EDPS Formal comments on the draft Commission Implementing Regulation 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

THE EUROPEAN DATA PROTECTION SUPERVISOR,

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

Having regard to Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals 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 ('EUDPR')[1], and in particular Article 42(1) thereof,

HAS ADOPTED THE FOLLOWING FORMAL COMMENTS:

1. Introduction and background

1. On 13 June 2024, the European Commission consulted the EDPS on the Commission Implementing Regulation 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 ('the draft implementing regulation').
2. The objective of the draft Implementing Regulation is to lay down rules in accordance with Regulation (EU) 2021/2282[2], concerning the conflicts of interests of the representatives[3] and the individual experts[4] 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')[5].

[1] OJ L 295, 21.11.2018, p. 39.
[2] OJ L 458, 22.12.2021, p. 1–32.
[3] The Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') is established pursuant to Article 3(1) of Regulation (EU) 2021/2282. Pursuant to Article 3(2) and (3) of Regulation (EU) 2021/2282, Member States shall designate their members of the Coordination Group, and the members of the Coordination Group shall appoint their representatives in the Coordination Group and its subgroups.
[4] Pursuant to recital 3 of the draft implementing regulation, individual experts are patients, clinical experts and other relevant experts involved in joint clinical assessments and joint scientific consultations.
[5] Recital 4 of the draft Implementing Regulation.

EUROPEAN DATA PROTECTION SUPERVISOR
Postal address: rue Wiertz 60 - B-1047 Brussels
Offices: rue Montoyer 30 - B-1000 Brussels
E-mail: edps@edps.europa.eu
Website: edps.europa.eu
Tel.: 32 2-283 19 00 - Fax: 32 2-283 19 50

3. The draft Implementing Regulation is adopted pursuant to Article 5(7) and Article 25(1)(a) of 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.

4. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) of EUDPR. The EDPS welcomes the reference to this consultation in recital 21 of the draft Implementing Regulation. The EDPS also positively notes that he was previously consulted informally pursuant to recital 60 of EUDPR.

5. These formal comments do not preclude any additional comments by the EDPS in the future, in particular if further issues are identified or new information becomes available, for example as a result of the adoption of other related Implementing or Delegated acts[6].

6. Furthermore, these formal comments are without prejudice to any future action that may be taken by the EDPS in the exercise of his powers pursuant to Article 58 of the EUDPR and are limited to the provisions of the draft Implementing Regulation that are relevant from a data protection perspective.

2. Comments

2.1. Processing of personal data through the IT platform

7. The draft Implementing Regulation lays down the rules for processing of personal data of representatives and individual experts pursuant to the draft Implementing Regulation through the HTA IT platform[7].

8. The EDPS welcomes Article 11 of the draft Implementing Regulation that details the controller role of the Commission. The EDPS considers it important that the draft regulation lists the categories of personal data processed per category of data subjects.

9. The EDPS considers particularly relevant that the draft Implementing Regulation explicitly provides that declaration of interests ('DOI') and curriculum vitae ('CV') of patients involved in joint clinical assessments and joint scientific consultations shall

[6] In case of other Implementing or Delegated acts with an impact on the protection of individuals' rights and freedoms with regard to the processing of personal data, the EDPS would like to remind that he needs to be consulted on those acts as well. The same applies in case of future amendments that would introduce new or modify existing provisions that directly or indirectly concern the processing of personal data.
[7] Article 11(1) of the draft Implementing Regulation. The HTA IT platform is set up pursuant to Article 30 of Regulation (EU) 2021/2282.

not be made publicly available[8], considering the sensitive nature of such data. The draft Implementing Regulation also provides for suitable and specific safeguards to protect special categories of data, as required by Article 10(2)(i) of the EUDPR[9].

10. The EDPS welcomes that the draft Implementing Regulation defines the storage period of personal data, that ensures that data is kept no longer than necessary for the processing purposes, and in any event no longer than 15 years after the date on which the representatives or individual experts no longer participate in the joint work[10]. The draft Implementing Regulation provides that 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[11]. In this regard, the EDPS particularly appreciates the requirement of bi-annual review to ensure that personal data is not stored longer than necessary in practice[12].

2.2. Collection and publication of personal data

11. The draft Implementing Regulation provides that representatives and individual experts shall submit the DOI, and 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 the draft Implementing Regulation[13]. The DOI shall be accompanied by a comprehensive CV of the representative or of the individual expert based on the Europass CV template[14].

12. The draft Implementing Regulation further provides that 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[15].

13. The preamble to the draft Implementing Regulation[16] explains that pursuant to Article 30(3)(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

[8] Article 11(3) of the draft Implementing Regulation.
[9] Article 11(3) of the draft Implementing Regulation.
[10] Article 11(4) of the draft Implementing Regulation.
[11] Recital 17 of the draft Implementing Regulation.
[12] Article 11(4) of the draft Implementing Regulation.
[13] Article 2(1) of the draft Implementing Regulation.
[14] Article 3(1) of the draft Implementing Regulation.
[15] Article 5(2) of the draft Implementing Regulation.
[16] Recital 9 the draft Implementing Regulation.

and of clinical experts and other relevant experts involved in the joint work should be made publicly available. As already indicated above, the draft Implementing Regulation expressly provides that the DOI and CV of patients involved in joint clinical assessments and joint scientific consultations shall not be published[17].

14. The EDPS observes that the information which is to be made publicly available is capable of enabling a profile to be drawn up about the individuals concerned, insofar as the information relates not only to the identity of representatives and experts, but also to their previous functions and roles, financial interests, financial interests of immediate family members, and the representatives' and experts' qualifications and expertise[18].

15. It is inherent in making that information available to the general public in such a manner that it is then accessible to a potentially unlimited number of persons, with the result that such processing of personal data is liable to enable that information to be freely accessed also by persons who, for reasons unrelated to the objective pursued by that measure, seek to find out about the representatives and experts, for example in relation to their interests, knowledge, experience, background, etc., and – to a certain extent – their financial situation or those of their family members[19]. Furthermore, the potential consequences for the data subjects resulting from possible abuse of their personal data are exacerbated by the fact that, once those data have been made available to the general public, they can not only be freely consulted, but also retained and disseminated and that, in the event of such successive processing, it becomes increasingly difficult, or even illusory, for those data subjects to defend themselves effectively against abuse[20].

16. In light of the above, the EDPS considers that the publication of the DOI and CV of representatives and experts may give rise to a serious interference with the fundamental rights enshrined in Articles 7 and 8 of the Charter of Fundamental Rights of the EU ('Charter')[21]. The seriousness of that interference must be weighed against the importance of the objective of preventing conflicts of interest[22] in order to ensure the highest standards of independence, impartiality and transparency.

17. The fundamental rights enshrined in Articles 7 and 8 of the Charter are not absolute rights. Under the first sentence of Article 52(1) of the Charter, any limitation on the

[17] Article 11(3) of the draft Implementing Regulation.
[18] See by analogy also Judgment of the Court of Justice of 22 November 2022, *WM, Sovim SA v Luxembourg Business Registers,* Joined Cases C-37/20 and C-601/20, ECLI:EU:C:2022:912, paragraphs 40-41.
[19] Ibid, paragraph 42. See also judgment of the Court of Justice of 1 August 2022, *Vyriausioji tarnybinės etikos komisija*, C-184/20, ECLI:EU:C:2022:601, paragraphs 102-103.
[20] Judgment of the Court of Justice of 22 November 2022, *WM, Sovim SA v Luxembourg Business Registers,* Joined Cases C-37/20 and C-601/20, ECLI:EU:C:2022:912, paragraph 43.
[21] Ibid, paragraph 44; judgment of the Court of Justice of 1 August 2022, *Vyriausioji tarnybinės etikos komisija*, C-184/20, ECLI:EU:C:2022:601, paragraph 105.
[22] Judgment of the Court of Justice of 1 August 2022, *Vyriausioji tarnybinės etikos komisija*, C-184/20, ECLI:EU:C:2022:601, paragraph 106.

exercise of the rights and freedoms recognised by the Charter must be provided for by law and respect the essence of those rights and freedoms. According to the second sentence of Article 52(1) of the Charter, subject to the principle of proportionality, limitations may be made on those rights and freedoms only if they are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others. In that connection, Article 8(2) of the Charter states that personal data must, inter alia, be processed '*for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law*'[23].

18. The EDPS notes that Article 30(2) of Regulation (EU) 2021/2282 provides that the Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member States, members of the stakeholder network and the general public. Articles 30(3)(a) and (b) of the said Regulation provide that the publicly accessible webpage of the IT platform shall contain, *in particular*, an up-to-date list of the members of the Coordination Group and their appointed representatives and of the members of the subgroups and their appointed representatives, together with their qualifications and areas of expertise and their declarations of conflict of interest after the finalisation of the joint work. In doing so, Regulation (EU) 2021/2282 provides a lawful basis for publishing certain categories of personal data relating to representatives.

19. The EDPS observes that the draft implementing regulation contains publication requirements that are not explicitly provided for under Article 30(3) of Regulation (EU) 2021/2282, in particular by requiring the publication of information about clinical experts and other relevant experts other than members and appointed representatives. At the same time, the EDPS observes that Articles 30(3) of Regulation (EU) 2021/2282 does not provide for an exhaustive description of the information to be included on the publically available webpage (using the wording 'in particular').

20. In case the Commission considers that publication of the information is necessary for a task carried out in the public interest of ensuring the robustness of the system of the management of conflicts of interest of representatives, clinical experts and other relevant experts pursuant to Article 5(7) and Article 25(1)(a) of Regulation (EU) 2021/2282, it needs to duly justify this. Moreover, the Commission needs to take into account that the case law of the Court of Justice[24] makes clear that the necessity and proportionality of measures providing for the publication of personal data should be carefully assessed. As part of this assessment, it should be ascertained whether the objective of managing conflicts of interest might reasonably be achieved just as

[23] Judgment of the Court of Justice of 22 November 2022, *WM, Sovim SA v Luxembourg Business Registers,* Joined Cases C-37/20 and C-601/20, ECLI:EU:C:2022:912, paragraphs 45-46.

[24] See Judgment of the Court of Justice of 22 November 2022, *WM, Sovim SA v Luxembourg Business Registers,* Joined Cases C-37/20 and C-601/20, ECLI:EU:C:2022:912; judgment of the Court of Justice of 1 August 2022, *Vyriausioji tarnybinės etikos komisija*, C-184/20, ECLI:EU:C:2022:601.

effectively by less restrictive measures. In this regard, the EDPS notes that the Commission is tasked to assess whether a conflict of interest exists.

21. In any event, the EDPS considers that, from the perspective of foreseeability, it would be beneficial for Regulation (EU) 2021/2282 to provide an exhaustive description of the publication requirements. If the publication of information about clinical experts and other relevant experts other than members and appointed representatives proves necessary, the EDPS recommends explicitly providing for this publication requirement in Regulation (EU) 2021/2282 in case of future amendments to that regulation.

22. Finally, concerning the personal data that might become publicly available, the EDPS underlines the importance of ensuring compliance with the data minimisation principle[25].

Brussels,

[25] Article 4(1)(c) EUDPR.