Executive summary of the Opinion of the European Data Protection Supervisor on the Commission proposal for a regulation on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(The full text of this Opinion can be found in English, French and German on the EDPS website http://www.edps.europa.eu)

(2013/C 253/05)

1. Introduction

1.1. *Consultation of the EDPS*

1. On 17 July 2012, the Commission adopted a proposal for a regulation on clinical trials on medicinal products for human use (the proposed Regulation) [1], and repealing Directive 2001/20/EC. This proposal was sent to the EDPS for consultation on 19 July 2012.

2. The EDPS welcomes the fact that he is consulted by the Commission and recommends that a reference to the consultation be included in the preambles of the proposed Regulation.

3. Before the adoption of the proposed Regulation, the EDPS was given the possibility to provide informal comments to the Commission. Some of these comments have been taken into account. As a result, the data protections safeguards in the proposed Regulation have been strengthened.

1.2. *Objectives and scope of the proposed Regulation*

4. The proposed Regulation aims at facilitating the application process for clinical trials on medicinal products for human use, especially for multinational trials. It contains a legal framework for establishing an EU-wide central database (EU database), controlled by the Commission, as the single application platform for clinical trials in the EU. The proposed Regulation also introduces an electronic database (EMA database), controlled by the European Medicines Agency (EMA), for reporting of suspected unexpected serious adverse reactions.

1.3. *Aim of the EDPS Opinion*

5. The proposed Regulation may affect the rights of individuals related to the processing of their personal data. Amongst other issues, it deals with the processing of sensitive data (health data), databases and record keeping.

6. Although the EDPS welcomes that the Commission has made an effort to guarantee the correct application of EU rules concerning the protection of personal data in the proposed Regulation, the EDPS has identified certain unclarities and inconsistencies in the way the proposed Regulation deals with the issue of whether and what categories of personal data will be processed under the proposed Regulation, in particular where sensitive data regarding health might be processed and stored. The EDPS therefore sees a need for clarification in relation to this category of personal data, both regarding the authorisation procedure in the EU Portal and database and the reporting of adverse effects in the EMA database.

3. Conclusions

32. The EDPS welcomes the attention paid specifically to data protection in the proposed Regulation, but identified some scope for further improvement.

33. The EDPS recommends that:

— Article 89 of the proposed Regulation clarifies the reference to Directive 95/46/EC by specifying that the provisions will apply in accordance with the national rules which implement Directive 95/46/EC,

— the proposed Regulation explicitly refers to Article 8 of Directive 95/46/EC and Article 10 of Regulation (EC) No 45/2001 regarding the processing of personal data concerning health in Article 89,

— Article 78 clarifies whether personal data concerning health will be processed in the EU database, and if so, for what purpose,

[1] COM(2012) 369 final.

— Article 78 refers to the right of the data subjects to block their personal data,

— the proposed Regulation inserts, for the EMA database, a provision which more clearly defines in what situations and subject to what safeguards information containing patient data will be processed and stored,

— it should be explicitly mentioned in Article 39 of the proposed Regulation that the annual reports should only be using anonymous data,

— implementing measures to be adopted under the proposed Regulation specify in detail the data protection implications of the functional and technical characteristics of the EU database and the EMA database and that the EDPS be consulted on these measures, and

— Article 55 of the proposed Regulation replaces or complements the minimum retention period of 5 years by a maximum retention period.

Done at Brussels, 19 December 2012.

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