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from: European Data Protection Supervisor  
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Subject: 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

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Delegations will find attached 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.

**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 EUROPEAN DATA PROTECTION SUPERVISOR,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16 thereof,

Having regard to the Charter of Fundamental Rights of the European Union, and in particular Articles 7 and 8 thereof,

Having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>1</sup>,

Having regard to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>2</sup>, and in particular Article 28(2) thereof,

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<sup>1</sup> OJ L 281, 23.11.1995, p. 31.

<sup>2</sup> OJ L 8, 12.1.2001, p. 1.

HAS ADOPTED THE FOLLOWING OPINION:

## **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')<sup>3</sup>, 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.

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<sup>3</sup> COM (2012) 369 final.

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.

## **2. ANALYSIS OF THE PROPOSAL**

### **2.1. Applicability of data protection legislation**

7. Recitals and provisions of the proposed Regulation mention Articles 7 and 8 of the Charter of Fundamental Rights, Directive 95/46/EC and Regulation (EC) No 45/2001<sup>4</sup>.
8. In particular, Article 28(1)(e) states that a clinical trial may only be conducted if data concerning the subject<sup>5</sup> is protected in accordance with Directive 95/46/EC. Article 89 of the proposed Regulation states that Member States shall apply Directive 95/46/EC to the processing of personal data pursuant to the proposed Regulation and that Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the EMA in the context of the proposed Regulation.
9. The EDPS welcomes these provisions but recommends that Article 89 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.

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<sup>4</sup> See Articles 28, 78 and 89 and Recitals 52, 59 and 65.

<sup>5</sup> A 'Subject' is defined in Article 2 (15) of the proposed Regulation as 'an individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control'.

10. These references to data protection law are relevant, for example, in relation to the various provisions concerning exchanges of personal data between national authorities/sponsors<sup>6</sup> of clinical trials on the one side and the Commission/EMA on the other. These provisions are legitimate but need to be applied in a way which is consistent with data protection legislation. The risk is to be avoided in particular that they could be construed as a blanket authorisation to exchange all kind of personal data<sup>7</sup>.

## 2.2. Consent

11. The proposed Regulation deals extensively with the issue of informed consent in Articles 28-32. Furthermore, Recital 22 of the proposed Regulation states that the Charter of Fundamental Rights of the European Union requires that any intervention in the field of medicine has to be performed with free and informed consent of the person concerned.
12. The notion of informed consent is central in data protection law. However, the EDPS understands that consent, even if it is the basis for a patient's participation in the clinical trial, is not the basis for processing and storage of personal data under the proposed Regulation. He will therefore not comment on the specific provisions concerning informed consent in the proposed Regulation<sup>8</sup>.

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<sup>6</sup> A 'Sponsor' is defined in Article 2 (13) of the proposed Regulation as 'an individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical trial'.

<sup>7</sup> The proposed Regulation contains provisions allowing or requiring national authorities to exchange information between them and the Commission or with the EMA. In particular, the Articles concerning the EU Portal and database (Articles 77-78) and the articles concerning the EMA database (Articles 36-43) clearly imply that exchanges of personal data will take place under the proposed Regulation.

<sup>8</sup> For a more in-depth analysis of the notion of consent in data protection law, see Article 29 Data Protection Working Party Opinion 15/2011 of 13 July 2011 on the definition of consent, 01197/11/EN, WP 187.

### 2.3. Processing of personal data concerning health

13. Clinical trials are by nature dependent on the processing and storage of personal data of patients at different levels (local, national and European). Personal data of patients participating in clinical trials can be considered as data relating to health ('health data') of the persons concerned since they reveal information about medicine use and associated health problems.
14. Processing of such data is subject to strict data protection rules as laid down in Article 10 of Regulation (EC) No 45/2001 and Article 8 of Directive 95/46/EC and its implementing national laws. Among the grounds, which allow for processing of personal data relating to health, Article 10(3) of Regulation (EC) No 45/2001 and Article 8(3) of Directive 95/46 are applicable in this case. These provisions lift the prohibition of processing health related data if the processing is 'required for the purpose of preventive medicine...'. The EDPS wishes to underline that this sets a high standard.
15. The importance of protecting such data has repeatedly been emphasised by the European Court of Human Rights in the context of Article 8 of the European Convention of Human Rights. The Court has stated: 'The protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention'<sup>9</sup>. The EDPS therefore recommends inserting in Article 89 of the proposed Regulation an explicit reference to Article 10 of Regulation (EC) No 45/2001 and Article 8 of Directive 95/46/EC .

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<sup>9</sup> See ECHR 17 July 2008, I v Finland (appl. No 20511/03), paragraph 38 and ECHR 25 November 2008, Armonas v Lithuania (appl. No 36919/02), paragraph 40.

## **2.4. Other data than patient health data**

16. Personal data other than health data will be processed and retained under the proposed Regulation. For example, the explanatory memorandum<sup>10</sup> states that personal data of Investigators<sup>11</sup> will be kept in the EU database in order to aid the detection of misconduct. The EMA database might also contain personal information about the (employees of) Sponsors when they are providing information to the database. The EDPS wishes to underline that once identifiable data are processed, the party responsible for such processing (the Commission or the EMA) must comply with all the requirements of EU data protection legislation.

## **2.5. Processing of personal data concerning health in the central databases**

### *2.5.1. EU Portal and database*

17. The EU Portal and database are regulated in Articles 77 and 78 of the proposed Regulation. The EDPS welcomes the attention given to the protection of personal data in the wording of Article 78 about the EU database. Article 78(2) and 78(4) state that the EU database shall contain personal data if it is necessary to enable the co-operation between the competent authorities of the Member States. The EDPS understands that this purpose is legitimate within the framework of multi-national clinical trials and that it is necessary to process certain kinds of personal data to achieve the simplification and harmonisation that the proposed Regulation aims for.

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<sup>10</sup> See Section 3.4. of the explanatory memorandum to the proposed Regulation.

<sup>11</sup> An 'Investigator' is defined in Article 2 (14) of the proposed Regulation as 'an individual responsible for the conduct of a clinical trial at a clinical trial site'.

18. According to Recital 52, no personal data of individuals participating in the clinical trial (patients) will be collected in the EU database. This is a statement of intent that indeed the EU database will not include patient health data. Nevertheless, the attention given to the protection of personal data in the wording of Article 78, and especially the fact that no personal data of patients shall be publicly accessible might suggest that processing of patient health data cannot be avoided. This unclarity in the proposed Regulation must be rectified. The EDPS recommends that the exclusion of personal data of patients in the EU database be incorporated in Article 78 instead of in a recital.
19. The EDPS welcomes that the right of access for data subjects and the rights to correction and deletion of their personal data are addressed in the proposed Regulation in Article 78(7). He also welcomes that the last sentence of Article 78(7) states that corrections and deletions shall be carried out as soon as possible, but no later than within 60 days. However, the right of the data subject to block their personal data has not been addressed and should be included.
20. Moreover, any implementing measures to be adopted under the proposed Regulation should specify in detail the data protection implications of the functional and technical characteristics of the EU database and the EDPS should be consulted.

#### *2.5.2. European Medicines Agency Database*

21. According to Articles 36, 38 and 39 of the proposed Regulation, the EMA shall set up and maintain an electronic database for the reporting of suspected unexpected serious adverse reactions to medicines and the annual reporting by the Sponsor and in some cases the national authorities to the EMA. Annex III to the proposed Regulation specifies the requirements for this reporting. Neither these Articles nor the Annex prohibit the processing of personal data of patients. Hence, processing of personal data of patients is allowed in the EMA database.
22. The Commission states in the explanatory memorandum to the proposed Regulation<sup>12</sup> that the direct reporting of suspected unexpected serious adverse reactions to the European database EudraVigilance that is in place under Directive 2001/20/EC shall remain unchanged.

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<sup>12</sup> See Section 3.5. on p. 7 of the proposed Regulation.



23. The issue of the reporting of adverse reactions to medicines (pharmacovigilance) has been a subject on which EDPS has commented on a number of occasions. In 2009, the EDPS published an Opinion on the amendments to Regulation (EU) No 1345/2010 and Directive 2010/84/EU<sup>13</sup>. The EDPS also published an Opinion on a notification for prior checking regarding the EudraVigilance database<sup>14</sup> and provided informal comments to the Commission before the publication of the implementing regulation on the performance of pharmacovigilance activities (the Implementing Regulation)<sup>15</sup>.
24. A large quantity of patient data concerning health is, at the moment, being recorded and kept in the EudraVigilance database concerning clinical trials. A general issue the EDPS wishes to raise is the actual necessity of processing directly identifiable patient health data at EU level.
25. Article 28(1) of the Implementing Regulation provides that in certain cases the individual case safety report shall include information identifying the patient. Indeed, even in case the patient is not mentioned by name, it is possible by putting the different pieces of information together (e.g. hospital, birth date, initials) and/or under specific conditions (e.g. in closed communities or small places) to identify him or her. Therefore, information processed in the context of safety reporting falls in principle within the scope of data protection law. This fact is also recognised in the Guidelines on the EudraVigilance database where it is stated that ‘the information should be as complete as possible, taking into account EU legislation on data protection’.

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<sup>13</sup> EDPS Opinion of 22 April 2009,  
[http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2009/09-04-22\\_pharmacovigilance\\_EN.pdf](http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2009/09-04-22_pharmacovigilance_EN.pdf).

<sup>14</sup> EDPS Opinion of 7 September 2009,  
[http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Priorchecks/Opinions/2009/09-09-07\\_EMEA\\_EudraVigilance\\_EN.pdf](http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Priorchecks/Opinions/2009/09-09-07_EMEA_EudraVigilance_EN.pdf).

<sup>15</sup> Commission Implementing Regulation on the performance of pharmacovigilance activities, (EU) No 520/2012 of 19 June 2012.

26. It may be necessary to include information identifying patients in the primary reports collected and maintained by the sponsor or the national authority. However, the EDPS does not see the need for this information to be preserved in a central database like the EMA database. It would be sufficient to provide for a traceability mechanism (e.g. through pseudonymisation of the data). Sponsors should submit their reports to the EMA database only after having pseudonymised the data (i.e. substituting direct identification elements like the name with a code). This would still enable the traceability of the data along the whole system, whereas at the same time this would render direct identifiability in the central EMA database impossible. Duplication of reporting can be avoided through the application of well structured data reporting procedures.
27. The EDPS recommends inserting a provision in the proposed Regulation that clearly defines in which situations and subject to what safeguards information containing patient health data will be processed and stored in the EMA database. In particular, the proposed Regulation should require that a risk assessment be carried out by the EMA before the processing and storage of any patient health data in the EMA database.
28. When referring to periodic safety reports (annual reports) from the sponsor to the EMA in Article 39 of the proposed Regulation, the EDPS recommends that it should be explicitly mentioned that the annual reports should only be using anonymous data.
29. As stated above regarding the EU database, any implementing measures to be adopted under the proposed Regulation should specify in detail the data protection implications of the functional and technical characteristics of the EMA database and the EDPS should be consulted.

## 2.6. Record keeping under the proposed Regulation

30. The only provision of the proposed Regulation that concerns record keeping is Article 55 in relation to archiving of the clinical trial master file. This provision obliges the sponsor and the investigator to archive the content of the clinical trial master file for at least 5 years unless other Union legislation requires archiving for a longer period. There is no such obligation foreseen in the proposed Regulation regarding the EU and EMA databases. The explanatory memorandum explains that it is important to keep the personal data of investigators for several years after the conclusion of the clinical trial, to be able to retroactively detect cases of misuse<sup>16</sup>.
31. Article 6(1)(e) of Directive 95/46/EC requires that personal data are not kept for longer than is necessary for the purposes for which the data were collected or for which they are further processed. In order to comply with this requirement, the EDPS suggests inserting a maximum retention period for personal data under the proposed Regulation. The chosen period should be necessary and proportionate for the purposes for which personal data are collected and processed.

## 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;

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<sup>16</sup> This is based on the exception to erasure of data for historical, statistical and scientific research purposes provided for in Article 17.3 (c) of the proposed Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (general data protection regulation), COM (2012) 11 final.

- 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;
- 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 in Brussels, 19 December 2012

**(signed)**

Giovanni BUTTARELLI

Assistant European Data Protection Supervisor

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