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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 medicinal products for human use 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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**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 medicinal products for human use at Union level, as well as templates for those joint clinical assessments**

(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<sup>1</sup>, and in particular Article 15(1), points (a) and (c), Article 25(1), point (b), and Article 26(1) 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) Under Article 15 of Regulation (EU) 2021/2282, the Commission is to lay down detailed procedural rules for the implementation of Articles 8 to 14 of that Regulation as regards conducting and updating joint clinical assessments. In particular, under Article 15(1), points (a) and (c), of Regulation (EU) 2021/2282, the Commission is to adopt detailed procedural rules for the cooperation, in particular by exchange of information, with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products and for the interaction, including timing thereof, with and between the Coordination Group, its subgroups and the health technology developers, patients, clinical experts and other relevant experts during joint clinical assessments and updates.
- (3) In addition, under Article 3(7), points (d), (e) and (g), of that Regulation, the Coordination Group is to adopt further rules on conducting joint clinical assessments, namely methodological guidance on joint work, detailed procedural steps and the timeframe for the conduct of joint clinical assessments and their updates and guidance on the appointment of assessors and co-assessors for joint clinical assessments.
- (4) In order to ensure the highest scientific quality of joint clinical assessment reports, Articles 8(6) and 11(4) of Regulation (EU) 2021/2282 provide for the involvement of patients, clinical experts and other relevant experts in joint clinical assessments. Under Article 25(1), point (b), of Regulation (EU) 2021/2282, the Commission is to adopt,

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

after consulting all relevant stakeholders, general procedural rules on the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts in joint clinical assessments at Union level. Based on these rules, the Coordination Group, pursuant to Article 3(7), point (j), of Regulation (EU) 2021/2282, is to ensure appropriate involvement of stakeholder organisations and experts in its work.

- (5) Under Article 26(1) of Regulation (EU) 2021/2282, the Commission is to adopt the format and templates for the dossiers for information, data, analyses and other evidence to be provided by health technology developers for joint clinical assessments, as well as for joint clinical assessment reports and summary joint clinical assessment reports. This Implementing Regulation lays down those formats and templates, to ensure a uniform approach on the presentation of the evidence provided by the health technology developers to the Coordination Group and of the information contained in the joint clinical assessment reports.
- (6) In order to allow sufficient time for a high quality joint clinical assessment, that clinical assessment should start at the same time as the centralised procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>2</sup>, that is to say upon the confirmation by the European Medicines Agency of a valid submission of an application for marketing authorisation in accordance with Regulation (EC) No 726/2004 or for a variation to the terms of an existing marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008<sup>3</sup>. Therefore, it is appropriate to require the health technology developer to submit information necessary for the development of the assessment scope provided for in Article 8(6) of Regulation (EU) 2021/2282 ('the assessment scope') to the Commission acting as secretariat of the Coordination Group ('the HTA secretariat') at the same time as the health technology developer submits an application for marketing authorisation, or for a variation to the terms of an existing marketing authorisation, to the European Medicines Agency.
- (7) The joint clinical assessment of a medicinal product under Regulation (EU) 2021/2282 is carried out in parallel to the centralised procedure provided for in Regulation (EC) No 726/2004, and the Coordination Group should endorse the joint clinical assessment report no later than 30 days following the adoption of a Commission decision granting a marketing authorisation for that medicinal product. The joint clinical assessment should be discontinued, for example, where an application for a marketing authorisation or for a variation to the terms of an existing marketing authorisation is withdrawn, or where the outcome of the centralised procedure is negative for the application for a marketing authorisation or for a variation to the terms of an existing marketing authorisation. Therefore, the Coordination Group should be informed of valid submissions of applications for marketing authorisation and for a variation to the terms of existing marketing authorisations of medicinal products falling within the

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<sup>2</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1., ELI: <http://data.europa.eu/eli/reg/2004/726/oj>).

<sup>3</sup> Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7, ELI: <http://data.europa.eu/eli/reg/2008/1234/oj>).

scope of Regulation (EU) 2021/2282 and of updates on steps in the centralised procedure, including changes in the envisaged timelines.

- (8) The assessment scope is based on the therapeutic indication(s) of the medicinal product. Therefore, with a view to enabling the subgroup on joint clinical assessments ('the JCA Subgroup') to update the assessment scope where deemed appropriate, while preserving the separation of the respective remits of the Coordination Group and the European Medicines Agency, the European Medicines Agency should inform the HTA secretariat on substantial questions or outstanding issues that might impact the therapeutic indication(s) proposed by the applicant for the medicinal products subject to a joint clinical assessment.
- (9) The assessor and co-assessor and the JCA Subgroup should get early access to the draft summary of product characteristics and to the assessment report referred to in Article 9(4), points (a) and (e) respectively, of Regulation (EC) No 726/2004.
- (10) Pursuant to Article 28, point (h), of Regulation (EU) 2021/2282, the HTA secretariat is to facilitate the cooperation, in particular through the exchange of information, with the European Medicines Agency, on the joint work referred to in Articles 7 to 22 of Regulation (EU) 2021/2282 related to medicinal products, including the sharing of confidential information. The exchange of information relevant to concrete joint clinical assessments and updates of joint clinical assessments should therefore take place through the HTA secretariat. The HTA secretariat should ensure that all the information it receives is communicated to the Coordination Group, its relevant subgroups and/or assessor and co-assessor, as appropriate, upon receipt thereof.
- (11) The health technology developer should be informed of the start of a joint clinical assessment, of the steps of that 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.
- (12) It is necessary to set out general procedural rules for the selection of patients, clinical experts and other relevant experts to be consulted during the joint clinical assessment. The selection should start as early as possible, whenever the Coordination Group, via the HTA secretariat, receives information about upcoming submissions of applications for marketing authorisations for the medicinal products referred to in Article 7(1) of Regulation (EU) 2021/2282.
- (13) The JCA Subgroup should aim to select patients, clinical experts and other relevant experts who have the required expertise in the therapeutic area of the joint clinical assessment, from a European or international perspective. These experts should be consulted during the joint clinical assessment.
- (14) In order to ensure that patients, clinical experts and other relevant 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 concluded on their conflicts of interest, in accordance with the rules set out in Article 5 of Regulation (EU) 2021/2282 and with the general procedural rules adopted under Article 25(1), point (a), of that Regulation. Only patients, clinical experts and other relevant experts who have signed a confidentiality agreement should be involved in joint clinical assessments.

- (15) The JCA Subgroup should give the opportunity to patient organisations, healthcare professional organisations and clinical and learned societies to provide their input on joint clinical assessments.
- (16) 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.
- (17) In order 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. These members should consult national authorities and stakeholders in accordance with the procedural rules of the respective Member State.
- (18) The Commission should set out procedural rules in order to ensure that the assessment scope is developed, taking into account information provided by the health technology developer and input received from patients, clinical experts and other relevant experts.
- (19) Article 10(1) and Article 11(1), point (a), of Regulation (EU) 2021/2282 set the timeframe for joint clinical assessments for medicinal products by reference to the timeframe applicable to the centralised procedure provided for in Regulation (EC) No 726/2004. The Commission should set the deadlines for the finalisation of the assessment scope and of the draft joint clinical assessment reports by the JCA Subgroup. These deadlines should refer to the main steps of the centralised procedure. Where Article 11(1), point (a), of Regulation (EU) 2021/2282 does not apply, the Commission should set these deadlines with the aim of improving timely patient access to health technologies.
- (20) Where necessary for the high quality of the dossier and for the smooth conduct of the joint clinical assessment, the JCA Subgroup may invite the health technology developer to an assessment scope explanation meeting.
- (21) The Commission should set deadlines that should give the health technology developer sufficient time to prepare and submit the dossier for joint clinical assessment of the medicinal product. The Commission should set the rules that provide a possibility to extend the deadline to submit the dossier in justified instances, without however going beyond the deadline specified in Article 10(1) of Regulation (EU) 2021/2282.
- (22) Similarly, the Commission should set deadlines that give sufficient time to the health technology developer to take the following actions: a) provide missing information, data, analysis and other evidence as indicated in the Commission's second request; b) provide further specifications or additional information, data, analyses, or other evidence; c) provide updates to previously provided information referred to in Articles 10(8) and 11(2) of Regulation (EU) 2021/2282; d) signal technical or factual inaccuracies in the draft joint clinical assessment and summary reports and any information the health technology developer considers to be confidential.
- (23) The Commission should set deadlines for its assessment on whether the dossier submitted by the health technology developer for joint clinical assessment of the medicinal product meets the requirements laid down in Article 9(2), (3) and (4) of

Regulation (EU) 2021/2282. The Commission should consult, as appropriate, the assessor and co-assessor when carrying out this assessment.

- (24) The Commission should set procedural rules to ensure that patients, clinical experts and other relevant experts are involved in the assessment process by being given the opportunity to provide input on the draft joint clinical assessment and summary reports.
- (25) According to Article 11(2) of Regulation (EU) 2021/2282, the health technology developer is to proactively inform the Coordination Group where new clinical data becomes available during the joint clinical assessment process. The Commission should set the deadline by which the health technology developer is to submit such new clinical data so that these data are considered in the draft joint clinical assessment and summary reports.
- (26) The Commission should set the deadline for finalising the revised draft joint clinical assessment and summary reports by the JCA Subgroup. This should ensure the delivery of joint clinical assessment reports in a timely manner and allow the Coordination Group to comply with the deadline for the conclusion of the joint clinical assessment set out in Article 11(1), point (a), of Regulation (EU) 2021/2282. The Commission should also set the deadline for the Coordination Group to endorse the revised draft joint clinical assessment and summary reports, with the aim of improving timely patient access to health technologies.
- (27) Where, during the centralised procedure, there is a change in the therapeutic indication(s) initially submitted in the application for marketing authorisation or for a variation to the terms of an existing marketing authorisation, the JCA Subgroup should decide whether the joint clinical assessment should continue or be restarted. The Commission should set the procedural rules that apply in case a new assessment scope is to be prepared.
- (28) Certain specific procedural rules and deadlines should apply where the Coordination Group re-initiates a joint clinical assessment pursuant to Article 10(7) of Regulation (EU) 2021/2282 or where an update of a joint clinical assessment is carried out pursuant to Article 14 of Regulation (EU) 2021/2282.
- (29) In order to ensure transparency, traceability and professional secrecy, as well as to contribute to the procedural compliance of joint clinical assessment reports, any correspondence with and between the Coordination Group, the JCA Subgroup, the HTA secretariat, the health technology developer, patients, clinical experts and other relevant experts during joint clinical assessments should be sent in a digital format through the IT platform referred to in Article 30 of Regulation (EU) 2021/2282 ('the HTA IT platform').
- (30) This Implementing Regulation lays down, in accordance with Article 5(1), point (a), of Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>4</sup>, the rules for processing, through the HTA IT platform, personal data for the purposes of conducting joint clinical assessments and their updates. In particular, it specifies the

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<sup>4</sup> 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>).

personal data that may be processed through that platform, namely certain personal data relating to the patients, clinical experts and other relevant 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 members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282 ('the HTA stakeholder network'). This Implementing Regulation also determines that the Commission is to be considered the controller of the processing of personal data through the HTA IT platform in the sense of Article 3(8) of Regulation (EU) 2018/1725.

- (31) The identity of the patient may reveal the patient's health status in relation to the subject-matter of the joint clinical assessment and therefore should be considered a special category of personal data under Article 10 of Regulation (EU) 2018/1725 of the European Parliament and of the Council. Therefore, such data should only be processed where the criteria of Article 10(2), point (i), of that Regulation are met. This Implementing Regulation provides for suitable and specific measures to safeguard the rights and freedoms of the data subject. In particular, no personal data of patients shall 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 patients, clinical experts and other relevant experts involved in joint clinical assessments and their updates, are subject to a requirement of professional secrecy, even after their duties have ceased. Finally, this Implementing Regulation specifies that only patients, clinical experts and other relevant experts who have signed confidentiality agreements be involved in joint clinical assessments.
- (32) In order to ensure transparency, on the one hand, and the protection of confidential data for commercial reasons, on the other hand, the Commission should publish 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, after having considered the views of the JCA Subgroup as to the commercially sensitive nature of the information contained in this documentation, which the health technology developer has requested to be treated as confidential.
- (33) Joint clinical assessments of medicinal products are to be conducted from the date as of which Regulation (EU) 2021/2282 applies, that is, 12 January 2025. This Implementing Regulation should therefore apply from 12 January 2025.
- (34) The measures provided for in this Implementing 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 clinical assessments of medicinal products at Union level, as regards:

- (a) cooperation, in particular by exchange of information, with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;
- (b) interaction, including the timing thereof, with and between the Coordination Group established under Article 3 of Regulation (EU) 2021/2282, its subgroups and health

technology developers, patients, clinical experts and other relevant experts during joint clinical assessments of medicinal products and their updates;

- (c) general procedural rules on the selection and consultation of stakeholder organisations and patients, clinical experts, and other relevant experts in joint clinical assessments at Union level;
- (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 joint clinical assessment reports.

## *Article 2*

### *Relevant information for the development of the assessment scope*

1. Health technology developers shall, at the same time as they submit to the European Medicines Agency an application for marketing authorisation for medicinal products referred to in Article 7(1), point (a), of Regulation (EU) 2021/2282, provide the HTA secretariat with relevant information for developing the assessment scope of a joint clinical assessment of those medicinal products. That information shall consist of:
  - (a) the summary of the product characteristics proposed by the applicant;
  - (b) the clinical overview section of the submission file to the European Medicines Agency.
2. Health technology developers shall, at the same time as they submit to the European Medicines Agency an application for a variation to the terms of an existing marketing authorisation for medicinal products referred to in Article 7(1), point (b), of Regulation (EU) 2021/2282, provide the HTA secretariat with relevant information on the development of the assessment scope of a joint clinical assessment of those medicinal products. That information shall consist of the new therapeutic indication proposed by the applicant and the clinical overview section of the submission file to the European Medicines Agency.
3. If the JCA Subgroup considers it necessary, the HTA secretariat shall invite the health technology developer to provide further information relevant for the development of the assessment scope in a meeting with the JCA Subgroup or in writing.

## *Article 3*

### *Exchange of information with the European Medicines Agency*

1. The European Medicines Agency shall notify the HTA secretariat of the submission of an application for a marketing authorisation or for a variation to the terms of an existing marketing authorisation referred to in Article 2 of this Regulation upon receipt thereof.
2. With regard to the medicinal products referred to in Article 7(1), points (a) and (b), of Regulation (EU) 2021/2282, the European Medicines Agency shall inform the HTA secretariat of the following:
  - (a) a valid submission of an application for marketing authorisation in accordance with Article 3(1) and (2), point (a), of Regulation (EC) No 726/2004, including



- the date on which the application for marketing authorisation was validated and the timetable for the initial evaluation during the centralised procedure;
- (b) a valid submission of an application for a variation to the terms of an existing marketing authorisation which corresponds to a new therapeutic indication in accordance with Commission Regulation (EC) No 1234/2008, including the date on which the application for a variation to an existing marketing authorisation was validated and the timetable for the initial evaluation during the centralised procedure.
3. The European Medicines Agency shall provide the HTA secretariat with the information referred to in paragraph 2 on the day it issues the health technology developer the receipt of a valid application.
4. During the centralised procedure for medicinal products subject to a joint clinical assessment, the European Medicines Agency shall inform the HTA secretariat of the following:
- (a) updates on steps in the centralised procedure, including changes in the envisaged timelines;
- (b) substantial questions or outstanding issues that might impact the therapeutic indication(s) of the medicinal products proposed by the applicant.
- Point (a) also applies to medicinal products of which the joint clinical assessment was discontinued pursuant to Article 10(6) of Regulation (EU) 2021/2282.
- The main steps for the exchange of the information referred to in the first subparagraph, as well as the exact content of the information to be communicated at those steps, shall be agreed upon by the European Medicines Agency, the HTA secretariat and the JCA Subgroup.
5. The European Medicines Agency shall send the draft summary of product characteristics and the assessment report referred to in Article 9(4), points (a) and (e) respectively, of Regulation (EC) No 726/2004 to the HTA secretariat at the latest within 7 days from the adoption by the Committee for Medicinal Products for Human Use of its final opinion.

#### *Article 4*

##### *Information to the Coordination Group*

The HTA secretariat shall ensure that all the information received from the health technology developer, the European Medicines Agency, patients, clinical experts and other relevant experts and Member States related to joint clinical assessments and updates of joint clinical assessments is communicated to the Coordination Group, to its relevant subgroups and/or to the assessor and co-assessor, as appropriate, upon receipt of that information.

#### *Article 5*

##### *Information to the health technology developer about the start of a joint clinical assessment*

Upon the appointment by the JCA Subgroup of an assessor and a co-assessor to conduct the joint clinical assessment, the HTA secretariat shall inform the health technology developer of the start of the joint clinical assessment.

## Article 6

### *Selection of patients, clinical experts and other relevant experts*

1. The JCA subgroup shall specify, for each particular joint clinical assessment, the disease, the therapeutic area concerned and other specific expertise, based on which the HTA secretariat shall identify patients, clinical experts and other relevant experts to be consulted during that joint clinical assessment.
2. The HTA secretariat shall compile a list of relevant patients, clinical experts and, where necessary, other relevant experts, in consultation with the JCA Subgroup and the appointed assessor and co-assessor. When compiling the list, the HTA secretariat may consult:
  - (a) the members of the HTA stakeholder network;
  - (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 ('Orphanet');
  - (d) the national contact points designated in accordance with Article 83 of Regulation (EU) No 536/2014 of the European Parliament and of the Council<sup>5</sup>;
  - (e) the European Medicines Agency.
3. To identify relevant patients, clinical experts and other relevant experts, the HTA secretariat may consult other existing databases or directories or contact members of the Coordination Group, its subgroups and relevant European Union and international agencies and organisations.
4. The HTA secretariat shall provide the JCA Subgroup with a list of available patients, clinical experts and, where necessary, other relevant experts, after the Commission has concluded on their conflicts of interest, in accordance with the rules set out in Article 5 of Regulation (EU) 2021/2282 and with the general procedural rules adopted under Article 25(1), point (a), of that Regulation.
5. The JCA Subgroup shall make the final selection of patients, clinical experts and, where necessary, other relevant experts to be consulted during the joint clinical assessment. In making the final selection, the JCA Subgroup shall give priority to patients, clinical experts and other relevant experts who have expertise, covering several Member States, in the therapeutic area of the joint clinical assessment.

## Article 7

### *Professional secrecy obligations of patients, clinical experts and other relevant experts*

The HTA secretariat shall ensure that only patients, clinical experts and other relevant experts who have signed a confidentiality agreement are involved in joint clinical assessments.

<sup>5</sup> 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>).

## Article 8

### *Consultation of stakeholder organisations during joint clinical assessments*

At any time during the joint clinical assessment, the JCA Subgroup may seek input on the disease and therapeutic area from patient organisations, healthcare professional organisations or clinical and learned societies via the members of the HTA stakeholder network.

## Article 9

### *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 under Article 2. At any time during the preparation of the assessment scope proposal, the assessor and/or co-assessor may seek, via the HTA secretariat, input on the assessment scope from the patients, clinical experts and/or other relevant experts selected in accordance with Article 6. The HTA secretariat shall make this 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 Member States, the assessor, with the assistance of the co-assessor, shall prepare a consolidated assessment scope proposal reflecting the Member States' needs.
3. The HTA secretariat shall share the consolidated assessment scope proposal with the patients, clinical experts and other relevant experts selected in accordance with Article 6 and give them the opportunity to provide input.

## Article 10

### *Finalisation of the assessment scope*

1. The JCA Subgroup shall discuss the consolidated assessment scope proposal referred to in Article 9(2) of this Regulation, as well as the input of patients, clinical experts and other relevant experts during an assessment scope consolidation meeting. The JCA Subgroup, via the HTA secretariat, may invite patients, clinical experts and other relevant 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 20 days after the Committee for Medicinal Products for Human Use adopts its list of questions.  
  
The JCA Subgroup shall finalise the assessment scope within 100 days from the day on which the European Medicines Agency validates the application for a variation to the terms of an existing marketing authorisation, where the joint clinical assessment is conducted for a medicinal product referred to in Article 7(1), point (b), of Regulation (EU) 2021/2282, for which a variation to the terms of an existing marketing authorisation is of the type referred to in point 2(a) of Annex II to Commission Regulation (EC) No 1234/2008 and corresponds to a new therapeutic indication.
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 11*

### *Assessment scope explanation meeting*

If the JCA Subgroup considers it necessary, 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 30 days from the day on which the JCA Subgroup finalises the assessment scope.

## *Article 12*

### *Dossier and further data for joint clinical assessment provided by the health technology developer*

1. The health technology developer shall submit the dossier for joint clinical assessment of the medicinal product, 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 dossier, as well as any additional information, data, analyses and other evidence submitted by the health technology developer for joint clinical assessment of the medicinal product, or its update, shall be presented in accordance with the template set out in Annex I to this Regulation.
2. The deadline to submit the dossier referred to in paragraph 1 shall be 90 days from the date of the notification of the first request to the health technology developer. However, that deadline shall be 60 days where:
  - (a) the application for a marketing authorisation for a medicinal product is assessed under the accelerated procedure referred to in Article 14(9) of Regulation (EC) No 726/2004;
  - (b) the joint clinical assessment is conducted for a medicinal product referred to in Article 7(1), point (b), of Regulation (EU) 2021/2282, for which a variation to the terms of an existing marketing authorisation is of the type referred to in point 2(a) of Annex II to Commission Regulation (EC) No 1234/2008 and corresponds to a new therapeutic indication.
3. In justified cases, with the consent of the assessor and co-assessor and considering the timetable for the evaluation during the centralised procedure, the HTA secretariat may extend the deadline referred to in paragraph 2. However, that extension shall not exceed the deadline specified in Article 10(1) of Regulation (EU) 2021/2282.
4. 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 10 days where:
  - (a) the application for a marketing authorisation of a medicinal product is assessed under the accelerated procedure referred to in Article 14(9) of Regulation (EC) No 726/2004;
  - (b) the joint clinical assessment is conducted for a medicinal product referred to in Article 7(1), point (b), of Regulation (EU) 2021/2282, for which a variation to the terms of an existing marketing authorisation is of the type referred to in point 2(a) of Annex II to Commission Regulation (EC) No 1234/2008 and corresponds to a new therapeutic indication.

The deadlines referred to in the first subparagraph shall be 7 days for cases where only minor information is missing.

5. 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, under 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.
6. 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.
7. If during the joint clinical assessment, the health technology developer submits new data from clinical studies to the European Medicines Agency, it shall notify the HTA secretariat thereof and provide this data upon request of the assessor, with the assistance of the co-assessor. The deadlines referred to in paragraph 5 apply to that request.
8. Once the HTA secretariat receives the dossier and further data submitted by the health technology developer pursuant to paragraphs 1, 4, 5, 6 and 7, it shall make the dossier and these data available to the assessor, co-assessor and the JCA Subgroup at the same time.

#### *Article 13*

##### *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 medicinal product meets the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282.

#### *Article 14*

##### *Draft joint clinical assessment and summary reports*

1. The assessor, with the assistance of the co-assessor, shall prepare the draft joint clinical assessment and summary reports using the templates set out in Annex II and Annex III to this Regulation. At any time during the preparation of the draft joint clinical assessment and summary reports, the assessor and/or co-assessor, via the HTA secretariat, may seek input from the patients, clinical experts and/or other relevant experts selected in accordance with Article 6 of this Regulation. The HTA secretariat shall make that input available to the entire JCA Subgroup.

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. After having considered the comments from the members of the JCA Subgroup, 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 patients, clinical experts and other relevant experts selected in accordance with Article 6 of this Regulation 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 signal 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.

The deadline referred to in the first subparagraph shall be 5 days from the date on which the health technology developer received the revised draft joint clinical assessment and summary reports where:

- (a) the application for a marketing authorisation for a medicinal product is assessed under the accelerated procedure referred to in Article 14(9) of Regulation (EC) No 726/2004;
  - (b) the joint clinical assessment is conducted for a medicinal product referred to in Article 7(1), point (b), of Regulation (EU) 2021/2282, for which a variation to the terms of an existing marketing authorisation is of the type referred to in point 2(a) of Annex II to Commission Regulation (EC) No 1234/2008 and corresponds to a new therapeutic indication;
  - (c) a new assessment scope was developed during the joint clinical assessment, pursuant to Article 16 of this Regulation.
5. Where the health technology developer submits new clinical data on its own initiative under Article 11(2), third sentence, of Regulation (EU) 2021/2282, the JCA Subgroup shall ensure that the new clinical data is considered in the joint clinical assessment report, if received no later than 7 days after the adoption by the Committee for Medicinal Products for Human Use of its final opinion.

#### *Article 15*

##### *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 14(3) and (4), in a meeting. The JCA Subgroup, via the HTA secretariat, may invite patients, clinical experts and/or other relevant 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 at the latest on the date of the adoption of the Commission decision

granting the marketing authorisation and submit them 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 or initiates an update of a joint clinical assessment pursuant to Article 14 of Regulation (EU) 2021/2282, and no update of the assessment scope is necessary, the JCA Subgroup shall finalise the revised draft joint clinical assessment and summary reports within 180 days from the date of re-initiation of the joint clinical assessment or of the initiation of the update of the joint clinical assessment and 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 an update of the assessment scope is necessary, the JCA Subgroup shall validate the revised updated draft joint clinical assessment and summary reports within 330 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. If the deadline specified in Article 11(1), point (a), of Regulation (EU) 2021/2282 does not apply, the Coordination Group shall endorse the revised draft joint clinical assessment and summary reports within 30 days from their receipt.

#### *Article 16*

##### *Changes to the therapeutic indication(s)*

1. Where during the centralised procedure, there is a change of the therapeutic indication(s) initially submitted to the European Medicines Agency, the assessor, with the assistance of the co-assessor, shall assess whether that change affects the assessment scope and inform the JCA Subgroup.
2. The JCA Subgroup shall decide whether the joint clinical assessment shall continue, or whether the assessor, with the assistance of the co-assessor, shall prepare a new assessment scope proposal. The HTA secretariat shall inform the health technology developer of the JCA Subgroup's decision.
3. If a new assessment scope proposal is prepared, Articles 9 and 10(1) of this Regulation shall apply with the necessary modifications.
4. The HTA secretariat shall inform the health technology developer of the new assessment scope finalised by the JCA Subgroup and shall request the health technology developer to submit an updated dossier. The deadlines referred to in Article 12(5) shall apply to that request. Articles 14 and 15(1) of this Regulation shall apply with the necessary modifications.

#### *Article 17*

##### *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 least 30 days before the end of the deadline referred to in Article 10(7) thereof, the 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 confirm whether, based on

the information available at the time, the requirements laid down in Articles 9(2), (3) and (4) of Regulation (EU) 2021/2282 have been met.

2. The Commission shall provide the confirmation referred to in paragraph 1 within 10 working days from the date on which the Member State shared these data 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 14 and Article 15(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 18*

#### *Updates of joint clinical assessments*

1. Where 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 thereof.
2. The health technology developer may also provide, on their 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 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 involve in the update the same patients, clinical experts and/or other relevant experts. 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 request the submission of the updated dossier for a joint clinical assessment of the medicinal product. The deadlines referred to in Article 12(6) shall apply to that request. Article 14 and Article 15(1), (3) and (5) of this Regulation 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 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 9(2) and (3)



and Article 10(1) of this Regulation shall apply with the necessary modifications. The JCA Subgroup shall finalise the updated assessment scope within 90 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 request the submission of the updated dossier for joint clinical assessment of the medicinal product. Article 12(1) and Article 13 of this Regulation shall apply with the necessary modifications. The deadlines referred to in Article 12(2) first sentence, (4) first sentence and (5) apply.
8. 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 summary reports. Article 14 and Article 15(1), (4) and (5) of this Regulation shall apply to the preparation and finalisation of the updated draft joint clinical assessment and summary reports.

#### *Article 19*

##### *Correspondence during joint clinical assessments*

Any correspondence with and between the Coordination Group, the JCA Subgroup, the HTA secretariat, the health technology developer, patients, clinical experts and other relevant experts during joint clinical assessments and updates of joint clinical assessments shall be sent in a digital format through the HTA IT platform.

#### *Article 20*

##### *Confidentiality requests*

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.

#### *Article 21*

##### *Personal data processing*

1. The Commission shall be the controller of the processing, through the HTA IT platform, of personal data collected for the purpose of conducting joint clinical assessments and their updates under this Regulation.
2. The categories of personal data necessary for the purpose referred to in paragraph 1 shall be:
  - (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 patients, clinical experts and other relevant experts that were identified to be selected for, and consulted in, joint clinical assessments and their updates;
  - (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 HTA stakeholder network.
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 and 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 purpose of conducting joint clinical assessments 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 work. The Commission shall review the necessity of storing the personal data every 2 years.

*Article 22*

*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**