EDPS Formal comments on the draft Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level

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 11 October 2024, the European Commission consulted the EDPS on the Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level ('the draft Implementing Regulation').
2. The objective of the draft Implementing Regulation is to lay down detailed procedural rules for joint scientific consultations as regards:
   a) submission of requests from health technology developers for joint scientific consultation on medicinal products for human use ('medicinal products');
   b) the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts ('individual experts') in joint scientific consultation on medicinal products;
   c) cooperation, in particular by exchange of information, with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried out in parallel with the scientific advice on medicinal products by the European Medicines Agency pursuant to Article 57(1), point (n), of Regulation (EC) No 726/2004 ('scientific advice')[2].

[1] OJ L 295, 21.11.2018, p. 39.
[2] Article 1 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 20(1), points (a), (b) and (c) 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[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) of EUDPR. The EDPS welcomes the reference to this consultation in recital 21 of the draft Implementing Regulation.

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. Selection of individual experts for joint scientific consultations on medicinal products

7. The draft Implementing Regulation provides for rules on the identification and selection of individual experts to be consulted during the joint scientific consultations on medicinal products[5]. It provides, with the necessary modifications, for similar rules as Article 6 of Commission Implementing Regulation (EU) 2024/1381[6], which provides for the selection of patients, clinical experts and other relevant experts for joint clinical assessments of medicinal products for human use at Union level. In this regard, the EDPS refers to its formal comments on the Commission Implementing

[3] 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] Article 5 and recital 9 of the draft Implementing Regulation.

[6] Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 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, OJ L, 2024/1381, 24.5.2024.

Regulation (EU) 2024/1381 and welcomes that Article 5 of the draft Implementing Regulation takes into account his previous recommendation[7].

2.2. Processing of personal data through the HTA IT Platform

8. Under Article 30(1) of Regulation (EU) 2021/2282, the Commission is to set up and maintain an IT platform consisting of, inter alia, a secure system for the exchange of information developers and experts participating in the joint work ('the HTA IT platform')[8].
9. The EDPS welcomes that recital 17 of the draft Implementing Regulation recalls that any processing of personal data by the European Medicines Agency and by the members of the Coordination Group and the JSC Subgroup and their representatives outside of the HTA IT platform is to take place in accordance with, respectively, the EUDPR and the GDPR[9].
10. The EDPS also welcomes that the draft Implementing Regulation lays down the rules for processing, through the HTA IT platform, of personal data for the purpose of conducting joint scientific consultations on medicinal products under the draft Implementing Regulation[10]. In particular, the EDPS welcomes that the draft Implementing Regulation:
    - details the role of the Commission as controller[11];
    - lists the categories of personal data processed per category of data subjects[12];
    - requires access controls to ensure that representatives of the Coordination Group and the JSC 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[13]; and

[7] See 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, issued on 4 April 2024, paragraphs 18-21. Article 5 of the draft Implementing Regulation provides that to compile a list of relevant patients, clinical experts and, where necessary, other relevant experts, the consultation of other sources than those specifically listed should only take place in case the consultation of the specifically listed sources does not lead to the identification of sufficient relevant individuals to compile a list.
[8] Recital 4 of the draft Implementing Regulation.
[9] 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.
[10] Article 15 and recital 17 of the draft Implementing Regulation.
[11] Article 15(1) of the draft Implementing Regulation.
[12] Article 15(2) of the draft Implementing Regulation.
[13] Article 15(3) of the draft Implementing Regulation.

– provides that patients shall not be obliged to disclose their identity to the health technology developer in meetings to which the developer participates[14], serving as a safeguard to protect patients' personal data[15]; and

– defines the storage period for processing 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 data subject no longer participates in the joint work[16]. The EDPS positively notes the requirement of bi-annual review to ensure that personal data is not stored longer than necessary in practice. The EDPS also positively notes that the draft Implementing Regulation provides for a shorter maximum storage period for personal data of individual experts not selected to be consulted in a joint scientific consultation.

11. Lastly, the EDPS welcomes that the draft Implementing Regulation further provides as an additional safeguard that only individual experts who have signed a confidentiality agreement should be involved in joint scientific consultations[17]. Insofar these individuals have access to personal data in the context of a joint scientific consultation, those confidentiality agreements can serve, among others, as a safeguard for the protection of personal data.

Brussels,

Digitally signed by:
WOJCIECH RAFAŁ
WIEWIÓROWSKI (EUROPEAN
DATA PROTECTION SUPERVISOR)
Date: 2024-11-06 10:44:39 UTC

[14] Article 15(4) of the draft Implementing Regulation.
[15] Recital 18 of the draft Implementing Regulation correctly recalls that the identity of the patient may reveal the patient's health status in relation to the subject matter of the joint scientific consultation and therefore should be considered a special category of personal data under Article 10 EUDPR, which should only be processed where the criteria of Article 10(2)(i) EUDPR are met and subject to suitable and specific measures to safeguard the rights and freedoms of the data subject.
[16] Article 15(5) of the draft Implementing Regulation. Recital 17 of the draft Implementing Regulation justifies the storage period to ensure the possibility to verify whether joint scientific consultations on medicinal products were conducted in an independent and impartial manner, notably in the event of complaints or litigation, to ensure the relevant in-depth specialised expertise in joint scientific consultation, as well as in order to verify compliance with the requirement set out in Article 8(4) of Regulation (EU) 2021/2282 that the assessor and co-assessor for joint clinical assessment is to be different from the assessor and co-assessor for joint scientific consultation.
[17] Article 6 of the draft Implementing Regulation.