EDPS Formal comments on the draft Commission Implementing Regulation 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

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 22 March 2024, the European Commission consulted the EDPS on the draft Commission Implementing Regulation 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 ('the draft implementing regulation').
2. The objective of the draft implementing regulation is to lay 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;

[1] OJ L 295, 21.11.2018, p. 39.

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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[2].

3. The draft implementing regulation is adopted pursuant to Articles 15(1), points (a) and (c), 25(1), point (b) and 26(1) of Regulation (EU) 2021/2282[3].

4. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) 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[4].

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. General comments

7. The EDPS notes that the draft implementing regulation provides for procedural rules as regards conducting and updating joint clinical assessments[5] of medicinal products[6]. It provides, among others, 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,

[2] Article 1 draft implementing regulation.
[3] 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, OJ L 458, 22.12.2021, p. 1–32.
[4] 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.
[5] See Article 2(6) of Regulation 2021/2282 for the definition of a 'joint clinical assessment' of a health technology.
[6] See Article 2(1) of Regulation 2021/2282 for the definition of a 'medicinal product'.

its subgroups and the health technology developers, patients, clinical experts and other relevant experts during joint clinical assessments and updates[7].

8. In addition, in order to ensure the highest scientific quality of joint clinical assessment reports, the draft implementing regulation provides for 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[8].

9. According to the draft implementing regulation, health technology developers would submit a dossier with relevant information for the joint clinical assessment, at the same time as they submit to the European Medicines Agency an application for marketing authorisation for medicinal products[9]. With the support of the Commission acting as the secretariat ('HTA secretariat')[10], the Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') would carry out joint clinical assessments on health technologies[11]. The HTA secretariat would facilitate the cooperation between Member States regarding carrying out joint clinical assessments of health technologies, including by providing an IT platform (the 'HTA IT platform') for this purpose[12].

10. Against this background, the EDPS welcomes recital (30) of the draft implementing regulation, which recalls the applicability of the EUDPR. The EDPS recommends to similarly recall that any processing of personal data by the Coordination Group and the JCA Subgroup representatives outside the HTA IT platform should take place in accordance with the GDPR[13].

11. The EDPS observes that the draft implementing regulation does not include a reference to the present EDPS consultation. For the sake of completeness, the EDPS recommends inserting a reference to the EDPS consultation in the recitals.

2.3. Processing of personal data through the HTA IT platform

12. The EDPS welcomes that the draft implementing regulation lays down the rules for processing of personal data through the HTA IT platform for the purposes of conducting joint clinical assessments and their updates[14].

[7] Article 15 of Regulation (EU) 2021/2282; recital 2 of the draft implementing regulation.
[8] Article 25(1), point (b), of Regulation (EU) 2021/2282; recital 4 draft implementing regulation.
[9] Article 2(1) of the draft implementing regulation; Article 9 of Regulation (EU) 2021/2282.
[10] Articles 3(6) and 28 of Regulation (EU) 2021/2282.
[11] Article 8(1) of Regulation (EU) 2021/2282.
[12] Set up pursuant to Article 30 of Regulation (EU) 2021/2282.
[13] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.
[14] Article 21 and recital 30 of the draft implementing regulation.

13. The EDPS also welcomes Article 21 of the draft implementing regulation that specifies the controller role of the Commission, and lists the categories of personal data per category of data subjects processed for the purpose of conducting joint clinical assessments and their updates[15].

14. The EDPS positively notes that the draft implementing regulation requires access controls to ensure that representatives of the Coordination Group and the JCA Subgroup would only have access to the parts of the secure system of the HTA IT platform which are relevant for the performance of their tasks[16].

15. The EDPS considers particularly relevant that the draft implementing regulation provides that personal data of patients involved in joint clinical assessments and their updates shall not be published[17], considering the sensitive nature of such data.

16. The EDPS also 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 purposes of conducting joint clinical assessments and their updates, and in any event no longer than 15 years after the date on which the data subject no longer participates in joint work[18]. 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. The EDPS recommends, however, to clearly explain the purposes for which data is retained and justify the necessity of the chosen maximum storage period in the recitals.

17. Lastly, the EDPS welcomes recital 31, which clarifies under which exception to the prohibition to process special categories of personal health data may be processed by the Commission. The recital provides that processing of personal health pursuant to the draft implementing regulation may only take place where the criteria of Article 10(2)(i) EUDPR are met, and sets out the safeguards provided for in the draft implementing regulation.

2.2. Selection of patients, clinical experts and other relevant experts

18. The EDPS welcomes the provision of rules applicable to the selection patients, clinical experts and other relevant experts to participate in the joint clinical assessment.

19. The draft implementing regulation provides sources that the HTA secretariat may consult when compiling a list of relevant patients, clinical experts and, where necessary, other relevant experts, in consultation with the subgroup on joint clinical assessments ('JCA Subgroup') and the appointed assessor and co-assessor[19]. Such specification of relevant sources ensures that searches for relevant individuals are

[15] Article 21(2) of the draft implementing regulation; see also recital 30 of the draft implementing regulation.
[16] Article 21(3) of the draft implementing regulation.
[17] Article 21(4) of the draft implementing regulation.
[18] Article 21(5) of the draft implementing regulation.
[19] Article 6(2) of the draft implementing regulation.

targeted and that the processing of personal data for the purpose of compiling a list of relevant individuals remains within set boundaries.

20. The EDPS understands that for the identification of patients, clinical experts and other relevant experts – for the purpose of compiling a list of relevant individuals – the HTA secretariat may also consult 'other' existing databases or directories or contact members of the Coordination Group, its subgroups and relevant European Union and international agencies and organisations[20]. The EDPS recommends clarifying that the consultation of such other sources should only take place in case the consultation of the sources in Article 6(2) of the draft implementing regulation does not lead to the identification of sufficient relevant individuals to compile a list.

21. The EDPS welcomes the requirement that only patients, clinical experts and other relevant experts who have signed a confidentiality agreement are involved in joint clinical assessments. Insofar these individuals have access to personal data in the context of the joint clinical assessment, the EDPS agrees that confidentiality agreements serve, among others, as a safeguard for the protection of personal data[21]. In addition, the representatives appointed to the Coordination Group and its subgroups – including the JCA Subgroup that has access to the data concerning the relevant individuals[22] – as well as patients, clinical experts and other relevant experts involved in the work of any subgroup shall, even after their duties have ceased, be subject to a requirement of professional secrecy[23]. The EDPS agrees that also such professional secrecy requirement may serve as a safeguard for the protection of personal data. Such safeguards are in particular relevant for the participating patients, as their participation in the role of a patient in a joint clinical assessment for a particular medicinal product may reveal information about their health. Health personal data is a special category of personal data pursuant to Article 9 GDPR and Article 10 EUDPR, for which the processing should be subject to safeguards.

Brussels, 4 April 2024

(e-signed)
Wojciech Rafał WIEWIÓROWSKI

[20] Article 6(3) of the draft implementing regulation.
[21] Article 7 of the draft implementing regulation.
[22] Articles 6 and 21(3) draft implementing regulation.
[23] Article 5(6) of Regulation (EU) 2021/2282; recital 31 of the draft implementing regulation.