EUROPEAN COMMISSION

RULES OF PROCEDURE OF THE EUROPEAN COMMISSION EXPERT PANELS ON MEDICAL DEVICES (EXPAMED)

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Contents

1. INTRODUCTION AND BACKGROUND

1. Regulation (EU) 2017/745 on medical devices (“MDR”), mandates 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 *in vitro* diagnostic medical device Regulation 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 produced 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 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, providing 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 EMA Expert Management Tool in accordance with the instructions. 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 opinion 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 advisors is understood as confirmation that there are no COIs 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.

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.
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 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 in case of advice outline in 6.4 a fixed timeline of 60 days from submission of the final documentation to the expert panels is envisioned.

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

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 as described in the Commission Implementing Decision.
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 or additional expertise that is needed, 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 I 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. (1–) - 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-Panel report to the Chair and Vice-Chair of the thematic panel any request that has been directed to their Sub-Panel when it is assigned.

4.5 *Ad Hoc* Expert Groups

1. Requests originating in MDR Article 55(3), 61(2) as well as 106(10), (11) describing the *ad hoc* tasks of the experts' panels are handle by *Ad Hoc* Expert Groups in representation of the thematic panel or panel subgroup appropriate for the requested advice.
2. *Ad Hoc* Expert Groups are created individually for each request and are chaired by the Chair/Vice-Chair of the thematic panel or panel subgroup associated.
3. The Secretariat suggests the *Ad Hoc* Expert Group composition based on expertise and declared conflicts, to the Chair/Vice-Chair for confirmation.
4. Any advisor appointed to the expert panels can be part of an *Ad Hoc* Expert Group irrespective of the panel they belong to.

5. The *Ad Hoc* Expert Group will only be created for the purpose of one individual request and will be dissolved once the advice has been delivered.

4.6 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. The Screening Panel Representatives/Vice Representatives will, amongst themselves, elect two of the Representatives as Chair and Vice-Chair of the Screening Panel.

2. Nominations for Representative and Vice-Representative should be submitted in writing to the EMA secretariat after having received an E-Mail to do so.

3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

4. The election of the Representative and the Vice- Representative shall be by simple majority of the Members. In the case of a tie a decisive round is organised with two remaining candidates. In case this does not resolve the situation, the Secretariat will

seek an agreement by direct interaction with the candidates.

5. In the event of resignation of the Representative, the Vice-Representative shall take the chair until a new election is convened.

6. After the election of the Representative and Vice-Representative the EMA calls for nomination of Chair and Vice-Chair among the Representative and Vice-Representative

7. Nominations for Chair and Vice-Chair should be submitted in writing to the EMA secretariat after having received an E-Mail to do so.

8. Candidates shall submit a brief résumé in support of their candidature at the time of the time of the nomination.

9. The election of the Chair and the Vice-Chair shall be by simple majority of the Representatives. In the case of a tie a decisive round, is organised with two remaining candidates. In case this does not resolve the situation, the Secretariat will seek an agreement by direct interaction with the candidates.

10. In the event of resignation of the Chair, the Vice-Chair shall take the chair until a new election is convened.

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

1. The Chair and Vice-Chair of the Thematic panel and if applicable Sub-Panel shall be elected by and from amongst its members for a term of three years.

2. Nominations for Chair and Vice-Chair should be submitted in writing to the EMA secretariat.

3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

4. The election of the Chairand the Vice-Chair shall be simple majority of the Members. In the case of a tie a decisive round, is organised with two remaining candidates. In case this does not resolve the situation, the Secretariat will seek an agreement by direct interaction with the candidates.

5. In the event of resignation of the Chair, the Vice-Chair shall take the chair until a new election is convened.

5.3 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 when they are assigned a specific task supported by the secretariat, in particular coordinating the 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);. Organising the work in view of timely completion of tasks, in particular by:

      - confirm assignment proposal by the secretariat of Rapporteurs and Co-Rapporteurs as well as Reviewing members to a specific request
      - initiating written procedures as described in point 6.6 and by proposing teleconferences if needed.

   b. Informing the Secretariat in case additional advisors with specific expertise are needed;

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

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

   e. 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;

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

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

   h. 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;

   i. 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.

5.4 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.

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 full panel and the Secretariat. In case no consensus can be found, the Rapporteur and Co-Rapporteur will describe the divergent positions in the scientific opinion. 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.

7. 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.

5.5 Responsibilities of reviewing members

1. Two members (a maximum of four members) are suggested to be reviewing members to the Chair, based on their expertise, declared interest and availability.

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.

5.6 Temporary members of the panels

1. In case that a procedure would benefit from a specific expertise that is not present in the panel, the Chair can request a temporary assigned advisors to join the expert group.
2. In these cases the Secretariat suggests additional expertise to the Chair, and in case of agreement the advisor will be assigned to the specific procedure.

5.7 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.

5.8 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. Advisors shall adhere to the requirements set out in the Implementing decision.
3. 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 THE EXPERT PANELS, SUB-GROUPS AND THE 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 electronic means until Eudamed is fully available.
2. The documents required for such consultations will be submitted by notified bodies to the Secretariat through Eudamed or alternative electronic means until Eudamed is fully available.
3. The Secretariat checks the completeness of the clinical evaluation consultation procedure (CECP) documentation as well as compliance with the instructions made available to notified bodies.
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.

6. The Rapporteur and Co-Rapporteur, under supervision of the Secretariat, will need to make the decision 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. 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).

8. 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.

9. 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.

10. The Secretariat communicates the decision of the Screening Panel to the notified body, using the decision template for that effect.

11. 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.

12. 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).

13. In case the screening advisors do not deliver a decision (point 8 above) within the 21 days timeline, the advisors will not be remunerated and any decision provided after this timeline cannot be considered.

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

1. Taking into account their expertise and an even workload distribution, the Secretariat defines a group of up to 5 members of the panel or subpanel 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 and the proposal of composition and roles for the subgroup.
3. After agreement from the Chair, the Secretariat checks the availability of the proposed Rapporteur, Co-Rapporteur and Reviewing members. In case one of the members is not available, a new expert needs to be confirmed by the Chair. Once the availability of the members is confirmed, the Secretariat provides them access rights in the electronic platform to the procedure file and communicates the deadline for delivery of the scientific opinion.
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 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 sub-group members at least 10 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 and send it to the Secretariat via the appropriate means.
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.
8. The thematic expert panel or subpanel 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 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 until Eudamed is fully available.
3. The Secretariat checks the completeness of the performance evaluation consultation procedure (PECP) dossier as well as the compliance with the instructions made available to notified bodies.

4. Taking into account their expertise and an even workload distribution, the Secretariat defines an *ad hoc expert* group of up to 5 members without dossier-specific conflicts of interest after having checked their up-to-date DOIs.

   After agreement from the Chair, the Secretariat checks the availability of the proposed Rapporteur, Co-Rapporteur and Reviewing members. In case one of the members is not available, a new expert needs to be confirmed by the Chair. Once the availability of the members is confirmed, the Secretariat provides them access rights in the electronic platform to the procedure file and communicates the deadline for delivery of the scientific view.

5. 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 and other Reviewing members (if applicable, see 5.7.2. b)) and adhere to the template provided by the Secretariat.

6. The draft view must be made available to the Chair and Reviewing members at least 10 calendar days before the deadline for comments and adoption.

7. 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 to the Secretariat should be done using the appropriate means.".

8. 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 Requests for the expert panel's advice from the European Commission or the Medical Device Coordination Group (MDCG)

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 and the Chair of the adequate panel, a mandate for the thematic expert panel. The 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 mandate to the Chair of the appropriate thematic expert panel, together with a proposal, based on expertise and an even workload distribution, for an *ad hoc* expert group of up to 5 panel members without dossier-specific conflict of

interests after having checked their up to date DOIs.

3. After agreement from the Chair, the Secretariat checks the availability of the proposed Rapporteur, Co-Rapporteur and Reviewing members. In case one of the members is not available, a new expert needs to be confirmed by the Chair. Once the availability of the members is confirmed, the Secretariat provides them access rights in the electronic platform to the procedure file and communicates the deadline for delivery of the advice.

4. 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.

5. The draft advice must be made available to the Chair and remaining sub-group members 10 working days before the deadline for the draft advice specified in the mandate.

6. The 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 Requests for advice from the medical device manufacturers

1. According to article 61.2 of the MDR, manufacturers of class III devices or of the class IIb devices referred to in point (b) of Article 54(1) may consult an expert panel for reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation.

2. The documents required for such consultations will be submitted by the manufacturers through an electronic system adequate for the degree of confidentiality of such information.

3. The Secretariat checks the adequacy and the completeness of the request and might accept the applicant’s request for a presubmission meeting destined to clarify the content of the support documentation. The Secretariat will provide comments in written to the applicant, irrespectively of the existence of a pre-submission meeting.

4. The Secretariat forwards the request of advice and the support documentation (“briefing document”) to the Chair of the appropriate thematic expert panel, together with a proposal, based on expertise and an even workload distribution, for an *ad hoc* expert group of up to 5 panel members without dossier-specific conflict of interests after having checked their up-to-date DOIs.

5. After agreement from the Chair, the Secretariat checks the availability of the proposed Rapporteur, Co-Rapporteur and Reviewing members. In case one of the members is not available, a new expert needs to be confirmed by the Chair. Once the availability of the members is confirmed, the Secretariat provides them access rights in the electronic platform to the procedure file and communicates the deadline for delivery of the advice.

6. The Rapporteur and Co-Rapporteur collaborate in drafting the scientific advice using the corresponding templates. See also paragraph 5.6 on Rapporteur and Co-

Rapporteur.

7. The draft advice must be made available to the Chair and remaining sub-group members 10 working days before the deadline agreed.

8. The sub-group must finalise the scientific advice within the deadline for adoption specified in Chapter 3.6. 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).

6.5 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.

6.6 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 to 6.4 require that the advice is prepared and finalised exclusively by remote involving written procedure for adoption.

2. Download of the documentation is understood as acknowledgement of the handling instructions concerning commercially sensitive information as provided to the panels by the Secretariat.

3. If necessary, the Chair or the Secretariat can convene a remote conference at any point in time.

6.7 Decision making

1. The Secretariat determines, where applicable, which advisors 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.

2. The Chair of the sub-group is responsible for managing and facilitating the decision-making process.

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 to 6.4.

4. If consensus cannot be reached, the sub-group will take a decision by voting. The outcome is decided by simple majority of sub-group members with voting rights (i.e. 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.

6.8 Communication

1. E-mail and secure 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. Upon request by the Chair, the Secretariat can arrange remote conferences (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.

4. During the course of their mandate, advisors should respond to requests or other communications related to the expert panels' work in a timely manner.

6.9 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.

6.10 Meetings

1. Meetings are organised by the Secretariat and held at the European Medicines Agency's premises. In case physical meetings cannot be held for whatever reason, remote meetings will be organised (see section 6.10).

2. The Secretariat and the members of the Coordination Committee collaborate in drawing up the latter meeting agenda. The Secretariat provides the draft agenda to the members of the expert panel(s) or sub-group(s).

3. 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.

4. At each 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.

5. Minutes of 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. Online meetings via appropriate videoconference platforms are organised by the Secretariat.

6.11 Reimbursement of advisors

1. Only the members of the Coordination Committee are entitled to remuneration.

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).