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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member State Coordination Group on Health Technology Assessment and its subgroups

(Text with EEA relevance)

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

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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laying down rules for the application of Regulation (EU) 2021/2282 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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU[1], and in particular Article 5(7) and Article 25(1), point (a), 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) In accordance with Regulation (EU) ~~2021/~~2282, the members of the Coordination Group and its subgroups are to appoint their representatives who are individuals, on an *ad hoc* or permanent basis ('representatives').

(3) Regulation (EU) 2021/2282 requires that patients, clinical experts and other relevant experts ('individual experts') be involved in joint clinical assessments and joint scientific consultations. Those experts are to be selected for their expertise in the therapeutic area concerned and act in individual capacity rather than representing any organisation, institution, or Member State.

(4) The conflicts of interests for the assessment of which the Commission is to lay down rules in accordance with Regulation (EU) 2021/2282, concern the conflicts of interests of the representatives and the individual experts in the health technology developers' industrial sector, who participate in the joint work of the Coordination Group and its subgroups carried out pursuant to Articles 7 to 22 of Regulation (EU) 2021/2282 ('the joint work'). The management of conflicts of interest of other individuals who might be involved in the joint work by the members of the Coordination Group and its subgroups remains within the responsibility of the Member States who are to ensure that these individuals have no financial or other interests in the health technology developers' industrial sector which could affect their independence or impartiality.

(5) The relevant activities with regard to the management of conflicts of interest in the Coordination Group and its subgroups should encompass the activities related to the

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

conduct of joint clinical assessments and joint scientific consultations, including where individual experts take part in this joint work, the development of methodological guidance on joint work and the preparation of reports on emerging health technologies.

(6) For the representatives appointed to the Coordination Group or its subgroups, the participation in the joint work should be subject to the submission to the Commission of a signed declaration of interests ('DOI') and a curriculum vitae ('CV'). For the individual experts, their ability to be selected for and to take part in a joint clinical assessment or a joint scientific consultation should be subject to the submission to the Commission of a signed DOI and a CV. When deciding on conflicts of interest in accordance with Article 28, point (b), of Regulation (EU) 2021/2282, the Commission should assess the interests declared in the DOI and the information in the CV of the representative or the individual expert. In case of failure to declare an interest, appropriate measures should be taken.

(7) In accordance with Regulation (EU) 2021/2282, the DOI is to be updated annually and whenever necessary. To ensure that the activities of the Coordination Group and its subgroups are carried out in an independent, impartial and transparent manner at any point in time, it should be specified that an update is necessary whenever there is a change in the information provided by the representative or individual expert. To reduce administrative burden, the representative or the individual expert should be able to confirm the information submitted in the DOI where no change in the declared interest has occurred. Where such confirmation is not provided in due time, the representative or the individual expert should no longer participate in the joint work.

(8) To ensure a uniform approach regarding the interests to be declared and a proper management of the conflicts of interest in the joint work, it is appropriate to set out rules on the content, format and the validity of the DOI, as well as the rules on its submission. As the joint work under Regulation (EU) 2021/2282 is to be conducted in parallel and in close cooperation with the European Medicines Agency and with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council[2], the DOI employed in the respective legal frameworks should be aligned as far as possible while preserving the separation of the respective remits of the Coordination Group, the European Medicines Agency and these expert panels.

(9) Pursuant to Article 30(3), points (a) and (b), of Regulation (EU) 2021/2282 and in order to ensure the highest standards of independence, impartiality and transparency related to the joint work, the DOI of the representatives of the Coordination Group and its subgroups and of clinical experts and other relevant experts involved in the joint work should be made publicly available. The DOI of patients should not be made publicly available.

(10) To ensure legal certainty, rules should be established for the assessment of the submitted DOI and the deadlines within which the assessment is to be completed or within which additional information is to be provided.

[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, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

(11) At the moment of the assessment by the Commission of the interests declared by the representatives in their DOI, it is not always possible to establish conflicts of interest, as the specific health technology developer or specific health technology with respect to which a conflict of interest might exist might not be under assessment in the Coordination Group or its subgroups at that time. It is not always possible to establish conflicts of interest even where the health technology is already being assessed by the Coordination Group or its subgroups, as a conflict of interest might exist with regard to the comparator health technology, which might not be yet known at the time of the assessment of the interests declared by the representatives or individual experts in their DOI. Therefore, the Commission should also decide on potential conflicts of interest of the representatives and of the individual experts.

(12) In addition to conflicts or potential conflicts of interest that are readily identifiable, there may be situations of appearance of a conflict of interest. Therefore, it is appropriate to consider incompatible with the participation in the joint work certain interests that, considering the role and responsibility of representatives, may give rise to doubts about their independence and impartiality, and to provide for cooling-off periods for such roles and responsibilities.

(13) To ensure appropriate access to the relevant expertise, the applicable measures in case of a conflict or potential conflict of interest should vary depending on the declared interest and the roles and responsibilities of the representative or individual expert. They should exclude or limit the participation of the representative or individual expert in the joint work. The Commission acting as secretariat of the Coordination Group ('the HTA secretariat') should be responsible for the enforcement of the imposed exclusions from, or limitations of the participation in the joint work.

(14) Under Regulation (EU) 2021/2282, the relevant subgroup is to ensure that individual experts are given the opportunity to provide their input during joint clinical assessments and joint scientific consultations. Where in exceptional cases only individual experts with conflicts of interests within the meaning of this Regulation are available, the relevant subgroup should ensure their appropriate involvement in the joint work considering their conflicts of interest, while ensuring transparency pursuant to Article 5(5) of Regulation (EU) 2021/2282.

(15) In order to ensure good management of conflict of interest, the members of the Coordination Group and its subgroups should be required to notify the HTA secretariat any changes of their representatives.

(16) Within its specific scope relating to the management of conflicts of interest in the joint work of the Coordination Group and its subgroups, this Regulation lays down, in accordance with Article 5(1), point (a), of Regulation (EU) 2018/1725 of the European Parliament and of the Council[3], the rules for processing, through the IT platform, as defined in Article 30 of Regulation (EU) 2021/2282 ('the HTA IT platform'), personal data for the purposes of ensuring that the joint work of the Coordination Group and its subgroups under Regulation (EU) 2021/2282 is carried out in an independent, impartial and transparent manner. In particular, it should be ensured that the

[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

representatives and individual experts participating in the joint work are free from conflicts of interest with regard to the health technology developers' industrial sector which could affect their independence or impartiality.

(17) This Regulation should specify the personal data that may be processed for the defined purposes, namely personal data included in the DOI and CV. It should determine that the Commission is to be considered the controller within the meaning of Article 3, point (8), of Regulation (EU) 2018/1725 for the processing of this data through the HTA IT platform. In order to ensure the possibility to verify whether the joint work was conducted in an independent and impartial 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.

(18) The identity of the patient may reveal the patient's health status in relation to the subject-matter of the joint clinical assessment or the joint scientific consultation. Therefore, that type of data should be considered a special category of personal data under Article 10 of Regulation (EU) 2018/1725, and the processing of such data should be made conditional on the fulfilment of the criteria laid down in Article 10(2), point (i), of that Regulation, including the set-up of suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.

(19) The Commission should make the information about the data processing available on the publicly accessible webpage of the HTA IT platform so that the categories of data subjects whose personal data is being processed can be informed of their rights under Chapter III of Regulation (EU) 2018/1725, as well as the means by which they can exercise those rights.

(20) As Regulation (EU) 2021/2282 applies with effect from 12 January 2025, this Regulation should also apply from that date.

(21) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/17258 and delivered an opinion on […].

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

HAS ADOPTED THIS REGULATION:

Article 1
Submission of the DOI

1. Before submitting a signed declaration of interests ('DOI') to the Commission and until the Commission has assessed the declared interests in accordance with Article 4, the representatives appointed to the Coordination Group and its subgroups referred to in Article 5(3) of Regulation (EU) 2021/2282 ('representatives') may not do any of the following:

   (a) access the parts of the secure system of the IT platform, as defined in Article 30 of Regulation (EU) 2021/2282 ('the HTA IT platform') relevant for the performance of their tasks;

   (b) take up the roles and responsibilities of a chair or a co-chair in the Coordination Group or its subgroups;

(c) take up the roles and responsibilities of an assessor or a co-assessor for a joint clinical assessment or a joint scientific consultation;

(d) attend meetings of the Coordination Group or its subgroups for conducting joint clinical assessments, joint scientific consultations, developing methodological guidance for joint work or for preparing reports on emerging health technologies.

2. Before submitting a signed declaration of interests ('DOI') to the Commission and until the Commission has assessed the declared interest in accordance with Article 4, patients, clinical experts and other relevant experts referred to in Article 5(5) of Regulation (EU) 2021/2282 ('individual experts') may not be selected and take part in a joint clinical assessment or a joint scientific consultation and may not access the parts of the secure system of the HTA IT platform relevant for the performance of their tasks.

Article 2
Content of the DOI

1. Representatives and individual experts shall declare in the DOI all financial or other interests, whether of direct or indirect nature, in the health technology developers' industrial sector, by answering the standard questions listed in the DOI form set out in Annex I to this Regulation. Representatives or individual experts who answer to the questions in the affirmative shall provide further details in the respective sections of the DOI form.

2. Representatives and individual experts shall assume full responsibility in relation to the content of the DOI submitted.

Article 3
Format of the DOI

1. The DOI of a representative or individual expert shall be submitted digitally through the HTA IT platform in the form set out in Annex I and shall be accompanied by a comprehensive curriculum vitae ('CV') of the representative or of the individual expert based on the Europass CV template. The DOI shall be deemed submitted only if it is duly completed, signed, and accompanied by such CV.

2. When an interest declared in the DOI referred to in paragraph 1 has changed, an updated DOI shall be submitted without undue delay in accordance with the procedure set out in paragraph 1.

Article 4
Assessment of information submitted in the DOI

1. The Commission shall assess the interests declared in the DOI, as well as the information in the CV of the representative or the individual expert, submitted in accordance with Article 3.

2. If necessary, the Commission may request that the representative or the individual expert submit any additional information needed for the assessment of the declared interests. The representative or the individual expert shall provide that information within 10 days from the day of the notification of the request.

3. Where no further information is needed for the assessment of the declared interests, the Commission shall complete the assessment within 15 working days from the submission of the DOI in accordance with Article 3.

4. If the Commission decides that the declared interest does not constitute a conflict or potential conflict of interest within the meaning of Annex II, the representative or the individual expert may participate in the joint work.

5. If the Commission decides that the declared interest constitutes a conflict or potential conflict of interest within the meaning of Annex II, Articles 6, 7 and 8 shall apply.

Article 5
Validity and publication of DOI

1. The DOI shall be valid as long as the representative or the individual expert is involved in the joint work if:

   (a) no change in the declared interest has occurred;

   (b) information referred to in point (a) has been confirmed by the representative or the individual expert by the end of each year starting on the day on which the DOI was submitted in accordance with Article 3(1) or (2). Where such confirmation is not provided, the HTA secretariat shall ensure that the representative or the individual expert is no longer involved in the joint work.

2. The DOI and the information on the qualifications and areas of relevant expertise from the accompanying CVs of the representatives, clinical experts and other relevant experts shall be made available on the publicly accessible webpage of the HTA IT platform for the period of their involvement in the joint work.

Article 6
Action with regard to conflicts or potential conflicts of interest of the representatives

1. If the Commission decides, in accordance with Article 28, point (b), of Regulation (EU) 2021/2282, that an interest declared in a DOI submitted by a representative in accordance with Article 3(1) of this Regulation constitutes a conflict of interest within the meaning of Annex II thereto that is deemed incompatible with the participation in the joint work, the HTA secretariat shall invite the member of the Coordination Group or its subgroup to appoint another representative. The member may re-appoint the same representative once the conflict of interest no longer exists.

2. If the Commission decides, in accordance with Article 28, point (b), of Regulation (EU) 2021/2282, that an interest declared in a DOI submitted by a representative in accordance with Article 3(2) of this Regulation constitutes a conflict of interest within the meaning of Annex II thereto that is deemed incompatible with the participation in the joint work, the HTA secretariat shall ensure that the representative is no longer involved in the joint work and shall inform the representative thereof. The HTA secretariat shall invite the member of the Coordination Group or its subgroup to appoint another representative. The member may re-appoint the same representative once the conflict of interest no longer exists.

3. If the Commission decides, in accordance with Article 28, point (b), of Regulation (EU) 2021/2282, that an interest declared in a DOI submitted by a representative in accordance with Article 3(1) or (2) of this Regulation constitutes a

conflict of interest within the meaning of Annex II thereto that is deemed incompatible with taking up certain roles and responsibilities in the joint work, or a conflict or potential conflict of interest in relation to the health technology developer or to the specific health technologies, the HTA secretariat shall inform the representative, the member of the Coordination Group or its subgroup and, as appropriate, the Coordination Group or its subgroups of the conflict or the potential conflict of interest of the representative and shall ensure the enforcement of the measures set out in Annex II to this Regulation.

Article 7

Action with regard to conflicts or potential conflicts of interest of individual experts

1. If the Commission decides, in accordance with Article 28, point (b), of Regulation (EU) 2021/2282, that an interest declared in a DOI submitted by an individual expert in accordance with Article 3(1) of this Regulation constitutes a conflict of interest within the meaning of Annex II thereto that is deemed incompatible with the participation in the joint work or a conflict of interest in relation to the health technology developer or to the specific health technologies, the HTA secretariat shall ensure that that individual expert is not selected to be involved in the joint clinical assessment or joint scientific consultation and shall inform the individual expert thereof.

2. If the Commission decides, in accordance with Article 28, point (b), of Regulation (EU) 2021/2282, that an interest declared in a DOI submitted by an individual expert in accordance with Article 3(2) of this Regulation constitutes a conflict of interest within the meaning of Annex II thereto that is deemed incompatible with the participation in the joint work or a conflict of interest in relation to the health technology developer or to the specific health technologies, the HTA secretariat shall ensure that the individual expert is no longer involved in the joint clinical assessment or joint scientific consultation and shall inform the individual expert thereof. The HTA secretariat shall inform, as appropriate, the relevant subgroup, assessor and co-assessor for the joint clinical assessment or joint scientific consultation of the exclusion of the individual expert from the relevant assessment or consultation.

3. By way of derogation from paragraph 1, where no individual experts free from conflicts of interests within the meaning of Annex II are available, the HTA secretariat shall provide the relevant subgroup with an explanation of the situation, as well as where considered appropriate by the Commission, with a list of available individual experts indicating their conflicts of interest. The relevant subgroup shall ensure the appropriate involvement of such individual experts in the joint work considering their conflicts of interest. The explanation of their conflict of interest and any mitigating measures shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question pursuant to Article 5(5) of Regulation (EU) 2021/2282.

   The same applies where the exclusion of an individual expert in accordance with paragraph 2, would result in no involvement of a patient or a clinical expert in a joint clinical assessment or a joint scientific consultation.

Article 8

Obligations of the representatives and individual experts in case of a new conflict of interest

1. If a representative or an individual expert involved in the joint work has a new interest listed in Annex II as constituting a conflict of interest that is deemed incompatible with the participation in the joint work, they shall immediately step down from their roles and responsibilities. The representative or the individual expert shall declare that interest in a DOI submitted in accordance with Article 3(2) of this Regulation. Alternatively, they may declare the interest in writing to the HTA secretariat.

2. If during a meeting of the Coordination Group or its subgroups a representative or an individual expert becomes aware of a new interest listed in Annex II as constituting a conflict of interest in relation to the items on the agenda, they shall immediately declare that interest to the chair or the co-chair of the Coordination Group or its subgroup and to the HTA secretariat and withdraw from the relevant part of the meeting. The representative or the individual expert shall update their DOI without undue delay.

3. If during a joint clinical assessment or joint scientific consultation or a meeting of the Coordination Group or its subgroups a representative or an individual expert becomes aware of new circumstances in which the limitations listed in Annex II apply to them, they shall immediately inform the HTA secretariat and, as appropriate, the assessor, co-assessor, chair or the co-chair of the Coordination Group or its subgroup and withdraw from the relevant assessment, consultation or part of the meeting.

4. If a representative or an individual expert involved in the joint work intends to be engaged in activities with a health technology developer and will therefore acquire an interest listed in Annex II as constituting a conflict of interest that is deemed incompatible with the participation in the joint work, they shall immediately declare that interest in a DOI submitted in accordance with Article 3(2) of this Regulation or in writing to the HTA secretariat irrespective of whether a contract with the health technology developer has been signed or not. Articles 6(2) and 7(2) shall apply with regard to the action to be taken.

5. By way of derogation from paragraphs 1 to 4, where the exclusion or the withdrawal of an individual expert would result in no involvement of a patient or a clinical expert in a joint clinical assessment or a joint scientific consultation and the Commission considers it appropriate, the relevant subgroup shall ensure the appropriate involvement of such individual experts in the joint work considering their conflicts of interest. The explanation of their conflict of interest and any mitigating measures shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question pursuant to Article 5(5) of Regulation (EU) 2021/2282.

Article 9

Obligations of the members of the Coordination Group and its subgroups

Members of the Coordination Group and its subgroups shall notify the HTA secretariat in writing, if a representative has resigned or has been removed from their duties, at the latest by the day of their actual resignation or removal.

Article 10
Failure to declare an interest

1. If the Commission becomes aware of information that is not consistent with the information included in the DOI of a representative or an individual expert, it shall inform the representative or individual expert in writing and request a clarification of the situation. The representative or the individual expert shall provide the requested clarification within 14 days from the day of the notification of the request.

2. If the representative or the individual expert does not provide the requested clarification within the period referred to in paragraph 1, the Commission may decide to exclude the representative or the individual expert from participation in the joint work until the clarification is provided and assessed by the Commission.

3. If the requested clarification is provided, and irrespective of the assessment of the interests at issue, the Commission may exclude the representative or the individual expert from the joint work for a period up to 2 years, if the representative or the individual expert failed to declare the interest intentionally or by gross negligence.

4. The HTA secretariat shall inform the representative, the individual expert and, as appropriate, the member of the Coordination Group or its subgroup, the Coordination Group or its subgroups of the decisions of the Commission referred to in paragraph 3 and shall ensure the enforcement of the measures imposed in those decisions.

Article 11
Personal data processing

1. The Commission shall be controller of the processing, through the HTA IT Platform, of personal data of representatives and individual experts collected under this Regulation.

2. The categories of personal data referred to in paragraph 1 of this Article shall be the DOI and CV listed in Article 3 and Annex I, information confirmed in accordance with Article 5(1), point (b), as well as other related personal data.

3. The DOI and CV of patients involved in joint clinical assessments and joint scientific consultations, as well as the information submitted by them in accordance with Article 4(2), shall not be made publicly available. Such documents and information shall be only made available to the Commission when performing its tasks under this Regulation with restricted access on a need-to-know basis and subject to safeguards as required by Article 10(2), point (i), of Regulation (EU) 2018/1725. Such safeguards may include in particular pseudonymisation, prevention of unauthorised access, prevention of unauthorised reading, copying, modification or deletion of personal data, as well as organisational measures ensuring that personnel authorised to process data have access only to data covered by their access authorisation, and that it is possible to verify and establish what data have been accessed, by which member of the personnel and at what time.

4. The Commission shall keep the personal data included in DOI and CV submitted in accordance with Article 3, and information confirmed in accordance with Article 5(1), point (b), as well as other related personal data, of the representatives and individual experts only for as long as necessary for the purpose referred to in paragraph 1 of this Article and no longer than 15 years after the date on which the representatives or individual experts no longer participate in the joint work. The Commission shall review the necessity of storing the personal data every 2 years.

Article 12
Entry into force and 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