Formal comments of the EDPS on Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed)

1. Introduction and background

- The following comments concern the Proposal for a Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices ('Eudamed') ('the Proposal').

- Regulations (EU) 2017/745 and (EU) 2017/746 provide that the Commission, competent authorities, authorities responsible for notified bodies, notified bodies, manufacturers, authorised representatives, importers, producers of systems and procedure packs and sponsors of clinical investigations and performance studies should have access to and use Eudamed for the purpose of complying with their obligations and carrying out their tasks under those Regulations.

- In this regard, Article 33 of Regulation (EU) 2017/745 on medical devices ('MDR') provides that the Commission, by means of implementing act, shall lay down the detailed arrangements necessary for the setting up and maintenance of the Eudamed. The Proposal therefore aims to establish the detailed rules necessary to set up and maintain the Eudamed database.

- These comments are provided in reply to the formal request by the Commission of 27 May 2021 pursuant to Article 42(1) of Regulation (EU) 2018/1725 ('the EUDPR')[1] . We limited our comments below to the provisions of the Proposal that are relevant from a data protection perspective.

- These formal comments do not preclude any future additional comments by the EDPS, in particular if further issues are identified or new information becomes available. 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.

[1] 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.

2. Comments

2.1 General comments

- The EDPS welcomes recital 8 of the Proposal, which stipulates that "(...) *[i]n order for Eudamed to function in a secure manner, protected against threats to the availability, integrity and confidentiality of its functions and data, additional security rules should be laid down.*" Moreover, the EDPS gladly notes the reference made to the privacy statement in Articles 3(6) and 10(1)(c) of the Proposal.

2.2 Specific comments

2.2.1 Personal data categories

- The EDPS notes that the MDR does not list the categories of personal data that would be processed in Eudamed. In this regard, the EDPS recommends identifying the categories of personal data processed in Eudamed in the Proposal[2].

- The EDPS wishes to stress that personal data related to clinical trials would normally imply the processing of data related to health, which constitutes a special category of personal data within the meaning of data protection rules. It will therefore be of paramount importance to ensure that the processing takes place in full compliance with the EUDPR and Regulation (EU) 2016/679 ('GDPR')[3].

2.2.2 Transparency and data subject rights

- The EDPS notes that both Articles 3(6) and 10(1)(c) of the Proposal make reference to a privacy statement. In order to facilitate the exercise of data subject rights, the EDPS recommends identifying a specific contact point for dealing with data subject's requests and ensuring that this contact point is communicated to data subjects. This would not only provide more clarity and transparency of information to data subjects, but could also guarantee that adequate follow-up is provided to each request.

- The EDPS also notes that the Commission, competent authorities, authorities responsible for notified bodies, notified bodies, manufacturers, authorised representatives, importers, producers of systems and procedure packs and sponsors of clinical investigations and performance studies should have access to and use Eudamed for the purpose of complying with their obligations and carrying out their tasks under those Regulations[4].

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[2] The EDPS recalls that in accordance with Article 33(9) MDR the Commission is considered to be the controller of Eudamed and its electronic systems in relation to its responsibilities under this Article and the processing of personal data involved therein.

[3] 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.

[4] Recital 3 of Proposal.

In this regard, for the sake of transparency, the EDPS recalls that data subjects should be clearly informed of all recipients or categories of recipients, in accordance with Articles 12-14 GDPR and 12-14 EUDPR.

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