2025/1324

8.7.2025

COMMISSION IMPLEMENTING DECISION (EU) 2025/1324

of 7 July 2025

amending Implementing Decision (EU) 2019/1396 as regards certain administrative aspects related to expert panels and as regards the designation of an additional expert panel 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) Article 1 of Commission Implementing Decision (EU) 2019/1396 ([2]) designates expert panels in several medical areas. The tasks of those expert panels are set out in Article 106(9) and (10) of Regulation (EU) 2017/745.

(2) In order to provide scientific and clinical advice in relation to medical devices and *in vitro* diagnostics intended for small size patient populations, such as for patients with a rare disease or for children, an additional expert panel should be designated in that field.

(3) Since 1 March 2022, pursuant to Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council ([3]), the European Medicines Agency, on behalf of the Commission, provides the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745. Implementing Decision (EU) 2019/1396 should therefore be amended to reflect that change.

(4) Experience with the application of Implementing Decision (EU) 2019/1396 has demonstrated the need to adapt some of its technical or administrative aspects, such as the timing of the publication of scientific opinions and the remuneration of experts for the development and review of guidance, common specifications and standards.

(5) The Medical Device Coordination Group has been consulted.

(6) Implementing Decision (EU) 2019/1396 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2019/1396 is amended as follows:

(1) Article 1(1) is amended as follows:

(a) point (11) is replaced by the following:

'(11) *In vitro* diagnostic medical devices (IVD);';

([1]) OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.

([2]) 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 (OJ L 234, 11.9.2019, p. 23, ELI: http://data.europa.eu/eli/dec_impl/2019/1396/oj).

([3]) 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 (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

(b) the following point (12) is added:

'(12) Paediatrics and rare diseases.';

(2) Article 2(6) is replaced by the following:

'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 a specific role or task and for a limited period of time.';

(3) Article 3(1) is replaced by the following:

'1. An expert panel may, in agreement with the Secretariat referred to in Article 10, establish permanent or ad hoc sub-groups entrusted with specific tasks and composed of a certain number of its members.';

(4) Article 8 is amended as follows:

(a) the title is replaced by the following:

'Preparation of opinions, views or advice';

(b) paragraph 1 is replaced by the following:

'1. For each opinion, view or advice under preparation, the Chair of the expert panel or of the sub-group may appoint a rapporteur, a co-rapporteur and reviewers.';

(5) Article 9 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

'On a proposal by the Secretariat referred to in Article 10 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.';

(b) paragraph 3 is replaced by the following:

'3. The Committee shall, in agreement with the Secretariat referred to in Article 10 and the Commission services, update the common rules of procedure when needed.';

(c) paragraph 4 is replaced by the following:

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

(6) in Article 10, paragraphs 1 and 2 are replaced by the following:

'The European Medicines Agency, acting as secretariat for the expert panels in accordance with Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council (*), shall also provide the secretariat for the Committee referred to in Article 7 of this Decision (the "Secretariat").

_____

(*) 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 (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).';

(7) in Article 11, paragraph 2 is replaced by the following:

'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 Secretariat in accordance with the provisions in force at the European Medicines Agency. Those expenses shall be reimbursed within the limits of the available appropriations allocated to the European Medicines Agency under the annual procedure for the allocation of resources.';

(8) Article 12(5) is replaced by the following:

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

(9) Article 14 is amended as follows:

(a) in introductory part, the second sentence is replaced by the following:

'The Secretariat shall, in particular, make the following information available to the public on a dedicated website:';

(b) point (d) is replaced by the following:

'(d) opinions, views and advice in accordance with Article 8.';

(10) Article 15(3) is replaced by the following:

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

(11) the Annex is amended in accordance with the Annex to this Decision.

Article 2

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, 7 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Decision (EU) 2019/1396 is amended as follows:

(1) Table 1 is replaced by the following:

'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	3	3
Rapporteur	1	5	5
Co-rapporteur	1	5	5
Reviewer	N/A	1	1
Advisor assigned for a specific task	N/A	1	1'

(2) Table 2 is replaced by the following:

'Table 2

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

Complexity of task (indicative criteria (*))	Acting as	Remuneration in in full-day equivalents
Category I — 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	Chair/Vice-Chair	2
	Rapporteur	3
	Co-rapporteur	3
	Reviewer	0,5
	Advisor assigned for a specific task	0,5
Category II — 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	Chair/Vice-Chair	3
	Rapporteur	5
	Co-rapporteur	5
	Reviewer	1
	Advisor assigned for a specific task	1

Complexity of task (indicative criteria (*))	Acting as	Remuneration in in full-day equivalents
Category III — 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	Chair/Vice-Chair	4
	Rapporteur	7
	Co-rapporteur	7
	Reviewer	2
	Advisor assigned for a specific task	2
Category IV — contributions 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 12 months to accomplish task	Chair/Vice-Chair	8
	Rapporteur	21
	Co-rapporteur	21
	Reviewer	4
	Advisor assigned for a specific task	4

(*) Each of these criteria may be applied independently'