DECISIONS

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 106(1) thereof

Whereas:

(1) Expert panels are to be designated in order to provide scientific, technical and clinical assistance to the Commission, the Medical Device Coordination Group (MDCG), Member States, notified bodies and manufacturers in relation to the implementation of Regulation (EU) 2017/745 and in order to provide views in accordance with Article 48(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council ([2]).

(2) In particular, notified bodies are required to carry out consultations of expert panels on clinical evaluations of certain high-risk medical devices in the context of Regulation (EU) 2017/745 and on performance evaluations of certain high-risk *in vitro* diagnostic medical devices in the context of Regulation (EU) 2017/746.

(3) The Commission has, in consultation with the MDCG, identified areas in which the provision of consistent scientific, technical and/or clinical advice is needed. Expert panels should be designated in those areas and the principles of their organisation and operation should be defined, including the procedures for the selection and appointment of their members, as to ensure that they work according to the highest scientific competence, impartiality, independence and transparency. The list of designated expert panels can be revised, based on experience or newly identified needs.

(4) The advisors in the expert panels should be appointed on the basis of objective criteria and following a public call for expression of interest. The selection criteria included in the call for expression of interest should ensure that highly qualified advisors with a sufficient level of up-to-date clinical, scientific or technical expertise in the relevant identified areas are selected, and that advisors are able to act independently and in the public interest. The selection criteria should also ensure that the collective expertise of all advisors selected adequately covers all the identified areas and that the geographical origin of the advisors reflects the diversity of scientific and clinical approaches in the Union.

(5) The number of advisors to be appointed to each expert panel or included in the central list of available experts should be specified in the call for expression of interest, based on expected workload and necessary expertise.

(6) The organisation of the expert panels should ensure flexibility so that specialised knowledge can be deployed based on requisite needs. In addition to advisors appointed to expert panels, a central list of advisors who are not members of expert panels should therefore be established. Advisors on that list should be available to support the work of the expert panels as needed.

(7) In order to ensure timely and efficient exercise of their tasks, the expert panels should be able to establish sub-groups entrusted with specific tasks and composed of a certain number of their members.

([1]) OJ L 117, 5.5.2017, p. 1.
([2]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

(8) In order to facilitate the organisation of the expert panels and the communication between them, a coordination committee composed of the Chairs and Vice-Chairs of the panels should be established. In order to ensure the support necessary for the efficient functioning of the expert panels, the Commission should provide a secretariat for the expert panels and for the coordination committee.

(9) Expert panels should operate in a transparent and harmonised manner. To this end, common rules of procedure, internal guidance and methodologies for their operation should be established by the coordination committee and be publicly accessible. The common rules of procedure, the internal guidance and the methodologies should be reviewed regularly to ensure that they take account of the latest scientific developments and reflect state-of-the-art practice.

(10) Any personal data treated by the expert panels, the Secretariat or the coordination committee is to be processed in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council ([3]).

(11) Advisors should comply with the rules on security regarding the protection of Union classified information and sensitive non-classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 ([4]) and (EU, Euratom) 2015/444 ([5]).

(12) Given the contribution of expert panels to achieve the objectives of Union policies, by providing scientific, technical and clinical assistance to the Commission, the MDCG, manufacturers and notified bodies in relation to the implementation of Regulation (EU) 2017/745 and of Regulation (EU) 2017/746, and taking into account the principle of cost-effectiveness, advisors should receive adequate remuneration for their activities, beyond reimbursement of expenses. The level of remuneration should reflect the extent of work required from the advisors, notably in relation to the duration and nature of their tasks.

(13) The financing of the expert panel activities should be provided by the relevant budget line of the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Designation of expert panels

1. One expert panel is designated in each of the following areas to fulfil the tasks set out in paragraphs 9 and 10 of Article 106 of Regulation (EU) 2017/745 and in paragraph 6 of Article 48 of Regulation (EU) 2017/746:

(1) Orthopaedics, traumatology, rehabilitation, rheumatology;

(2) Circulatory system;

(3) Neurology;

(4) Respiratory system, anaesthesiology, intensive care;

(5) Endocrinology and diabetes;

(6) General and plastic surgery and 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).

2. An additional expert panel is designated to be in charge of the decision referred to in point (c) of Section 5.1 of Annex IX to Regulation (EU) 2017/745.

([3]) 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 (OJ L 295, 21.11.2018, p. 39).
([4]) Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).
([5]) Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

Article 2

Appointment of advisors and establishment of the central list

1. For the purpose of Article 106(5) of Regulation (EU) 2017/745, advisors shall be appointed to the expert panels following a call for expression of interest and consultation with the Medical Device Coordination Group ('MDCG'), based on selection criteria stipulated in that call for expression of interest.

2. The number of members of each expert panel shall be determined in the call for expression of interest referred to in paragraph 1.

3. For the purpose of Article 106(6) of Regulation (EU) 2017/745 and following consultation with the MDCG, advisors who satisfy the criteria stipulated in the call but who are not appointed to an expert panel shall be included in a central list of available experts (the 'central list').

4. Advisors shall be selected with regard to the need to ensure:

(a) adequate and up-to-date clinical, scientific or technical expertise in the areas referred to in Article 1(1);

(b) independence, impartiality, objectivity and absence of conflict of interest as outlined in Article 107 of Regulation (EU) 2017/745;

(c) balanced geographical representation.

5. Where it is necessary 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.

6. Where it is necessary 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.

7. The central list may be updated by launching subsequent calls for expression of interest.

Article 3

Sub-groups

1. An expert panel may, in agreement with the Commission, establish permanent or *ad-hoc* sub-groups entrusted with specific tasks and composed of a certain number of its members.

2. Sub-groups shall operate in accordance with the common rules of procedure for the expert panels, referred to in Article 9(1).

Article 4

Term of office

1. Advisors shall be appointed as members of an 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 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 expert panel's work, the Commission may dismiss that advisor.

3. Where an advisor is dismissed during his or her term of office, a replacement for that advisor shall be appointed for the remainder of the term from the central list.

Article 5

Election of the Chair and Vice-Chair

1. At the beginning of each term of office referred to in Article 4, each panel and its sub-groups shall, acting by simple majority, elect a Chair and a Vice-Chair from among its members.

2. The term of office of the Chair and Vice-Chair shall be three years, and shall be renewable. Any replacement of the Chair or Vice-Chair during that term of office shall take place according to the procedure referred to in paragraph 1 and shall be valid for the remainder of the term.

3. As regards sub-groups, the term of office of the Chair and Vice-Chair shall run from the moment of their election until the expiration of the mandate of the sub-group.

Article 6

Voting rules

When adopting scientific opinions or views, as applicable, in the context of Articles 54(1) and 61(2) of Regulation (EU) 2017/745 and Article 48(6) of Regulation (EU) 2017/746, the expert panel shall make decisions in accordance with Article 106(12) of Regulation (EU) 2017/745.

Article 7

Coordination committee

1. A coordination committee (the 'Committee') composed of the Chairs and Vice-Chairs of all expert panels shall be established following the election referred to in Article 5.

2. The Committee shall, inter alia:

— ensure effective exchange of information between expert panels;

— adopt and review the common rules of procedure for the expert panels in accordance with Article 9;

— adopt and review internal guidance and methodologies to be used by the expert panels.

3. The Committee shall operate in accordance with the common rules of procedure referred to in Article 9(1).

Article 8

Preparation of opinions, views or positions

1. For each opinion, view or position under preparation the Chair of the expert panel or the sub-group may appoint a rapporteur and co-rapporteur. In that context, all other members shall be reviewing members.

2. The expert panels shall follow the common rules of procedure referred to in Article 9 and any relevant guidance adopted by the Committee as referred to in Article 7(2) third indent.

3. In the context of the activities of expert panels referred to in Article 54(1) of Regulation (EU) 2017/745, the expert panels shall use the guidance to be provided by the Commission as set out in point (h) of Section 5.1 of Annex IX to Regulation (EU) 2017/745.

Article 9

Common rules of procedure

1. On a proposal by and in agreement with the Commission services, the Committee shall adopt common rules of procedure for all expert panels by simple majority of its members.

The Chairs shall consult their respective expert panels on the content of the common rules of procedure prior to adoption.

2. The common rules of procedure for the expert panels shall provide for, inter alia:

(a) procedures for carrying out the tasks of the expert panels as referred to in paragraphs 9 and 10 of Article 106 of Regulation (EU) 2017/745;

(b) rules ensuring the application of the principles laid down in Articles 12 to 15.

3. The Committee shall, in agreement with the Commission services, review the common rules of procedure at least every 3 years and update them to ensure that they take account of the latest scientific developments and that they reflect state-of-the-art practice.

4. The common rules of procedure shall be publicly available on a dedicated Commission website.

Article 10

Secretariat

1. The Commission shall provide a secretariat (the 'Secretariat') for the expert panels and for the Committee.

2. The Secretariat shall be responsible for the support necessary for the efficient functioning of the expert panels. The Secretariat shall, in particular:

— identify and manage potential conflicts of interests;

— supervise the consistent application of the criteria set out in point (c) of Section 5.1 of Annex IX to Regulation (EU) 2017/745 by the relevant expert panel in accordance with the Commission guidance referred to in Article 8(3);

— supervise the work of the expert panel referred to in Article 1(2);

— monitor compliance with the common rules of procedure referred to in Article 9, the guidance and methodologies referred to in Article 7(2) third indent and the requests for opinions, views and positions;

— publish their opinions, views and positions in accordance with the second subparagraph of Article 106(12) of Regulation (EU) 2017/745;

— process requests from expert panels for additional expertise.

Article 11

Remuneration

1. Advisors shall be remunerated for their preparatory work and participation (in person or by electronic means) in the meetings of the expert panel and in other activities of the expert panels governed by this Decision. The remuneration shall be established according to the criteria set out in the Annex.

2. Travel and, where appropriate, subsistence expenses of advisors in connection with the activities of the expert panels governed by this Decision shall be reimbursed by the Commission in accordance with the provisions in force at the Commission. Those expenses shall be reimbursed within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources.

Article 12

Independence, impartiality and objectivity

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

2. Advisors shall 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 shall 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 shall be submitted in writing, when applying to the call for expression of interest.

4. Advisors shall update their declarations of interest:

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

— whenever a change of circumstances so requires;

— prior to commencement of a specific task in the expert panel.

5. Where the obligations referred to in paragraphs 1 to 4 are not met, the Commission may take all appropriate measures.

Article 13

Commitment

1. Advisors shall commit to acting in the public interest and observing the principles listed in Articles 12 to 15. For that purpose, they shall sign a declaration of commitment.

2. Advisors shall respond to requests and other communications from the Chair of their respective expert panel or sub-group and from the Secretariat. They shall dedicate the necessary effort to complete the assigned tasks to the best of their ability and within the timelines as described in the common rules of procedure referred to in Article 9.

Article 14

Transparency

The activities of the expert panels shall be carried out in a transparent manner. The Secretariat shall in particular make available to the public on a dedicated Commission website, without undue delay:

(a) the names of the advisors appointed or assigned to the expert panels or included in the central list of available experts;

(b) the *curriculum vitae* and the declarations of interests, confidentiality and commitment of advisors appointed or assigned to the expert panels;

(c) the common rules of procedure of the expert panels referred to in Article 9;

(d) opinions, views and positions in accordance with Article 8.

Article 15

Confidentiality

1. Advisors shall not divulge any information of confidential nature acquired as part of their work in the expert panels or as a result of other activities governed by this Decision. For that purpose, they shall sign a declaration of confidentiality.

2. Advisors shall comply with the rules on security regarding the protection of Union classified information and sensitive non-classified information, laid down in Decisions (EU, Euratom) 2015/443 and (EU, Euratom) 2015/444.

3. Where the obligations referred to in paragraphs 1 and 2 are not met, the Commission may take all appropriate measures.

Article 16

Entry into force and date of application

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 September 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

REMUNERATION OF ADVISORS

1. The remuneration of advisors is 450 EUR for each full working day.

2. The total working time is calculated and rounded to the nearest half working day.

3. For tasks referred to in Article 54(1) of Regulation (EU) 2017/745 and Article 48(6) of Regulation (EU) 2017/746, the maximum number of working days for which experts may be remunerated is set out in Table 1.

Table 1

Maximum number of working days for which experts may be remunerated for tasks referred to in Article 54(1) of Regulation (EU) 2017/745 and Article 48(6) of Regulation (EU) 2017/746

	Regulation (EU) 2017/745 Article 54(1)		Regulation (EU) 2017/746 Article 48(6)
	Decision on whether a scientific opinion should be developed (Yes/No)	Development and provision of a scientific opinion	Provision of a view of the performance of an in vitro diagnostic medical device
Chair/Vice-Chair	N/A	2	2
Rapporteur	1	5	4
Co-rapporteur	1	5	4
Reviewing members (*)	N/A	0,5	0,5
Advisors assigned pursuant to Article 2(6) of this Decision	N/A	2	2

(*) advisors of the respective expert panel or sub-groups who validate the opinion or view produced by the rapporteur and the co-rapporteur

4. For tasks referred to in Articles 55(3), 61(2), 106(10)(a) to (f) and 106(11) of Regulation (EU) 2017/745 and Article 50(3) of Regulation (EU) 2017/746, divided into categories depending on their level of complexity, the maximum number of working days is specified in Table 2.

Table 2

Maximum number of working days for which experts may be remunerated for tasks under Articles 55(3), 61(2), 106(10)(a) to (f) and 106(11) of Regulation (EU) 2017/745 and Article 50(3) of Regulation (EU) 2017/746

Complexity of task (indicative criteria (*))	Acting as	Allowance in full day equivalents
Category I — simple matter — opinion based on examination of a low volume of data, documents and literature — no consultation of other scientific bodies — no information available from stakeholders including patient organisations and healthcare professionals — indicatively, less than three months to accomplish task	Chairperson	2
	Rapporteur	3
	Co-rapporteur	3
	Reviewing member	0,5
	Advisors assigned pursuant to Article 2(6) of this Decision	1

Complexity of task (indicative criteria (*))	Acting as	Allowance in full day equivalents
Category II — complex matter — opinion based on a significant volume of data, documents and literature — feedback following consultation, if any, of other scientific bodies to be examined — information available from stakeholders including patient organisations and healthcare professionals, to be examined — indicatively, three to six months to accomplish task	Chairperson	3
	Rapporteur	5
	Co-rapporteur	5
	Reviewing member	1
	Advisors assigned pursuant to Article 2(6) of this Decision	2
Category III — very complex matter — opinion based on a significant volume of data, documents and literature — high volume of feedback following consultation, if any, of other scientific bodies to be examined — large amount of information available from stakeholders including patient organisations and healthcare professionals, to be examined — indicatively, more than six months to accomplish task	Chairperson	4
	Rapporteur	7
	Co-rapporteur	7
	Reviewing member	2
	Advisors assigned pursuant to Article 2(6) of this Decision	2

(*) Each of these criteria may be applied independently

5. The remuneration shall be conditional on the completion of the relevant tasks as per the common rules of procedure.