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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medical devices and *in vitro* diagnostic medical devices at Union level, as well as templates for those joint clinical assessments

(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.

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(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/EU¹, and in particular Article 15(1), points (b) and (c), Article 25(1), point (b), and Article 26(1) thereof,

Whereas:

- (1) Pursuant to Article 7(4) of Regulation (EU) 2021/2282, the Commission, after seeking a recommendation from the Member State Coordination Group on Health Technology Assessment established under Article 3 of that Regulation (“the Coordination Group”), is to adopt a decision, by means of an implementing act and at least every two years selecting for joint clinical assessment medical devices and *in vitro* diagnostic medical devices (“medical devices”). The Commission is to select those devices from the medical devices for which the relevant expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council² (“the expert panels”) provided a scientific opinion or their views.
- (2) Pursuant to Commission Implementing Regulation (EU) 2024/2699³, the European Medicines Agency is to provide the Commission acting as secretariat of the Coordination Group (“the HTA secretariat”) with information on all medical devices for which the expert panels provided a scientific opinion or their views no later than 15 days after the end of each quarter, pertaining to that quarter.

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

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 Commission Implementing Regulation (EU) 2024/2699 of 18 October 2024 laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and *in vitro* diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices (OJ L, 2024/2699, 21.10.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2699/oj).

- (3) Due to confidentiality related to the medical devices' certification process, the adoption of the Commission decision selecting medical devices for joint clinical assessment can only be launched after the certification process of the medical device is completed.
- (4) At the same time, in order to prevent the duplication of assessments on the same medical device by the Coordination Group and by Member States' health technology assessment authorities and bodies, joint clinical assessment of those devices should start as soon as the device is certified under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 of the European Parliament and of the Council⁴, as applicable. Therefore, first, upon the adoption of the recommendation of the Coordination Group, the HTA secretariat should inform the health technology developers of medical devices recommended by the Coordination Group to be selected for joint clinical assessment of that recommendation, and the reasons thereof. This will also allow for adequate preparation for health technology developers for the upcoming joint clinical assessment. Second, the notified bodies designated in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746 ('the notified bodies') should be required to inform the HTA secretariat of the results of the certification process of the medical devices covered in the recommendation of the Coordination Group. Finally, upon the granting of the certificate of conformity by the notified body, the health technology developers should be invited to submit to the HTA secretariat the information necessary for the development of the assessment scope provided for in Article 8(6) of Regulation (EU) 2021/2282 ('the assessment scope').
- (5) Where the Commission in its decision adopted by means of an implementing act selects for joint clinical assessment medical devices which were not recommended to be selected for joint clinical assessment by the Coordination Group, the health technology developers of those devices should provide information necessary for the development of the assessment scope.
- (6) It is necessary to ensure legal certainty for health technology developers of medical devices which the Coordination Group or its relevant subgroup considered in the preparation of its recommendation, but which it did not recommend to be selected for joint clinical assessment. Therefore, the HTA secretariat should also inform the health technology developers of such medical devices that the Coordination Group did not recommend to select those devices for joint clinical assessment.
- (7) In order to ensure the cooperation, in particular by exchange of information, of the Coordination Group with the expert panels on the preparation and update of joint clinical assessments of medical devices, in particular as regards the application of the selection criteria listed in Article 7(4) of Regulation (EU) 2021/2282, the HTA secretariat should inform the expert panels of the recommendation of the Coordination Group. Pursuant to Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council⁵, the European Medicines Agency is acting as secretariat for those expert panels. Therefore, the exchange of information between the

⁴ 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, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>).

⁵ 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>).

Coordination Group and the expert panels should be conducted via the HTA secretariat and the European Medicines Agency.

- (8) In light of the tasks of the HTA secretariat set out in Regulation (EU) 2021/2282, the exchange of information with the health technology developers, notified bodies, patients, clinical experts and other relevant experts ('individual experts') and Member States on the preparation and update of joint clinical assessments should take place through the HTA secretariat. The HTA secretariat should ensure that all the information it receives is communicated to the Coordination Group, the subgroup of the Coordination Group on joint clinical assessments ('the JCA Subgroup') and assessor and co-assessor for joint clinical assessment appointed pursuant to Article 8(4) of Regulation (EU) 2021/2282 ('the assessor and co-assessor'), as appropriate, upon receipt of that information.
- (9) To ensure the right to good administration, the health technology developer should be informed of the start of the scoping process, of the steps of the joint clinical assessment, of its update, as well as of its re-initiation under Article 10(7) of Regulation (EU) 2021/2282. The health technology developer should also be informed of the decision of the Coordination Group to include the update of the joint clinical assessment in its annual work programme, pursuant to Article 14 of Regulation (EU) 2021/2282.
- (10) To ensure the effective involvement of individual experts in joint clinical assessment of medical devices, the JCA Subgroup should specify the information necessary for their identification as early as possible, whenever the Coordination Group recommends selecting a medical device for joint clinical assessment. The HTA secretariat should identify individual experts on the basis of that information.
- (11) To identify individual experts with relevant in-depth specialised expertise, the HTA secretariat should be able to 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 order to ensure the highest scientific quality of the joint clinical assessment, in making the final selection, the JCA Subgroup should give priority to individual experts who have expertise, across several Member States, in the medical condition to be treated, therapeutic area, the type of health technology that is the subject of the joint clinical assessment or other specific expertise. These experts should be consulted during the joint clinical assessment.
- (12) To ensure that individual experts take part in joint clinical assessments in an independent and transparent manner, free from conflict of interest, they should only be selected and involved in joint clinical assessments after the Commission has assessed their declared interests, in accordance with Article 5(5) of Regulation (EU) 2021/2282 and with Article 4 of Commission Implementing Regulation (EU) 2024/2745⁶.
- (13) In order to ensure the transparency and appropriate involvement of stakeholder organisations in its work, the JCA Subgroup may give the opportunity to patient

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⁶ Commission Implementing Regulation (EU) 2024/2745 of 25 October 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, 2024/2745, 28.10.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2745/oj).

organisations, healthcare professional organisations and clinical and learned societies to provide their input on joint clinical assessments.

- (14) To achieve the objective that, during the development of the assessment scope, Member States' needs are translated in the lowest possible number of sets of parameters for the joint clinical assessment in terms of patient population, intervention, comparators and health outcomes, the assessor, with the assistance of the co-assessor, should prepare an assessment scope proposal that will serve as a basis for Member States to express their needs.
- (15) To ensure that the assessment scope is inclusive and reflects Member States' needs, the assessment scope proposal prepared by the assessor, with the assistance of the co-assessor, should be shared with the members of the JCA Subgroup.
- (16) It should be ensured that the assessment scope is developed respecting the right to good administration and taking into account information provided by the health technology developer and input received from individual experts.
- (17) Deadlines should be set for the finalisation of the assessment scope and of the draft joint clinical assessment reports by the JCA Subgroup with the aim of ensuring the timely availability of joint clinical assessment reports of medical devices. In order to maximise available resources, the assessment scope should only be finalised by the JCA Subgroup after the adoption of the Commission decision selecting the medical device for joint clinical assessment. Where the Commission decision does not select a medical device recommended to be selected for joint clinical assessment by the Coordination Group, the scoping process should be discontinued.
- (18) To contribute to the completeness and high quality of the dossier and the smooth conduct of the joint clinical assessment, the health technology developer should be able to request an assessment scope explanation meeting with the JCA Subgroup.
- (19) In order to ensure high quality of the dossier for joint clinical assessment and of the joint clinical assessment report, as well as to ensure the protection of confidential data for commercial reasons, deadlines should be set giving sufficient time to the health technology developer to prepare and submit that dossier and to take the following actions: (a) provide missing information, data, analysis and other evidence as indicated in the Commission's second request referred to in Article 10(5) of Regulation (EU) 2021/2282; (b) provide further specifications or additional information, data, analyses, or other evidence as provided for in Article 11(2) of Regulation (EU) 2021/2282; (c) provide updates to previously provided information referred to in Articles 10(8) of Regulation (EU) 2021/2282; (d) signal technical or factual inaccuracies in the draft joint clinical assessment and summary reports and any information considered as confidential.
- (20) In order to ensure good administration and timely availability of joint clinical assessment reports of medical devices, deadlines should be set for the Commission's assessment on whether the dossier submitted by the health technology developer for joint clinical assessment of the medical device meets the requirements laid down in Article 9(2), (3) and (4), of Regulation (EU) 2021/2282. In order to ensure the smooth conduct of joint clinical assessment, the Commission should consult, as appropriate, the assessor and co-assessor when carrying out the assessment.
- (21) To ensure the highest scientific quality of the joint clinical assessment, individual experts should be involved in the joint clinical assessment process by being given the

opportunity to provide input on the draft joint clinical assessment and summary reports.

- (22) Article 11(2) of Regulation (EU) 2021/2282 requires the health technology developer to proactively inform the Coordination Group where new clinical data becomes available during the joint clinical assessment process. In order to ensure, on the one hand, the smooth conduct of the joint clinical assessment and the compliance with the deadlines for the finalisation of the joint clinical assessment report and, on the other hand, legal certainty for the health technology developer, the deadline should be set where the JCA Subgroup is to ensure that the new clinical data received by that date are considered in the draft joint clinical assessment and summary reports.
- (23) In order to ensure the delivery of joint clinical assessment reports in a timely manner, deadlines should be set for finalising the revised draft joint clinical assessment and summary reports by the JCA Subgroup and for endorsing the revised draft joint clinical assessment and summary reports by the Coordination Group.
- (24) Article 10(7) and Article 14 of Regulation (EU) 2021/2282 provide respectively for the re-initiation and update of a joint clinical assessment. In order to ensure the effective application of these provisions, it is necessary to adopt certain detailed procedural rules and deadlines that should apply in those instances.
- (25) In order to ensure transparency, traceability and professional secrecy, as well as to contribute to the procedural compliance of joint clinical assessment reports, any documentation referred to in Regulation (EU) 2021/2282 and this Regulation should be sent in a digital format and should be exchanged during joint clinical assessments of medical devices with and between the Coordination Group, the JCA Subgroup, the HTA secretariat, the health technology developer and individual experts through the IT platform referred to in Article 30 of Regulation (EU) 2021/2282 ('the HTA IT platform').
- (26) In order to ensure transparency, on the one hand, and the protection of confidential data for commercial reasons, on the other hand, the joint clinical assessment and the summary reports, together with the documentation referred to in Article 30(3), points (d) and (i), of Regulation (EU) 2021/2282, should be published, after having considered the views of the JCA Subgroup as to the commercially sensitive nature of the information contained in that documentation, which the health technology developer has requested to be treated as confidential.
- (27) This Regulation lays down, in accordance with Article 5(1), point (a), of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷, the rules for processing of personal data for the purposes of conducting joint clinical assessments of medical devices and their updates. In particular, it specifies the personal data that may be processed, namely certain personal data relating to the individual experts involved in joint clinical assessments and their updates and certain personal data relating to the representatives appointed to the Coordination Group and the JCA Subgroup, the representatives of health technology developers and the representatives of the

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 (OJ L 295, 21.11.2018, p. 39, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).

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

- (28) To ensure the processing of personal data for the purposes of conducting joint clinical assessments of medical devices and their updates, the Commission should be considered the controller of that processing within the meaning of Article 3, point (8), of Regulation (EU) 2018/1725. Any processing of personal data by the members of the Coordination Group and the JCA Subgroup and their representatives outside of the HTA IT platform is to take place in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council⁸.
- (29) The identity of the patient may reveal the patient's health status in relation to the subject matter of the joint clinical assessment 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, no personal data of patients should be made publicly available. Moreover, under Article 5(6) of Regulation (EU) 2021/2282, the representatives appointed to the Coordination Group and the JCA Subgroup, as well as individual experts involved in joint clinical assessments and their updates, are subject to a requirement of professional secrecy, even after their duties have ceased. 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 clinical assessments and their updates.
- (30) To ensure the possibility to verify whether the joint clinical assessments were conducted in the procedurally compliant manner, notably in the event of complaints or litigation, it is appropriate to provide for a retention period of personal data and for its review at regular intervals. To ensure the relevant in-depth specialised expertise in joint clinical assessment, for example, in the event where the selected individual experts step down from their roles and responsibilities, it is appropriate to provide for a retention period of personal data of individual experts not selected to take part in a joint clinical assessment.
- (31) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on xx 2025.
- (32) The measures provided for in this Regulation are in accordance with the opinion of the committee referred to in Article 33(1) of Regulation (EU) 2021/2282,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down detailed procedural rules for joint clinical assessments of medical devices and *in vitro* diagnostic medical devices ('medical devices') at Union level, as regards:

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⁸ 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>).

- (a) cooperation of the Member State Coordination Group on Health Technology Assessment established under Article 3 of Regulation (EU) 2021/2282 ('the Coordination Group') and the Commission acting as secretariat of the Coordination Group ('the HTA secretariat') with the notified bodies designated in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746 ('the notified bodies') and with the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 ('the expert panels') in the form of exchange of information as regards the preparation and update of joint clinical assessments;
- (b) interaction, including the timing thereof, with and between the Coordination Group, its subgroups and health technology developers, patients, clinical experts and other relevant experts ('individual experts') during joint clinical assessments and their updates;
- (c) general procedural rules on the selection and consultation of stakeholder organisations and individual experts in joint clinical assessments;
- (d) the format and templates for dossiers with information, data, analyses and other evidence to be provided by health technology developers for joint clinical assessments;
- (e) the format and templates for joint clinical assessment reports and summary reports.

Article 2

Provision of information to the health technology developers on the selection of medical devices for joint clinical assessment

1. Upon the adoption by the Coordination Group of the recommendation referred to in Article 7(4) of Regulation (EU) 2021/2282, the HTA secretariat shall take the following actions:
 - (a) inform the health technology developers of the medical devices for which, during the period covered in the recommendation, the relevant expert panels provided a scientific opinion or their views as referred to in Article 7(1), points (c) and (d), of Regulation (EU) 2021/2282, whether or not the Coordination Group recommended to select their medical device for joint clinical assessment. Where the Coordination Group recommended to select their medical device for joint clinical assessment, the HTA secretariat shall also inform the health technology developers of the reasons for that recommendation;
 - (b) invite the health technology developers of the medical devices recommended by the Coordination Group to be selected for joint clinical assessment to submit the information listed in Article 3(1) of this Regulation.
2. Where the Commission in its decision referred to in Article 7(4) of Regulation (EU) 2021/2282 selects for joint clinical assessment medical devices not recommended to be selected by the Coordination Group, the HTA secretariat shall without delay inform the health technology developers of those medical devices thereof and shall request the health technology developers of those devices to submit the information listed in Article 3(1) of this Regulation.

The health technology developers shall provide the requested information within 5 days from the later one of the following events:

- (a) granting of the certificate of conformity by the notified body;

- (b) receipt of the request from the HTA secretariat.

Article 3

Provision of information by the health technology developer upon the certification of the device

1. The HTA secretariat shall invite the health technology developer of a medical device that was recommended by the Coordination Group to be selected for joint clinical assessment in the recommendation referred to in Article 7(4) of Regulation (EU) 2021/2282 to provide the HTA secretariat with the following information:
 - (a) the certificate of conformity referred to in Article 56 of Regulation (EU) 2017/745 or Article 51 of Regulation (EU) 2017/746, as applicable;
 - (b) the instructions for use referred to in Section 23.4 of Annex I to Regulation (EU) 2017/745 or Section 20.4.1 of Annex I to Regulation (EU) 2017/746, as applicable.
2. The HTA secretariat shall invite the health technology developer to provide the information listed in paragraph 1 within 5 days from the later one of the following events:
 - (a) granting of the certificate of conformity by the notified body;
 - (b) receipt of the request from the HTA secretariat referred to in Article 2(1), point (b).
3. If the subgroup of the Coordination Group on joint clinical assessments ('the JCA Subgroup') considers it necessary, the HTA secretariat shall invite the health technology developer to provide other information than the information listed in paragraph 1 necessary for the development of the assessment scope. The JCA Subgroup shall specify in the invitation whether the health technology developer is invited to provide that information in a meeting with the JCA Subgroup or in writing.

Article 4

Exchange of information with the notified body

1. At the same time as it sends the information referred to in Article 2(1) to the health technology developer of the medical device, the HTA secretariat shall inform the notified body responsible for the conformity assessment of that device whether the Coordination Group recommended to select the medical device for joint clinical assessment. Where the Coordination Group recommended to select the medical device for joint clinical assessment, the HTA secretariat shall also inform the notified body of the reasons for that recommendation.

At the same time as it sends the information referred to in Article 2(2) to the health technology developer of the medical device, the HTA secretariat shall inform the notified body that granted the certificate of conformity of the selection of that device for joint clinical assessment.
2. Regarding the medical devices which the Coordination Group recommends to be selected for joint clinical assessment, the notified body shall inform the HTA secretariat of the following:
 - (a) the granting of the certificate of conformity to the device;
 - (b) the refusal of the certification of the device;

- (c) the withdrawal by the health technology developer of the application for certification for the device.

The notified body shall provide the information referred to in the first subparagraph within 5 days from any of the following events:

- (a) the granting of the certificate of conformity;
- (b) the refusal of the certification;
- (c) the withdrawal of the application for certification;
- (d) the receipt of the information from the HTA secretariat referred to in paragraph 1, if at the time of that receipt the certificate of conformity had been granted or refused or the health technology developer had withdrawn the application for certification.

3. At the request of the HTA secretariat, the notified body shall communicate to the HTA secretariat by the deadline indicated in the request the information listed in Article 3(1) where that information was not obtained directly from the health technology developer and cannot be obtained from other sources available to the HTA secretariat.

Article 5

Provision of information to the expert panels

At the same time as it sends the information referred to in Article 2(1) to the health technology developer of the medical device, the HTA secretariat shall inform, via the European Medicines Agency, the expert panel that provided its scientific opinion or its views of the recommendation of the Coordination Group. Where the Coordination Group recommended to select the medical device for joint clinical assessment, the HTA secretariat shall also inform the expert panel of the reasons for that recommendation.

At the same time as it sends the information referred to in Article 2(2) to the health technology developer of the medical device, the HTA secretariat shall inform, via the European Medicines Agency, the expert panel that provided its scientific opinion or its views of the selection of the device for joint clinical assessment.

Article 6

Provision of information to the Coordination Group

The HTA secretariat shall ensure that all the information received from the health technology developer, the notified body, individual experts and Member States related to joint clinical assessments and updates of joint clinical assessments is communicated to the Coordination Group, to the JCA Subgroup and to the assessor and co-assessor for joint clinical assessment appointed pursuant to Article 8(4) of Regulation (EU) 2021/2282 ('the assessor and co-assessor'), as appropriate, without delay upon receipt of that information.

Article 7

Provision of information to the health technology developer about the start of the scoping process

Upon the appointment by the JCA Subgroup of an assessor and a co-assessor, the HTA secretariat shall inform without delay the health technology developer of the start of the scoping process.

Article 8
Selection of individual experts for joint clinical assessments

1. Without due delay after the adoption by the Coordination Group of the recommendation referred to in Article 7(4) of Regulation (EU) 2021/2282, the JCA Subgroup shall specify, for each medical device, the following information:
 - (a) the medical condition to be treated;
 - (b) the therapeutic area;
 - (c) other specific expertise of individual experts, if needed to carry out the joint clinical assessment, including, where needed, the expertise on the type of medical device under assessment.
2. On the basis of the information listed in paragraph 1, the HTA secretariat shall identify individual experts to be consulted during the joint clinical assessment and shall compile a list of relevant individual experts, in consultation with the JCA Subgroup and the assessor and co-assessor. When compiling the list, the HTA secretariat may consult one or more of the following sources of information:
 - (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 of Regulation (EU) No 536/2014 of the European Parliament and of the Council⁹;
 - (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 sources 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 has assessed, in accordance with the rules set out in Article 5(5) of Regulation (EU) 2021/2282 and Article 4 of Implementing Regulation (EU) 2024/2745, the declared interests of individual experts in the list compiled by the HTA secretariat in accordance with paragraphs 1, 2 and 3 of this Article, the HTA secretariat shall provide the JCA Subgroup with a list of available individual experts.
5. The JCA Subgroup shall make the final selection of individual experts to be consulted during the joint clinical assessment from the list of individual experts provided by the HTA secretariat in accordance with paragraph 4. In making the final selection, the JCA Subgroup shall give priority to individual experts who have expertise across a number of Member States in the medical condition, the therapeutic

⁹ 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>).

area or the type of health technology that is the subject of the joint clinical assessment.

Article 9

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 clinical assessments of medical devices.

Article 10

Consultation of stakeholder organisations during joint clinical assessments

At specific steps and timeframes during the joint clinical assessment which the JCA Subgroup considers to be appropriate, it may give the opportunity to 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 to provide input on any of the following matters:

- (a) medical condition;
- (b) therapeutic area;
- (c) medical device under assessment;
- (d) comparator health technologies;
- (e) other areas relevant for the joint clinical assessment of the medical device.

The input referred to in the first subparagraph shall be sought, and provided, via the HTA secretariat.

Article 11

Assessment scope proposal

1. The assessor, with the assistance of the co-assessor, shall prepare an assessment scope proposal with a set of the parameters for the joint clinical assessment in terms of patient population, intervention, comparators, and health outcomes, taking into account the information provided by the health technology developer in accordance with Article 3(1).

When preparing the assessment scope proposal, the assessor and the co-assessor shall consult the scientific consultation outcome document, if the medical device had been subject to the joint scientific consultation carried out pursuant to Articles 16 to 21 of Regulation (EU) 2021/2282. The HTA secretariat shall make that document available to the entire JCA Subgroup.

When preparing the assessment scope proposal, the assessor and the co-assessor shall have access to the relevant scientific opinion or the views of the expert panel that was shared with the HTA secretariat pursuant to Article 3(1) of Implementing Regulation (EU) 2024/2699. The HTA secretariat shall make that opinion or those views available to the entire JCA Subgroup.

At any time during the preparation of the assessment scope proposal, the assessor and co-assessor may seek, via the HTA secretariat, input on the assessment scope from the individual experts selected in accordance with Article 8. The HTA secretariat shall make that input available to the entire JCA Subgroup.

2. The HTA secretariat shall share the assessment scope proposal with the members of the JCA Subgroup. Based on the input received from the members of the JCA Subgroup, the assessor, with the assistance of the co-assessor, shall prepare a consolidated assessment scope proposal reflecting the Member States' needs.
3. Upon the preparation by the assessor, with the assistance of the co-assessor, the consolidated assessment scope proposal, the HTA secretariat shall share that proposal with the individual experts selected in accordance with Article 8 and shall give them the opportunity to provide input.

Article 12

Finalisation of the assessment scope

1. The JCA Subgroup shall discuss the consolidated assessment scope proposal referred to in Article 11(2), as well as the input of individual experts referred to in Article 11(3), during an assessment scope consolidation meeting. The JCA Subgroup, via the HTA secretariat, may invite individual experts to provide their input during a dedicated part of the assessment scope consolidation meeting.
2. The JCA Subgroup shall finalise the assessment scope at the latest 60 days after the receipt of the information listed in Article 3(1), or 10 days after the adoption of the Commission decision selecting that medical device for joint clinical assessment, whichever is later.
3. The HTA secretariat shall share the assessment scope finalised by the JCA Subgroup with the health technology developer in the Commission's first request referred to in Article 10(1) of Regulation (EU) 2021/2282.

Article 13

Assessment scope explanation meeting

Upon request of the health technology developer, the HTA secretariat shall invite the health technology developer to an assessment scope explanation meeting with the JCA Subgroup. The meeting shall take place no later than 20 days from the day on which the JCA Subgroup finalises the assessment scope.

Article 14

Dossier and additional data for joint clinical assessment to be provided by the health technology developer

1. The health technology developer shall submit the dossier for joint clinical assessment of the medical device, requested by the Commission in its first request referred to in Article 10(1) of Regulation (EU) 2021/2282, to the HTA secretariat in a digital format. The health technology developer shall submit for joint clinical assessment of the medical device, and its update, the dossier, as well as any additional information, data, analyses and other evidence in accordance with the template set out in Annex I for medical devices and in Annex II for *in vitro* diagnostic medical devices.
2. The deadline to submit the dossier referred to in paragraph 1 shall be 100 days from the date of the notification of the first request to the health technology developer.
3. The health technology developer shall submit the missing information, data, analyses and other evidence indicated in the Commission's second request referred to in Article 10(5) of Regulation (EU) 2021/2282 within 15 days from the date of

notification of the Commission's second request to the health technology developer. However, that deadline shall be 7 days where only minor information is missing.

4. Where the assessor, with the assistance of the co-assessor, at any time during the preparation of the draft joint clinical assessment and summary reports, considers, in accordance with Article 11(2) of Regulation (EU) 2021/2282, 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 other evidence within the deadline set by the assessor and co-assessor depending on the nature of the information requested. That deadline shall be set at minimum 7 days and maximum 30 days counting from the date of notification of the request to the health technology developer.
5. Where the Coordination Group decides to re-initiate a joint clinical assessment pursuant to Article 10(7) of Regulation (EU) 2021/2282, the health technology developer shall submit, upon request of the HTA secretariat, updates of previously provided information, data, analyses and other evidence pursuant to Article 10(8) of Regulation (EU) 2021/2282 within the deadline set by the assessor and co-assessor depending on the nature of the information, data, analyses or other evidence requested. That deadline shall be set at a minimum 7 days and maximum 30 days counting from the date of notification of the request to the health technology developer.
6. Once the HTA secretariat receives the dossier and further data submitted by the health technology developer pursuant to paragraphs 1 to 5, it shall make the dossier and these data available to the assessor, co-assessor and the JCA Subgroup at the same time.

Article 15

Commission's confirmation of the dossier for a joint clinical assessment

Within 15 working days from the date on which the health technology developer submitted the dossier, and as appropriate in consultation with the assessor and co-assessor, the Commission shall confirm whether, based on the information available at the time, the dossier for a joint clinical assessment of the medical device meets the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282.

Article 16

Draft joint clinical assessment and summary reports

1. The assessor, with the assistance of the co-assessor, shall prepare the draft joint clinical assessment reports using the template set out in Annex III for medical devices and the template set out in Annex IV for *in vitro* medical devices, and summary reports using the template set out in Annex V. At any time during the preparation of the draft joint clinical assessment and summary reports, the assessor and co-assessor, via the HTA secretariat, may seek input from the individual experts selected in accordance with Article 8. The HTA secretariat shall make that input available to the entire JCA Subgroup without delay.
2. The HTA secretariat shall share the draft joint clinical assessment and summary reports prepared by the assessor, with the assistance of the co-assessor, for comments with the JCA Subgroup without delay. After having considered the comments from

the members of the JCA Subgroup and any input from the individual experts referred to in paragraph 1, the assessor, with the assistance of the co-assessor, shall prepare the revised draft joint clinical assessment and summary reports.

3. The HTA secretariat shall share the revised draft joint clinical assessment and summary reports with the individual experts selected in accordance with Article 8 and give them the opportunity to provide input on the revised draft joint clinical assessment and summary reports.
4. The HTA secretariat shall provide the revised draft joint clinical assessment and summary reports to the health technology developer. The health technology developer shall indicate any purely technical or factual inaccuracies and any information it considers to be confidential within 7 days from the date on which it received the revised draft joint clinical assessment and summary reports. The health technology developer shall demonstrate the commercially sensitive nature of the information it considers to be confidential.
5. Where the health technology developer submits new clinical data on its own initiative as provided for in Article 11(2) of Regulation (EU) 2021/2282, the JCA Subgroup shall make its best efforts in order that the new clinical data is considered in the joint clinical assessment report. Where the new clinical data is received no later than 60 days after the Commission's confirmation that the dossier meets the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282, the JCA Subgroup shall ensure that the new clinical data is considered in the joint clinical assessment report.

Article 17

Finalisation of the revised draft joint clinical assessment and summary reports

1. The JCA Subgroup shall discuss the revised draft joint clinical assessment and summary reports, as well as the input provided pursuant to Article 16(3) and (4), in a meeting. The JCA Subgroup, via the HTA secretariat, may invite individual experts in a dedicated part of the meeting discussing the relevant revised draft reports.
2. The JCA Subgroup shall finalise the revised draft joint clinical assessment and summary reports within 165 days after the Commission's confirmation that the dossier meets the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282. The JCA Subgroup shall submit the revised draft joint clinical assessment and summary reports to the Coordination Group for endorsement.
3. Where the Coordination Group re-initiates a joint clinical assessment pursuant to Article 10(7) of Regulation (EU) 2021/2282, the JCA Subgroup shall finalise the revised draft joint clinical assessment and summary reports within 165 days from the date of re-initiation of the joint clinical assessment and shall submit them to the Coordination Group for endorsement.
4. Where the Coordination Group initiates an update of a joint clinical assessment pursuant to Article 14 of Regulation (EU) 2021/2282, and provided that no update of the assessment scope is necessary, the JCA Subgroup shall finalise the revised draft joint clinical assessment and summary reports within 165 days from the Commission's confirmation that the dossier meets the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282. The JCA Subgroup shall submit the revised updated draft joint clinical assessment and summary reports to the Coordination Group for endorsement.

Where the Coordination Group initiates an update of a joint clinical assessment pursuant to Article 14 of Regulation (EU) 2021/2282 and provided that an update of the assessment scope is necessary, the JCA Subgroup shall finalise the revised updated draft joint clinical assessment and summary reports within 345 days from the date on which the Coordination Group initiated the update of the joint clinical assessment. The JCA Subgroup shall submit the revised updated draft joint clinical assessment and summary reports to the Coordination Group for endorsement.

5. The Coordination Group shall endorse the revised draft joint clinical assessment and summary reports within 30 days from their receipt, in accordance with Article 12(2) of Regulation (EU) 2021/2282.

Article 18

Re-initiation of joint clinical assessments

1. Where the joint clinical assessment has been discontinued pursuant to Article 10(6) of Regulation (EU) 2021/2282, and where, at the latest five months after the deadline for submission laid down in the Commission's first request referred to in Article 10(1) of Regulation (EU) 2021/2282, a Member State shares through the HTA IT platform the information, data, analyses and other evidence that formed part of the Commission's first request, the Commission shall assess whether, based on the information available, the requirements laid down in Article 9(2), (3) and (4), of Regulation (EU) 2021/2282 are met.
2. The Commission shall provide the results of the assessment referred to in paragraph 1 within 10 working days from the date on which the Member State shared the data referred to in paragraph 1 and as appropriate in consultation with the assessor and co-assessor. The HTA secretariat shall inform the Coordination Group and the health technology developer of the results of the Commission's assessment.
3. Where the Coordination Group decides to re-initiate a joint clinical assessment pursuant to Article 10(7) of Regulation (EU) 2021/2282, Article 16 and Article 17(1), (3) and (5), of this Regulation shall apply.
4. The HTA secretariat shall inform the health technology developer of the re-initiation of a joint clinical assessment.

Article 19

Updates of joint clinical assessments

1. Where pursuant to Article 14(1) of Regulation (EU) 2021/2282 the joint clinical assessment report specifies the need for an update and additional evidence for further assessment becomes available, the health technology developer concerned shall inform the Coordination Group of that evidence.
2. The health technology developer may also provide, on its own initiative, new relevant information, data, analyses and other evidence to the Coordination Group in cases where the joint clinical assessment report did not specify the need for an update. Based on this information, data, analyses and evidence, the Coordination Group may decide to include an update of the joint clinical assessment in its annual work programme.

3. The HTA secretariat shall inform the health technology developer of the decision of the Coordination Group on the inclusion of the update of the joint clinical assessment in the annual work programme of the Coordination Group.
4. Where possible, the JCA Subgroup shall appoint the same assessor and co-assessor to conduct the update of the joint clinical assessment as the assessors in the initial joint clinical assessment and shall involve in the update the individual experts who were asked to provide input for the initial joint clinical assessment. Upon the appointment by the JCA Subgroup of the assessor and the co-assessor to conduct the update, the HTA Secretariat shall inform the health technology developer about the initiation of an update of the joint clinical assessment.
5. The JCA Subgroup shall decide whether an update of the assessment scope is necessary. If the JCA Subgroup concludes that an update of the assessment scope is not necessary, the HTA secretariat shall inform the health technology developer of the maintained assessment scope and shall request the submission of the updated dossier for a joint clinical assessment of the medical device. The deadlines referred to in Article 14(5) shall apply to that request. Article 15 shall apply to the confirmation by the Commission with the necessary modifications. Article 16 and Article 17(1), (4) and (5), shall apply to the preparation and finalisation of the updated draft joint clinical assessment and summary reports.
6. If the JCA Subgroup concludes that an update of the assessment scope is necessary, the HTA secretariat shall share the initial assessment scope for the purposes of collecting the information on Member States' needs. Based on the input received from the Member States, the assessor, with the assistance of the co-assessor, shall prepare an updated assessment scope proposal reflecting the Member States' needs. Article 11(2) and (3), and Article 12(1) shall apply to the input on the updated assessment scope proposal with the necessary modifications. The JCA Subgroup shall finalise the updated assessment scope within 60 days from the initiation of the update.
7. If the assessment scope is updated, the HTA secretariat shall inform the health technology developer of the updated assessment scope and shall request the submission of the updated dossier for joint clinical assessment of the medical device. Article 14(1) to (4) and (6) and Article 15 shall apply to the submission of the updated dossier for joint clinical assessment and its confirmation by the Commission with the necessary modifications.
8. If the assessment report is updated and if the Commission confirms that the requirements laid down in Article 9(2), (3) and (4), of Regulation (EU) 2021/2282 are met, the assessor, with the assistance of the co-assessor, shall prepare an updated draft joint clinical assessment and updated draft summary reports. Article 16 and Article 17(1), (4) and (5) shall apply to the preparation and finalisation of the updated draft joint clinical assessment and summary reports with the necessary modifications.
9. When deciding whether an update of the assessment scope is necessary pursuant to paragraph 5 of this Article, the JCA Subgroup shall consult the scientific consultation outcome document, if the medical device had been subject to the joint scientific consultation carried out pursuant to Articles 16 to 21 of Regulation (EU) 2021/2282. The HTA secretariat shall make that document available to the JCA Subgroup.

Article 20
Correspondence during joint clinical assessments

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 JCA Subgroup, the HTA secretariat, the health technology developer and individual experts during joint clinical assessments and updates of joint clinical assessments through the HTA IT platform.

Article 21
Confidentiality requests

1. The Commission shall publish the joint clinical assessment and summary reports as referred to in Article 12(4) of Regulation (EU) 2021/2282, together with other documentation listed in Article 30(3), points (d) and (i), thereof, after having considered the views of the JCA Subgroup as to the commercially sensitive nature of the information contained in that documentation, which the health technology developer has requested to be treated as confidential.
2. Before publishing the documentation referred to in paragraph 1, the Commission shall provide the health technology developer with the list of information that it does not consider as confidential, having assessed the justification provided by the health technology developer and considered the views of the JCA Subgroup. It shall inform the health technology developer of the right to appeal the refusal to redact that information.

Article 22
Personal data processing

1. The Commission shall be the controller of the processing of personal data collected for the purpose of conducting joint clinical assessments of medical devices and their updates under this Regulation.
2. The categories of personal data necessary for the purpose referred to in paragraph 1 shall be the following:
 - (a) the identity, email address and affiliation of the representatives appointed to the Coordination Group and the JCA Subgroup;
 - (b) the identity and email address of individual experts in any of the following cases:
 - (1) they are identified as relevant for joint clinical assessment or its update;
 - (2) they are selected to be consulted in a joint clinical assessment or its update;
 - (3) they are consulted in a joint clinical assessment or its update;
 - (c) the identity, email address and affiliation of the representatives of health technology developers of medical devices;
 - (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.

3. The representatives appointed to the Coordination Group and the JCA Subgroup shall have access only to the parts of the secure system of the HTA IT platform relevant for the performance of their tasks. Representatives may collaborate, through the HTA IT platform, with other representatives appointed to the Coordination Group, or the JCA Subgroup to which they belong, for the purposes of conducting joint clinical assessments of medical devices and their updates.
4. The personal data of patients involved in joint clinical assessments and their updates shall not be published.
5. The Commission shall keep the personal data listed 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 clinical assessment. 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 take part in a joint clinical assessment only for as long as necessary in order to ensure the relevant in-depth specialised expertise in joint clinical assessment and no longer than 3 years after the date on which the Commission received this data.

Article 23

Entry into force

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

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