Commitment

While contributing to the activities of the expert panel for medical devices and *in vitro* diagnostic medical devices, I will:

- Act independently in the public interest and make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence;
- Comply with the expert panels' rules on the handling of conflict of interest;
- Contribute actively to the work of the expert panel by remote work, and when necessary by attending meetings;
- Always set an exemplary conduct in all activities linked to the expert panel;
- Comply with the rules on reimbursement of travel expenses and payment of allowances and indemnities in place at the European Medicines Agency;
- Ensure appropriate use of scientific publications provided by the Commission Services and/or the European Medicines Agency and respect copyrights as outlined below;
- When communicating with media, stakeholders or the general public on a matter that falls within the expert panels' remit always contact the Secretariat.

2. Copyrights and library working tools

In case the undersigned is involved in the preparation of scientific outputs, she/he may receive from the Secretariat scientific publications and journals protected by copyrights as hand-outs or via e-mail.

The undersigned will be allowed to make limited use of journals and scientific publications, but shall not:

- Distribute copies of articles and journals to third parties;
- Use articles or journals for commercial purposes;
- Use the materials for other purposes than the assignment with the expert panel.

Date:
Signature:

Duration: The validity of the present Declaration is limited to one mandate of expert panel (3 years) from the date of signature, unless the undersigned informs the Secretariat on the termination of her/his activities within the expert panel.

8. References

1. [MDR] 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, *Official Journal of the European Union*, L 117, pp. 1-175, 5 May 2017.
2. [IVDR] 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, *Official Journal of the European Union*, L 117, pp. 176-332, 5 May 2017.
3. [Decision] Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices, *Official Journal of the European Union*, L 234, pp. 23-30, 11 September 2019.
4. [Guidance] Commission guidance 2020/C 259/02 for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure, *Official Journal of the European Union*, C 259, pp. 2-8, 7 August 2020.
5. Commission Decision (EU, Euratom) 2015/443 of 13 March 2015, on Security in the Commission, *Official Journal of the European Union*, L 72, pp. 41-52, 17 March 2015.
6. Commission Decision (EU, Euratom) 2015/444 of 13 March 2015, on the security rules for protecting EU classified information, *Official Journal of the European Union*, L 72, pp. 53-88, 17 March 2015.
7. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, *Official Journal of the European Union*, L 295, pp. 39-98, 21 November 2018.
8. 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 document, *Official Journal of the European Union*, L 145, pp. 43-48, 31 May 2001.
9. Consolidated version of the Treaty on the Functioning of the European Union (TFEU), *Official Journal of the European Union*, C 326, pp. 47-390, 26 October 2012.
10. Procedural guidance on inclusion of declared interests in the European Commission's electronic declaration of interests form for the expert panels on medical devices and *in vitro* diagnostic medical devices.
11. European Commission policy on the management of competing interests of members of the expert panels on medical devices and *in vitro* diagnostic medical devices.
12. Procedural guidance 'Navigating the screening step of the Clinical Evaluation Consultation Procedure (CECP)'.
13. Procedural guidance 'Navigating the scientific opinion step of the Clinical Evaluation Consultation Procedure (CECP)'.

14. Procedural guidance ‘Navigating the Performance Evaluation Consultation Procedure’.
15. Handling instructions and security measures for the Commission Expert Panels on medical devices and *in vitro* diagnostic medical devices (EXPAMED).
16. Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, *Official Journal of the European Union*, Publications Office (europa.eu).