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*Committee on Civil Liberties, Justice and Home Affairs*

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**2012/0192(COD)**

9.4.2013

## **OPINION**

of the Committee on Civil Liberties, Justice and Home Affairs

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council  
on clinical trials on medicinal products for human use, and repealing Directive  
2001/20/EC  
(COM(2012)0369 – C7-0194/2012 – 2012/0192(COD))

Rapporteur: Juan Fernando López Aguilar

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## SHORT JUSTIFICATION

The proposal aims at boosting and facilitating clinical research in the EU by simplifying the current rules for conducting clinical trials on medicinal products for human use. The proposal will replace current Directive 2001/20/EC by a Regulation which will establish a modern uniform legal framework at EU level, cutting red-tape and ending with national divergences in the implementation of Directive 2001/20/EC.

The proposal provides for the establishment of an electronic database (the EMA database), controlled by the European Medicines Agency (EMA) for the reporting of suspected unexpected serious adverse reactions. It also provides for the establishment of an EU-wide central data base (EU database) controlled by the Commission, as the single application platform for clinical trials in the EU.

Your rapporteur supports the objectives pursued by the proposal. It particularly welcomes the choice of a Regulation. It is the correct instrument to establish a uniform legal system in the Union and, hence, to create greater legal certainty and to finish with the existing regulatory and administrative burden resulting from the divergent application and implementation of Directive 2001/20/EC by the Member States.

Clinical trials have a major impact on fundamental rights of individuals, particularly the right to human dignity (Article 1), the right to life (Article 2), the right to integrity of the person (Article 3), the right for respect of private and family life (Article 7), the right to the protection of personal data (Article 8), the rights of the child (Article 24) or the right to health care (Article 35). It is essential that the future Regulation ensures the full respect of the EU Charter of Fundamental Rights. Although Recital 65 indicates that the proposal respects the fundamental rights and observes principles recognised in particular by the EU Charter of Fundamental Rights, no specific mechanism is established in order to ensure this respect. Therefore it is necessary that a provision is made to ensure that the assessment of the respect of fundamental rights and of the measures taken to safeguard them will be part of the process of assessment regarding a clinical trial application. Articles 7(1), 31, and Annex I, Section 4, point 13 and Annex II, Section 4, should be amended accordingly.

The conducting of clinical trials implies the processing of personal data at several levels (at least sponsors, investigators, processors, EU Commission and the EMA). Personal data processed shall relate to different categories of data by which subjects are affected e.g.: subjects undergoing a clinical trial, persons giving the informed consent, sponsors, investigators, etc. Moreover different categories of personal data shall be processed, particularly "sensitive data". Your rapporteur welcomes that Recitals 52 and 59 and Article 89 (Data Protection) clearly set out that Directive 95/46/EC applies to the processing of personal data carried out pursuant to this Regulation in the Member States and Regulation (EC) No 45/2001 to the processing of personal data carried out by the Commission and the EMA in the context of this Regulation.

The Electronic database for reporting, established by the European Medicines Agency (EMA) should not contain personal data that would enable identification of patients. It should only contain pseudonymised data (key coded data) that only enable the identification of the data

subject at the level of those who actually would need this information (for instance, to provide the necessary treatment), whereas this would render direct identifiable of the data subject in the EMA database impossible. Article 36 of the proposal should indicate this.

The purpose of the EU database,(Article 78), of is to streamline and facilitate the flow of information between sponsors and Member States and between the Member States. Although Recital 52 declares that no personal data of data subjects participating in a clinical trial should be recorded in the EU database, the wording of Article 78 is not clear. It provides for the "inclusion of personal data in the EU database insofar as this is necessary for the purposes for which the database is established". This does not preclude the inclusion of personal data of patients. Since the prohibition of processing of patient's personal data in the EU database is one of its essential elements, Article 78(4) should be amended to clearly establish this condition as a recital as it currently is not sufficient due to the lack of legally binding effect.

Article 78(7) refers to the rights of data subjects of information, access, rectification and deletion. It establishes a deadline of 60 days after a request is made by the data subject to have the personal data rectified or deleted. This provision should be completed in order to include the right to block personal data which is recognised by the Union's data protection law along with the subsequent rights referred to in this provision.

The proposal does not contain a provision regarding the retention period of files and personal data processed in the EMA database and in the EU database. The establishment of a retention period is an essential data protection principle. It seems that the reason for not having fixed a retention period would be the need to keep personal data of investigators for several years after the conclusion of a clinical trial so as to detect retroactively cases of misuse. However, this does not justify an unlimited period of storage of personal data. EU data protection law provides for the possibility to set longer periods of storage of personal data in the case of scientific research subject to the establishment of appropriate safeguards. Your rapporteur therefore considers that adequate and sufficiently long data retention periods which would enable to detect retroactively cases of misuse of clinical trials should be set.

The amendments proposed will improve the legal certainty of the proposal and will strengthen the safeguards and protections of individuals, thereby ensuring compliance with Articles 8 of the EU Charter, 16 of the Treaty on the Functioning of the European Union, Directive 95/46/EC and Regulation (EC) No 45/2001

## **AMENDMENTS**

The Committee on Civil Liberties, Justice and Home Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

**Amendment 1**  
**Proposal for a regulation**

**Recital 55**

*Text proposed by the Commission*

(55) In order to carry out the activities provided for in this Regulation, Member States should be allowed to levy fees. ***However, Member States should not require multiple payments to different bodies assessing, in a given Member State, an application for authorisation of a clinical trial.***

*Amendment*

(55) In order to carry out the activities provided for in this Regulation, Member States should be allowed to levy fees.

**Amendment 2**

**Proposal for a regulation**  
**Article 7 – paragraph 1 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

***(ha) assessment of the respect of the rights of the subjects to human dignity, the right to physical and mental integrity, the right for respect of private and family life and the right of the child.***

*Justification*

*The proposal admits that it has a major impact on fundamental rights and indicates that it respects fundamental rights. However, it does not contain a mechanism that would ensure this respect. The amendment seeks to ensure that when assessing a clinical trial application, the respect of the fundamental rights will also be assessed.*

**Amendment 3**

**Proposal for a regulation**  
**Article 29 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3a. Consent shall not waive the rights of***

*subjects to the respect of their rights to human dignity, the right to physical and mental integrity, the right for respect of private and family life and the right of the child.*

*Justification*

*Consent may not be a means to waive the fundamental rights to human dignity, the right to physical and mental integrity, the right for respect of private and family life and the right of the child.*

**Amendment 4**  
**Proposal for a regulation**

**Article 31 – paragraph 1 – point c**

*Text proposed by the Commission*

(c) the explicit wish of a minor *who is capable of forming an opinion and assessing this information* to refuse participation in, or to be withdrawn from, the clinical trial at any time, is *duly taken into consideration by the investigator in accordance with his or her age and maturity*;

*Amendment*

(c) the explicit wish of a minor to refuse participation in, or to be withdrawn from, the clinical trial at any time, is *respected, irrespective of the position of his or her legal representative, no matter what the age or maturity of the minor may be*;

**Amendment 5**

**Proposal for a regulation**  
**Article 31 – paragraph 1 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

*(ha) the interest of the patient shall always prevail over those of science and society.*

*Justification*

*Current Directive 2001/20/EC expressly provides, amongst the conditions to meet to conduct a clinical trial on minors that the interest of the patient shall always prevail over those of science and society. This condition should be maintained so as to make it clear that the rights of minors are protected.*

**Amendment 6**  
**Proposal for a regulation**

**Article 36 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 36a**

**Personal data**

***Personal data of patients shall be processed in the database referred to in Article 36 in a manner that shall not permit the direct identification of the patient (without patients name or address) and shall be kept separately from other information processed in the database. However, persons who need to know the identity of the patient for the purposes of protecting his or her vital interest shall have the possibility to do so (via an appropriate key).***

*Justification*

*The purpose of the ESMA database is such that it does not need to enable the direct identification of patients. Therefore the ESMA database should only contain pseudonymised data that only enable the identification of the data subject at the level of those who actually need this identification to provide the necessary care on patients if needed.*

**Amendment 7**

**Proposal for a regulation**

**Article 39 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. The annual report referred to in paragraph 1 shall only contain aggregate and anonymous data.***

*Justification*

*An annual report must only contain aggregate information and does not need to contain personal details of patients. This amendment takes into consideration the opinion of the European Data Protection Supervisor (EDPS).*

**Amendment 8 Proposal for a regulation**  
**Article 41 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 41 a**

**Storage of personal data**

***Personal data processed in the electronic database set up by the Agency shall be stored for a maximum period of 5 years after the conclusion of a clinical trial. Upon expiry of this period, the personal data processed shall be stored separately for an additional period of 20 years in a pseudonymised manner (key coded) and with access restricted during this period for the purpose of detecting cases of misuse. Once this period has elapsed, personal data shall be deleted.***

*Justification*

*Data conservation is an essential principle of Union's data protection law. The proposal does not provide for a retention period in the EMA database and in the EU data base. An unlimited retention period does not respect data protection law. The amendment fixes retention periods sufficiently long to enable to detect retroactively cases of misuse of clinical trials. This amendment takes into consideration the opinion of the European Data Protection Supervisor (EDPS).*

**Amendment 9**

**Proposal for a regulation**  
**Article 55 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

Unless other Union legislation requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical trial master file for **at least** five years after the end of the clinical trial. However, the medical files of subjects shall be archived in accordance with national legislation.

Unless other Union legislation requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical trial master file for **a maximum period of** five years after the end of the clinical trial. However, the medical files of subjects shall be archived in accordance with national legislation.



### *Justification*

*Data conservation is an essential principle of Union' data protection law. The proposal should set a maximum retention period and not a minimal one. A minimum retention period does not contribute to ensure legal certainty. This amendment takes into consideration the opinion of the European Data Protection Supervisor (EDPS).*

#### **Amendment 10**

##### **Proposal for a regulation**

##### **Article 76 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. The Commission shall report to the European Parliament annually on the controls and inspections conducted pursuant to this Article.***

#### **Amendment 11**

##### **Proposal for a regulation**

##### **Article 78 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

4. The EU database shall contain personal data only insofar as this is necessary for the purposes of paragraph 2.

4. The EU database shall contain personal data only insofar as this is necessary for the purposes of paragraph 2. ***In no case personal data of patients participating in a clinical trial shall be processed in the EU database.***

### *Justification*

*Recital 52 declares that no personal data of data subjects participating in a clinical trial should be recorded in the EU database. The wording of Article 78 is not clear and does not preclude the inclusion of personal data of patients. Since the prohibition of processing of patient's personal data in the EU database is one of its essential elements, it must be clearly in the legal provision establishing it and not only in a recital. It also takes account of the opinion of the (EDPS).*

## Amendment 12

### Proposal for a regulation Article 78 – paragraph 7

*Text proposed by the Commission*

7. The Commission and Member States shall ensure that the data subject may effectively exercise his or her rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and national data protection laws implementing Directive 95/46/EC respectively. They shall ensure that the data subject may effectively exercise the right of access to data relating to him or her, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request being made by a data subject.

*Amendment*

7. The Commission and Member States shall ensure that the data subject may effectively exercise his or her rights to information, to access, to rectify, **to block** and to object in accordance with Regulation (EC) No 45/2001 and national data protection laws implementing Directive 95/46/EC respectively. They shall ensure that the data subject may effectively exercise the right of access to data relating to him or her, and the right to have inaccurate or incomplete data corrected, **blocked** and erased. Within their respective responsibilities, the Commission and Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections, **blocking** and deletions shall be carried out as soon as possible, but no later than within 60 days after a request being made by a data subject.

*Justification*

*The right to block personal data, which is also recognised by EU data protection law along with the rights referred to in this Article needs to be included in the proposal. This amendment takes account of the EDPS opinion.*

## Amendment 13

### Proposal for a regulation Article 78 – paragraph 7 a (new)

*Text proposed by the Commission*

*Amendment*

***7a. Personal data processed in the electronic database set up by the Agency shall be stored for a maximum period of 5 years after the conclusion of a clinical***

*trial. Upon expiry of this period, the personal data processed shall be stored separately for an additional period of 20 years in a pseudonymised manner (key coded) and with access restricted during this period for the purpose of detecting cases of misuse. Once this period has elapsed, personal data shall be deleted.*

#### *Justification*

*The proposal does not provide for a retention period in the EU data base. EU data protection law provides for the possibility to set longer periods of storage of personal data in the case of scientific research subject to the establishment of appropriate safeguards. The amendment fixes retention periods sufficiently long to enable to detect retroactively cases of misuse of clinical trials. It takes account of the opinion of the EDPS.*

#### **Amendment 14**

##### **Proposal for a regulation**

##### **Annex I – part 4 – point 13 – indent 16 a (new)**

*Text proposed by the Commission*

*Amendment*

*– a description of the assessment of the impact on the rights of the subjects to human dignity, the right to physical and mental integrity, the right for respect of private and family life and the right of the child and measures taken to safeguard them.*

#### *Justification*

*In order to assess that the clinical trial respects fundamental rights the Application dossier for initial application should include the description of the assessment conducted on the impact of fundamental rights and measures taken to safeguard them. This amendment is consistent with Amendment 1.*

#### **Amendment 15**

##### **Proposal for a regulation**

##### **Annex 1 – part 12 – point 54 – indent 1**

*Text proposed by the Commission*

– in trials with **minors or** incapacitated subjects, the procedures to obtain informed consent from the parent(s) or legal representative, and the involvement of the **minor or** incapacitated subject shall be described;

*Amendment*

– in trials with incapacitated subjects, the procedures to obtain informed consent from the parent(s) or legal representative, and the involvement of the incapacitated subject shall be described;

**Amendment 16**  
**Proposal for a regulation**

**Annex 1 – part 12 – point 54 – indent 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***– in trials with minors, the procedures to obtain informed consent from the minor and the parents or legal representative, and the involvement of the minor, shall be described;***

**Amendment 17**

**Proposal for a regulation**  
**Annex II – part 4 – point 4 – indent 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***– a description of the assessment of the impact on the rights of the subjects to human dignity, the right to physical and mental integrity, the right for respect of private and family life and the right of the child and measures taken to safeguard them.***

*Justification*

*In order to assess whether the clinical trial respects fundamental rights the Application dossier for initial application should include the description of the assessment conducted on the impact of fundamental rights and measures taken to safeguard them. This amendment is consistent with Amendment 1.*



## PROCEDURE

<b>Title</b>	Clinical trials on medicinal products for human use, and repeal of Directive 2001/20/EC
<b>References</b>	COM(2012)0369 – C7-0194/2012 – 2012/0192(COD)
<b>Committee responsible</b> Date announced in plenary	ENVI 11.9.2012
<b>Opinion by</b> Date announced in plenary	LIBE 11.3.2013
<b>Rapporteur</b> Date appointed	Juan Fernando López Aguilar 21.2.2013
<b>Discussed in committee</b>	21.2.2013                      8.4.2013
<b>Date adopted</b>	8.4.2013
<b>Result of final vote</b>	+:                      40 -:                      2 0:                      1
<b>Members present for the final vote</b>	Jan Philipp Albrecht, Edit Bauer, Emine Bozkurt, Arkadiusz Tomasz Bratkowski, Philip Claeys, Carlos Coelho, Agustín Díaz de Mera García Consuegra, Ioan Enciu, Frank Engel, Cornelia Ernst, Hélène Flautre, Kinga Gál, Kinga Göncz, Ágnes Hankiss, Anna Hedh, Salvatore Iacolino, Sophia in 't Veld, Lívia Járóka, Teresa Jiménez-Becerril Barrio, Timothy Kirkhope, Monica Luisa Macovei, Véronique Mathieu Houillon, Anthea McIntyre, Nuno Melo, Claude Moraes, Georgios Papanikolaou, Jacek Protasiewicz, Carmen Romero López, Birgit Sippel, Rui Tavares, Nils Torvalds, Wim van de Camp, Josef Weidenholzer, Tatjana Ždanoka, Auke Zijlstra
<b>Substitute(s) present for the final vote</b>	Jan Mulder, Salvador Sedó i Alabart, Marie-Christine Vergiat
<b>Substitute(s) under Rule 187(2) present for the final vote</b>	Preslav Borissov, Verónica Lope Fontagné, Gabriel Mato Adrover, Vittorio Prodi, José Ignacio Salafranca Sánchez-Neyra