EDPS Formal comments on the draft Commission Implementing Regulation laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and in vitro diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices

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 8 July 2023, the European Commission consulted the EDPS on the draft Commission Implementing Regulation laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council[2], detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and in vitro diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices ('the draft implementing regulation').
2. The objective of the draft implementing regulation is to lay down detailed procedural rules concerning cooperation, in the form of exchange of information, of the Member State Coordination Group on Health Technology Assessment ('Coordination Group'),

[1] OJ L 295, 21.11.2018, p. 39.
[2] 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.

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with the facilitation of the secretariat of the Coordination Group ('the HTA secretariat') which is provided by the Commission[3], with the European Medicines Agency on the joint clinical assessment and joint scientific consultation referred to in Articles 7 to 21 of Regulation (EU) 2021/2282 as regards:

a) planning and forecast of the joint clinical assessments and joint scientific consultations;

b) identification of patients, clinical experts and other relevant experts ('individual experts') to be involved in joint clinical assessments and joint scientific consultations;

c) general scientific and technical matters related to joint clinical assessment and joint scientific consultation;

d) security of sharing and protection of confidential information exchanged between the European Medicines Agency and the HTA secretariat and then shared by the HTA secretariat with the Coordination Group or its subgroups and their members within the context of joint clinical assessment and joint scientific consultation[4].

3. The draft implementing regulation is adopted pursuant to Article 15(1)(a) and (b), and Article 20(1)(c) and (d) of Regulation (EU) 2021/2282.

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 14 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[5].

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.

[3] Article 28 of Regulation (EU) 2021/2282.
[4] Article 1 of the draft implementing regulation.
[5] 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.

2. Comments

7. The preamble of the draft implementing regulation states that Regulation (EU) 2021/2282 provides for the involvement of patients, clinical experts and other relevant experts ('individual experts') having expertise in the therapeutic area concerned in joint clinical assessments and joint scientific consultations[6]. Similarly, individual patients and healthcare professionals having expertise in the therapeutic area concerned are being engaged by the European Medicines Agency in the context of the evaluation of medicinal products.

8. The preamble of the draft implementing regulation explains that joint clinical assessments and joint scientific consultations under Regulation (EU) 2021/2282 are conducted on the health technologies that are subject to the centralised procedure provided for under Regulation (EC) No 726/2004[7], the clinical evaluation consultation procedure pursuant to Article 54 of Regulation (EU) 2017/745[8] and the performance evaluation consultation procedure pursuant to Article 48(6) of Regulation (EU) 2017/746[9]. According to the draft implementing regulation, as the joint clinical assessments and joint scientific consultations under Regulation (EU) 2021/2282 are to be conducted in parallel with the centralised procedure and with the consultation of the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745 and in close cooperation with the European Medicines Agency, the HTA secretariat and the European Medicines Agency should cooperate to exchange information on individual experts to be engaged in the respective procedures.

9. Pursuant to the draft implementing regulation, the cooperation between the HTA secretariat and the European Medicines Agency on the identification of individual experts should include the exchange of personal data, namely the names, contact details and areas of expertise of individual experts[10]. Such data of potentially suitable individual experts shall, upon request and where that information is available, be provided to the HTA secretariat for its consideration to be proposed to the relevant subgroup as a patient, clinical expert or other relevant expert in a joint clinical assessment or joint scientific consultation[11]. The draft implementing regulation indicates that such processing is necessary for the performance by the Commission of its tasks laid down in Article 28 of Regulation (EU) 2021/2282, and based on Article

[6] Recital 7 of the draft implementing regulation.
[7] 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 and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1-33.
[8] 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, p. 1–175.
[9] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176–332.
[10] Article 5(1) and recital 9 of the draft implementing regulation.
[11] Article 5(1) of the draft implementing regulation.

5(1)(a) of the EUDPR, and Article 10(2)(i) of the EUDPR for data concerning health[12]. The EDPS welcomes that the draft implementing regulation explicitly provides the legal basis for the processing of personal data of potentially suitable individual experts, received by the Commission from the European Medicines Agency. The draft implementing regulation also provides for safeguards to protect special categories of data, as required by Article 10(2)(i) of the EUDPR[13].

10. In addition, the EDPS positively notes that the draft implementing regulation explicitly defines the role of controller of the Commission for the processing of the personal data received from the European Medicines Agency[14].

11. The EDPS recommends defining in the implementing regulation the storage period of the personal data of potentially suitable individual experts that the Commission processes as HTA Secretariat, in particular when such potentially suitable individual experts are not selected to be involved in joint clinical assessments and joint scientific consultations[15].

12. Lastly, the EDPS observes that pursuant to the draft implementing regulation, the summary minutes of the meeting as well as joint clinical assessment reports or joint scientific consultation outcome documents shall record whether an individual expert was engaged in the context of the evaluation of the same medicinal product during the centralised procedure or the same medical device or in vitro diagnostic medical device[16]. Pursuant to Article 30(3)(e), (i) and (k) of Regulation (EU) 2021/2282, respectively, the publicly accessible webpage of the IT platform shall contain the summary minutes of the Coordination Group's meetings; the joint clinical assessment reports; and anonymised, aggregated, non-confidential summary

[12] See Article 5(3) and recital 9 of the draft implementing regulation. In terms of safeguards, the draft implementing regulation specifies that the Commission shall take specific safeguards such as 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. In addition, Article 7 provides for the secure exchange of information between HTA secretariat and the European Medicines Agency and Articles 8 and 9 provides for additional protections to ensure confidentiality of information.
[13] Article 5(3) of the draft implementing regulation. See also recital 10 of the draft implementing regulation, which explains that the identity of the patient (an individual expert under the draft implementing regulation) may reveal the patient's health status in relation to the subject-matter of the joint clinical assessment or the joint scientific consultation and that therefore, such data should be considered a special category of personal data under Article 10 of the EUDPR and that the processing of such data requires pursuant to Article 10(2)(i) of the EUDPR suitable and specific measures to safeguard the rights and freedoms of data subjects.
[14] Article 5(3) and recital 9 of the draft implementing regulation.
[15] The EDPS understands that the processing of personal data of individual experts that are involved in joint clinical assessments and joint scientific consultations is governed by other implementing acts under Regulation (EU) 2021/2282, e.g. 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; and 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 (OJ L xx, xx, p. xx, ELI: xx).
[16] Article 5(2) of the draft implementing regulation.

information on joint scientific consultations. The EDPS recommends clarifying in the draft implementing regulation that insofar the summary minutes as well as joint clinical assessment reports contain personal data of individual experts, no personal data of patients shall be published on the publicly accessible webpage of the IT platform.

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