EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and *in vitro* diagnostic 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) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU[1], and in particular Article 20(1), points (a), (b) and (d), thereof,

Whereas:

(1) Regulation (EU) 2021/2282 lays down a support framework and procedures for cooperation between Member States on health technologies at Union level and establishes the Member State Coordination Group on Health Technology Assessment ('the Coordination Group').

(2) Pursuant to Article 16(1) of Regulation (EU) 2021/2282, the Coordination Group is to carry out joint scientific consultations in order to exchange information with health technology developers on their development plans for a medical device or *in vitro* diagnostic medical device. The aim of such consultations is to facilitate the process of preparing joint clinical assessments for medical devices and *in vitro* diagnostic medical devices, as they will allow health technology developers to obtain guidance from the Coordination Group on the information, data, analyses and other evidence that are likely to be required from clinical studies for the joint clinical assessment of those devices.

(3) In order to ensure sufficient predictability for health technology developers as to their opportunity to engage in joint scientific consultations on medical devices and *in vitro* diagnostic medical devices with the Coordination Group, it is necessary to specify the deadline for the Coordination Group to set the dates of request periods for joint scientific consultation on medical devices and *in vitro* diagnostic medical devices for the subsequent year, as well as the minimum number of such request periods per year. Under Article 6(2), point (b), of Regulation (EU) 2021/2282, the Coordination Group is to set out in its annual work programme the planned number of joint scientific consultations. To allow the health technology developers sufficient time to plan and prepare for joint scientific consultations, the Coordination Group should set the request periods at the latest by the day on which it adopts its annual work programme, that is, by 30 November each year.

[1] OJ L 458, 22.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/2282/oj.

(4) Under Article 30(1) of Regulation (EU) 2021/2282, the Commission is to set up and maintain an IT platform consisting of, *inter alia*, a secure system for the exchange of information between the Coordination Group and its subgroups with health technology developers and experts participating in the joint work ('the HTA IT platform'). The health technology developers should therefore submit the requests for joint scientific consultations, the dossier of information, data, analyses and other evidence for joint scientific consultation on medical devices and *in vitro* diagnostic medical devices including the list of questions ('the briefing package') and any further data through the HTA IT platform. Those requests and dossiers should be presented using the templates set out by the Coordination Group pursuant to Article 21, points (a) and (b), of Regulation (EU) 2021/2282.

(5) Upon request from a health technology developer, joint scientific consultations on medical devices may take place in parallel with the consultation with an expert panel designated in accordance with Article 106(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council[2] ('expert panel'), pursuant to Article 61(2), of that Regulation ('the expert panel consultation'). In order for the subgroup on joint scientific consultations of the Coordination Group ('JSC Subgroup') to be able to identify the requests for joint scientific consultation to be carried out in parallel with the expert panel consultation, the health technology developer should indicate in the request for joint scientific consultation whether, in parallel, it is requesting the expert panel consultation.

(6) Pursuant to Article 28, point (i), of Regulation (EU) 2021/2282, the Commission acting as secretariat of the Coordination Group ('HTA secretariat') is to facilitate the cooperation with the expert panels. Pursuant to Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council[3], the European Medicines Agency is acting as secretariat for the expert panels. The exchange of information with the expert panels on joint scientific consultations on medical devices should therefore take place through the HTA secretariat and the European Medicines Agency acting as secretariat for the expert panels.

(7) The HTA secretariat should share with the European Medicines Agency the list of requests for joint scientific consultation on medical devices for which the health technology developer indicated that it is requesting in parallel the expert panel consultation. The HTA secretariat and the European Medicines Agency should inform each other which of the requests were selected for joint scientific consultation and which ones were accepted for the expert panel consultation.

(8) Where joint scientific consultations on medical devices are conducted in parallel with the expert panel consultation, the HTA secretariat and the European Medicines Agency should exchange the appropriate information to ensure that the parallel consultations have synchronised timing.

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[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/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).

(9) Where pursuant to Article 17(4) of Regulation (EU) 2021/2282, the Coordination Group, via the HTA secretariat, informs the health technology developer that it will engage in the joint scientific consultation, it should also inform the health technology developer of the timetable for the joint scientific consultation, including the deadline to submit the briefing package. To ensure that joint scientific consultations on medical devices that are conducted in parallel with the expert panel consultation have synchronised timing, the timetable should be synchronised with the process for the expert panel consultation.

(10) Requesting expert panel consultation and joint scientific consultation on the clinical development plans is a new process for health technology developers of medical devices and *in vitro* diagnostic medical devices. Therefore, the health technology developers should be able to get assistance for the preparation of a timely and quality briefing package from the assessor and co-assessor for joint scientific consultation appointed pursuant to Article 18(3) of Regulation (EU) 2021/2282 ('the assessor and co-assessor') and from the staff members of the HTA secretariat responsible for providing secretariat support to the JSC Subgroup.

(11) To ensure the effective involvement of patients, clinical experts and other relevant experts ('individual experts') in joint scientific consultation on medical devices and *in vitro* diagnostic medical devices, the HTA secretariat should start their identification as early as possible. Therefore, at the same time as the JSC Subgroup selects medical devices and *in vitro* diagnostic medical devices that are to be subject to joint scientific consultation, the JSC Subgroup should also specify, for each joint scientific consultation, the medical condition, the therapeutic area concerned and other specific expertise, based on which the HTA secretariat is to identify individual experts to be consulted during that joint scientific consultation. To identify the individual experts, the HTA secretariat should consult the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282, the European reference networks for rare and complex diseases and other relevant sources, agencies and organisations. In making the final selection, the JSC Subgroup should give priority to individual experts who have expertise, across several Member States, in the medical condition, therapeutic area or the type of health technology that is the subject of the joint scientific consultation.

(12) The JSC Subgroup, via the HTA secretariat, should share with the selected individual experts the briefing package and should give them the opportunity to provide input on the joint scientific consultation. The HTA secretariat should invite the selected individual experts to the meeting for an exchange of views with the health technology developer referred to in Article 18(7) and (8) of Regulation (EU) 2021/2282. At any time during the joint scientific consultation, the JSC Subgroup should have the possibility to consult stakeholder organisations. In particular, such consultation should entail a more general input on the medical condition and therapeutic area from patient organisations, healthcare professional organisations or clinical and learned societies and should be conducted via the members of the stakeholder network.

(13) In order to ensure that individual experts take part in joint scientific consultation in an independent and transparent manner, free from conflict of interest, they should only be selected and involved in joint scientific consultations after the Commission has

assessed their declared interests, in accordance with Article 5 of Regulation (EU) 2021/2282 and with Article 4 of Commission Implementing Regulation (EU) …/…[4].

(14) To reduce administrative burden and avoid duplication, where joint scientific consultations on medical devices are conducted in parallel with the expert panel consultation, the health technology developer should submit the same documentation to the HTA secretariat and to the expert panel. For this purpose, before establishing the template of the briefing package pursuant to Article 21, point (b), of Regulation (EU) 2021/2282 to be used where the joint scientific consultation is carried out in parallel with the expert panel consultation, the Coordination Group should consult and reach agreement with the European Medicines Agency, in consultation with the expert panels, on the template.

(15) To ensure that joint scientific consultations on medical devices that are conducted in parallel with the expert panel consultation have synchronised timing, the health technology developer should submit the relevant documentation to the HTA secretariat and to the European Medicines Agency at the same time. Moreover, the JSC Subgroup or the Coordination Group and the expert panel should, within the set timetable, approve, issue and submit to the health technology developer the lists of issues, the joint scientific consultation outcome document and the advice letter.

(16) With the view of facilitating the discussion with the health technology developer and consultation of individual experts at the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282, the JSC Subgroup, via the HTA secretariat, should share with the health technology developer the list of issues indicating the topics to be addressed at the meeting and where relevant the specific questions to be addressed only in writing before that meeting ('the list of issues'). The JSC Subgroup should give the health technology developer the opportunity to respond to the list of issues in writing in due time before the meeting.

(17) Where joint scientific consultations on medical devices are conducted in parallel with the expert panel consultation, the HTA secretariat and the European Medicines Agency should exchange the respective lists of issues. The JSC Subgroup and the expert panel should discuss the lists of issues with the health technology developer in one single meeting. It should be specified which parties are to be invited to this joint meeting. The meeting should be held virtually and be co-chaired by the assessor or co-assessor for joint scientific consultation and one of the rapporteurs for the expert panel consultation.

(18) To ensure transparency, traceability and professional secrecy, the documentation related to joint scientific consultations on medical devices and *in vitro* diagnostic medical devices should be sent in a digital format and should be exchanged with and between the Coordination Group, the JSC Subgroup, the HTA Secretariat, the health technology developer, and individual experts during joint scientific consultations through the HTA IT platform.

(19) In accordance with Article 5(1), point (a), of Regulation (EU) 2018/1725 of the European Parliament and of the Council[5], it is necessary to lay down the rules for

[4] Commission Implementing Regulation (EU) …/… of XXX laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member State Coordination Group on Health Technology Assessment and its subgroups (OJ L xx, xx, p. xx, ELI: xx).

processing of personal data for the purposes of conducting joint scientific consultations. In particular, it is necessary to specify the personal data that may be processed, namely certain personal data relating to the individual experts involved in joint scientific consultations and certain personal data relating to the representatives appointed to the Coordination Group and the JSC Subgroup, the representatives of health technology developers and the representatives of the members of the stakeholder network. Where joint scientific consultations on medical devices are conducted in parallel with the expert panel consultation, the Commission should receive from the European Medicines Agency the list of participants involved in the consultation with the expert panel that are invited to the meeting with the health technology developer.

(20) The Commission should be considered the controller of the processing of personal data within the meaning of Article 3, point (8), of Regulation (EU) 2018/1725. Any processing of personal data by the European Medicines Agency and by the members of the Coordination Group and the JSC Subgroup and their representatives outside of the HTA IT platform is to take place in accordance with, respectively, Regulation (EU) 2018/1725 and Regulation (EU) 2016/679 of the European Parliament and of the Council[6].

(21) To ensure the possibility to verify whether joint scientific consultations were conducted in an independent and impartial manner, for example, in the event of complaints or litigation, as well as to ensure the relevant in-depth specialised expertise in joint scientific consultation and to verify compliance with the requirement set out in Article 8(4) of Regulation (EU) 2021/2282 that the assessor and co-assessor for joint clinical assessment are to be different from the assessor and co-assessor for joint scientific consultation, it is necessary to provide for appropriate retention periods with regard to personal data and for their review at regular intervals.

(22) The identity of patients may reveal the patient's health status in relation to the subject matter of the joint scientific consultation and should therefore be considered a special category of personal data under Article 10 of Regulation (EU) 2018/1725. Such data should only be processed where the criteria set out in Article 10(2), point (i), of that Regulation are met. It is necessary to provide for suitable and specific measures to safeguard the rights and freedoms of the patient. In particular, patients should not be obliged to disclose their identity to the health technology developer. Under Article 5(6) of Regulation (EU) 2021/2282, the representatives appointed to the Coordination Group and the JSC Subgroup, as well as individual experts involved in joint scientific consultations, are subject to a requirement of professional secrecy, even after their duties have ceased. In order to ensure protection of personal data and of confidential information it is necessary to provide that only individual experts who have signed confidentiality agreements may be involved in joint scientific consultations.

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5 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 ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

6 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

(23) The Coordination Group was consulted on these procedural rules on 19 September 2024 in accordance with Article 20(1) of Regulation (EU) 2021/2282.

(24) Regulation (EU) 2021/2282 starts to apply on 12 January 2025 and this Regulation should apply from the same date.

(25) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on xx 2024.

(26) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Health Technology Assessment,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down detailed procedural rules for joint scientific consultations carried out pursuant to Articles 16 to 21 of Regulation (EU) 2021/2282, as regards:

(a) submission of requests from health technology developers for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices;

(b) the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts ('individual experts') in joint scientific consultation on medical devices and *in vitro* diagnostic medical devices;

(c) cooperation, in particular by exchange of information, with the expert panels on joint scientific consultations on medical devices where a health technology developer requests the consultation to be carried out in parallel with the expert panel consultation pursuant to Article 17(2) of Regulation (EU) 2021/2282 ('the expert panel consultation').

Article 2
Setting of request periods for joint scientific consultations

1. By 30 November each year, the Coordination Group shall set the dates of request periods for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices for the subsequent year and the planned number of joint scientific consultations for each of those request periods.

2. The Coordination Group shall set at least two request periods for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices per year.

3. By way of derogation from paragraphs 1 and 2, by 31 March 2025, the Coordination Group shall set at least one request period for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices for 2025.

Article 3
Submission of requests for joint scientific consultations

1. Any time during the request period published pursuant to Article 17(3) of Regulation (EU) 2021/2282, a health technology developer may submit a request for a joint scientific consultation on the medical device or *in vitro* diagnostic medical device through the IT platform referred to in Article 30 of that Regulation ('the HTA IT platform').

The request shall follow the template established by the Coordination Group pursuant to Article 21, point (a), of Regulation (EU) 2021/2282.

2. When submitting the request for joint scientific consultation on a medical device, the health technology developer shall indicate whether it is requesting the expert panel consultation to be carried out in parallel.

Article 4

Exchange of information on the selected requests for joint scientific consultation

1. By the end of a request period, the Commission acting as secretariat of the Coordination Group ('HTA secretariat') shall perform the following actions:

   (a) make available through the HTA IT platform the requests for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices complying with the requirements in Article 3(1), second subparagraph, to the subgroup on joint scientific consultations of the Coordination Group ('JSC Subgroup') and indicate for which of those requests relating to medical devices, the expert panel consultation has been requested to be carried out in parallel;

   (b) share with the European Medicines Agency the list of requests for joint scientific consultation on medical devices for which the health technology developer indicated that it is requesting the expert panel consultation to be carried out in parallel.

2. Within 15 working days after the end of each request period, the HTA secretariat shall inform the European Medicines Agency which of the requests referred to in paragraph 1, point (b), were selected for joint scientific consultation and the European Medicines Agency shall inform the HTA secretariat which of the requests for the expert panel consultation to be carried out in parallel, in accordance with paragraph 1, point (b), were accepted for the expert panel consultation.

Article 5

Provision of information to the health technology developer on engagement in joint scientific consultations

1. With regard to joint scientific consultations on medical devices and *in vitro* diagnostic medical devices, the information referred to in Article 17(4) of Regulation (EU) 2021/2282 shall be provided by the JSC Subgroup via the HTA secretariat and shall, where applicable, include a timetable for the joint scientific consultation.

2. Where the joint scientific consultation on medical devices is to be carried out in parallel with the expert panel consultation, the timetable referred to in paragraph 1 of this Article shall be agreed between the HTA secretariat, in consultation with the JSC Subgroup, and the European Medicines Agency, in consultation with the expert panel, and be synchronised with the timing of the process for the expert panel consultation as specified in Article 8(6), points (a) and (e), Article 10(2), point (a), Article 13(2) and Article 14, point (a).

Article 6

Selection of individual experts for joint scientific consultations

1. When selecting medical devices and *in vitro* diagnostic medical devices that are to be subject to joint scientific consultations, the JSC Subgroup shall specify, for each medical device and *in vitro* diagnostic medical device, the following:

   (a) the medical condition;

   (b) the therapeutic area;

   (c) other specific expertise, such as the type of health technology, if needed to carry out the joint scientific consultation.

2. On the basis of the information listed in paragraph 1, the HTA secretariat shall identify individual experts to be consulted during the joint scientific consultation and shall compile a list of relevant individual experts, in consultation with the JSC Subgroup and the assessor and co-assessor for joint scientific consultation appointed pursuant to Article 18(3) of Regulation (EU) 2021/2282 ('the assessor and co-assessor'). When compiling the list, the HTA secretariat may consult one or more of the following:

   (a) the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282;

   (b) the European reference networks for rare and complex diseases and their respective European patient advocacy groups;

   (c) the portal for rare diseases and orphan drugs;

   (d) the national contact points designated in accordance with Article 83(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council[7];

   (e) the European Medicines Agency.

3. Where the consultation of the sources referred to in paragraph 2 has not yielded a sufficient number of relevant individual experts, the HTA secretariat may consult the following for compiling a list of individual experts:

   (a) other databases or directories than the ones listed in paragraph 2;

   (b) members of the Coordination Group and its subgroups;

   (c) relevant Union and international agencies and organisations.

4. After the Commission, in accordance with the rules set out in Article 5 of Regulation (EU) 2021/2282 and Article 4 of Commission Implementing Regulation (EU) …/….[8], has assessed the declared interests of individual experts in the list compiled by the HTA secretariat in accordance with paragraphs 1 to 3 of this Article, the HTA secretariat shall provide the JSC Subgroup with a list of available individual experts.

[7] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).

[8] Commission Implementing Regulation (EU) 2024/xx of xx 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member State Coordination Group on Health Technology Assessment and its subgroups (OJ L …).

5. The JSC Subgroup shall make the final selection of individual experts to be consulted during the joint scientific consultation from the list of individual experts provided ~~to it~~ by the HTA Secretariat in accordance with paragraph 4. In making the final selection, the JSC Subgroup shall give priority to individual experts who have expertise across a number of Member States in the medical condition, the therapeutic area or the type of health technology that is the subject of the joint scientific consultation.

Article 7
Professional secrecy obligations of individual experts

The HTA secretariat shall ensure that only individual experts who have signed a confidentiality agreement are involved in joint scientific consultations on medical devices and *in vitro* diagnostic medical devices.

Article 8
Briefing package and further data for joint scientific consultations

1. The health technology developer shall submit the dossier of information, data, analyses and other evidence for joint scientific consultation pursuant to Article 21, point (b), of Regulation (EU) 2021/2282 including the list of questions ('the briefing package') by means of the template established by the Coordination Group pursuant to Article 21, point (b), of Regulation (EU) 2021/2282 or pursuant to Article 9 of this Regulation through the HTA IT platform.

2. When submitting the request referred to in Article 3(1), the health technology developer may ask for a meeting with the assessor and co-assessor and the staff members of the HTA secretariat responsible for providing secretariat support to the JSC Subgroup to seek assistance relevant for the preparation of the briefing package. The members of the JSC Subgroup shall be invited to that meeting.

3. The deadline to submit the briefing package shall be set in the timetable referred to in Article 5(1). The HTA secretariat shall make available through the HTA IT platform the briefing package complying with the requirements in paragraph 1 to the assessor and co-assessor and the JSC Subgroup.

4. Where the assessor or the co-assessor considers that further specifications or clarifications or additional information, data, analyses or other evidence are necessary in the briefing package, or that one or several questions submitted by the health technology developer are out of scope of joint scientific consultation, the HTA secretariat shall request the health technology developer to submit an amended briefing package within the deadline set in the timetable referred to in Article 5(1).

5. Where the assessor or the co-assessor, at any time during the preparation of the draft joint scientific consultation outcome document considers that further specifications or clarifications or additional information, data, analyses or other evidence are necessary, the HTA secretariat shall request the health technology developer to provide such information, data, analyses or evidence within the deadline set by the assessor and co-assessor.

6. In addition to the rules set out in paragraphs 1 to 5, where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, the following shall apply:

(a) the health technology developer shall submit the briefing package containing the information necessary for the joint scientific consultation on medical devices and for the expert panel consultation at the same time to the HTA secretariat and European Medicines Agency, by the deadline set in the timetable referred to in Article 5(1);

(b) one of the rapporteurs for the expert panel consultation and a staff member of the European Medicines Agency responsible for providing secretariat support to the expert panel shall participate in the meeting referred to in paragraph 2;

(c) advisors of the expert panel involved in the consultation shall be invited to this meeting;

(d) the HTA secretariat and the European Medicines Agency shall exchange their respective requests to submit an amended briefing package, if any, at the same time as they send these requests to the health technology developer;

(e) the health technology developer shall submit the amended briefing package at the same time to the HTA secretariat and the European Medicines Agency, by the deadline set in the timetable referred to in Article 5(1);

(f) the HTA secretariat and the European Medicines Agency shall exchange with each other confirmation of receipt of the briefing package referred to in points (a) and (e) at the same time as they send confirmation of receipt to the health technology developer;

(g) the European Medicines Agency shall notify the HTA secretariat of the validation by the expert panel of the application for the consultation with the expert panel;

(h) the HTA secretariat shall notify the European Medicines Agency of the acceptance of the briefing package for joint scientific consultation by the JSC Subgroup;

(i) the health technology developer shall submit the information, data, analyses or other evidence referred to in paragraph 5 at the same time to the HTA secretariat and the expert panel.

Article 9

Establishment of the template of the briefing package where the joint scientific consultation is carried out in parallel with the expert panel consultation

The Coordination Group shall, after consulting and reaching agreement with the European Medicines Agency, in consultation with the expert panels, establish a specific template of the briefing package to be used where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation.

Article 10

List of issues to be discussed in the meeting for an exchange of views

1. After having assessed the briefing package and where applicable the documentation referred to in Article 8(5), the JSC Subgroup, via the HTA secretariat, shall share with the health technology developer the list of issues indicating the topics to be addressed at the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282 and where relevant the specific questions to be addressed only in writing before that meeting (‘the list of issues’). The health technology developer shall provide the JSC

Subgroup, via the HTA secretariat, with written responses, if any, to the list of issues as well as any necessary materials or presentations for the meeting at the latest 10 days before that meeting.

2. In addition to the rules set out in paragraph 1, where the joint scientific consultation is carried out in parallel with the expert panel consultation, the following shall apply:

   (a) the JSC Subgroup, via the HTA secretariat, and the expert panel shall send their respective lists of issues to the health technology developer within the deadline set in the timetable referred to in Article 5(1);

   (b) the HTA secretariat and the European Medicines Agency shall exchange with each other the lists of issues on the same day as sending them to the health technology developer;

   (c) the health technology developer shall send to the JSC Subgroup, via the HTA secretariat, a copy of their written responses, if any, to the list of issues provided by the expert panel at the same time as it sends those responses to the European Medicines Agency;

   (d) the health technology developer shall send to the European Medicines Agency a copy of their written responses, if any, to the list of issues provided by the JSC Subgroup at the same time as it sends those responses to the HTA secretariat.

Article 11

Input of individual experts on joint scientific consultation

No later than 30 days after the submission of the amended briefing package referred to in Article 8(4) or, where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, no later than 30 days after the validation of the application referred to in Article 8(6), point (g), the JSC Subgroup, via the HTA secretariat, shall share the briefing package with the individual experts selected in accordance with Article 6 and give them the opportunity to provide input on the joint scientific consultation.

Article 12

Consultation of stakeholder organisations during joint scientific consultation

1. At any time during the joint scientific consultation, the JSC Subgroup, via the HTA secretariat, may seek input on the medical condition, therapeutic area or other areas relevant for the medical device or *in vitro* diagnostic medical device from patient organisations, healthcare professional organisations or clinical and learned societies via the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282.

2. Where the joint scientific consultation on medical devices is carried out in parallel with the expert panel consultation, the HTA secretariat shall share the input referred to in paragraph 1 with the European Medicines Agency at the same time as sharing it with the JSC Subgroup.

Article 13

Meeting with the health technology developer

1. The following participants shall be invited to the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282:

(a) the representatives of the heath technology developer;

(b) the assessor and co-assessor;

(c) individual experts selected in accordance with Article 6;

(d) other representatives of the JSC Subgroup than the ones listed in point (b);

(e) the staff members of the HTA secretariat responsible for providing secretariat support to the JSC Subgroup.

2. In addition to the participants listed in paragraph 1, where the joint scientific consultation is carried out in parallel with the expert panel consultation, the following participants shall be invited to the meeting as referred to in Article 18(8) of Regulation (EU) 2021/2282:

(a) the advisors of the expert panel involved in the expert panel consultation;

(b) the staff members of the European Medicines Agency providing secretariat support to the expert panel.

On request from the European Medicines Agency, patients selected in accordance with the relevant rules of the European Medicines Agency to participate during the consultation with the expert panels may be invited to the meeting for an exchange of views.

3. The meeting referred to in paragraph 2 shall be held virtually. It shall be co-chaired by the assessor or co-assessor and one of the rapporteurs for the expert panel consultation.

4. Before the meeting referred to in paragraph 2, the European Medicines Agency shall send to the HTA secretariat the list of meeting participants who are to be invited to the meeting in accordance with paragraph 2.

Article 14

Joint scientific consultation outcome document for joint scientific consultations carried out in parallel with the expert panel consultations

Where the joint scientific consultation is carried out in parallel with the expert panel consultation, the following shall apply:

(a) the Coordination Group shall approve the joint scientific consultation outcome document and the expert panel shall issue the advice letter to the health technology developer within the deadline set in the timetable referred to in Article 5(1);

(b) the HTA secretariat and the European Medicines Agency shall exchange with each other the outcome document approved by the Coordination Group and the advice letter issued by the expert panel on the same day as sending them to the health technology developer.

Article 15

Correspondence during joint scientific consultations

Any documentation referred to in Regulation (EU) 2021/2282 and in this Regulation shall be sent in a digital format and shall be exchanged with and between the Coordination Group, the JSC Subgroup, the HTA Secretariat, the health technology developer and individual experts during joint scientific consultations on medical devices and *in vitro* diagnostic medical devices through the HTA IT platform.

Article 16
Personal data processing

1. The Commission shall be the controller of the processing of personal data collected for the purpose of conducting joint scientific consultations on medical devices and *in vitro* diagnostic medical devices under this Regulation.

2. The categories of personal data necessary for the purpose referred to in paragraph 1 are:

   (a) the identity, email address and affiliation of the representatives appointed to the Coordination Group and the JSC Subgroup;

   (b) the identity and email address of individual experts in any of the following cases:

      (i) they are identified as relevant for joint scientific consultation;

      (ii) they are selected to be consulted in a joint scientific consultation;

      (iii) they are consulted in a joint scientific consultation;

   (c) the identity, email address and affiliation of the representatives of health technology developers;

   (d) the identity, email address and affiliation of the representatives of the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282;

   (e) the identity, email address and affiliation of participants involved in the expert panel consultation referred to in Article 13(2) that are to be invited to the meeting with the health technology developer.

3. The representatives appointed to the Coordination Group and the JSC Subgroup shall have access only to the parts of the secure system of the HTA IT platform that are relevant for the performance of their tasks. Representative**s** may collaborate, through the HTA IT platform, with other representatives appointed to the Coordination Group, or the JSC Subgroup to which they belong, for the purposes of conducting joint scientific consultations on medical devices and *in vitro* diagnostic medical devices.

4. During the meeting referred to in Article 13, patients shall not be obliged to disclose their identity to the health technology developer.

5. The Commission shall keep the personal data referred to in paragraph 2 only for as long as necessary for the purpose referred to in paragraph 1 and no longer than 15 years after the date on which the data subject no longer participates in joint scientific consultation. The Commission shall review the necessity of storing the personal data every 2 years.

   The Commission shall keep the personal data of individual experts not selected to be consulted in a joint scientific consultation only for as long as necessary in order to ensure the relevant in-depth specialised expertise in joint scientific consultation and no longer than 3 years after the date on which the Commission received this data.

Article 17
Entry into force and date of application

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

It shall apply from 12 January 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN