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European Federation of Pharmaceutical Industries and Associations

13 June 2012

EFPIA Position on Reform of the 1995 Data Protection Directive:
Biomedical Research Under the EC Proposed General Data Protection Regulation (COM(2012) 11 final)

EFPIA welcomes the Commission's efforts to further harmonise data protection requirements in the EU. The inconsistent application of privacy requirements impedes our industry's ability to conduct meaningful biomedical research that leads to the discovery of new medicines, and it creates particular challenges for the collection and reporting of safety data concerning medicines.

EFPIA also welcomes recognition that the public interest in advances in medical science warrants **special rules on the collection and use of personal data for medical research purposes** *(Art. 83)*, and **justifies collection and use of data for public health purposes** *(Art. 81(1))*. Both of these activities already take place under highly controlled and regulated conditions which are designed to protect patient privacy.

However, **EFPIA believes that there are still some limited changes needed to avoid unintended impacts on medical research:**

- **Application of certain requirements to key-coded data:** patient identities are disguised before clinical trial data are reported by study sites to pharmaceutical companies. "Key-coded data" can be directly re-identified only through access to a key held securely by each study site.
  - **Key-coding should be added as a recognized means for appropriately safeguarding personal data prior to transferring it to a third country** *(Art. 42)*. A transfer of key-coded data for scientific research purposes should not require any further authorisation or consultation where the recipient does not reasonably have access to the key and contractual or legal restrictions prohibit re-identification of the data subjects.
  - **Key-coded data should not be subject to the Regulation's mandated breach notification requirements that apply to data that directly identifies a natural person, provided the key is not compromised** *(Art. 31)*. Key-coded data is not readily identifiable without a parallel breach of the key.
  - **Scientific research conducted in accordance with Art. 83 should be expressly considered a legal and compatible basis to further process personal data.** Although the existing text implies this interpretation, a more express statement is needed for the avoidance of doubt. An affirmative statement to this effect would be consistent with Art. 6(1)(b) of the 1995 Data Protection Directive, which provides that "Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards." It also reflects the objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area.

- **A single data protection impact assessment should be permitted to cover processing of personal data that is of a similar nature and presents the same privacy risks** (Art. 33). A requirement to conduct multiple, duplicative assessments for similar data processing activities would add administrative burden without substantively increasing data protection.
  - A single assessment should be sufficient to identify potential risks and risk mitigation strategies related to similar uses of key-coded data for scientific research purposes. The same applies to the collection and reporting of information on drug adverse events.

- The **proposed definition of "genetic data" is overly broad** and would turn inherited characteristics such as eye and hair colour into sensitive data requiring heightened protections *(Art. 4(10))*.
  - A **more targeted definition based on existing international standards** would be: Information on the hereditary characteristics, or alteration thereof, of an identified or identifiable person, obtained through nucleic acid analysis.

- **Measures will need to be adopted to implement the regulation. The process for adoption of such implementing measures should include consultation with relevant stakeholders**.
  - For example, researchers should be consulted on the application of Art. 17(3) (retention of personal data necessary for public health or scientific research purposes) and Art. 83(3) (limitations on the rights of notice and access where necessary for scientific research purposes).

13 June 2012

Further Information

For further information, please contact:

[redacted] Government Affairs
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Or visit the EFPIA website:
www.efpia.eu

The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 35 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,000 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

This Position Paper is also supported by:

- **EuropaBio -** the European Association for Bioindustries. EuropaBio was created in 1996 to provide a voice for the biotech industry in Europe. Its mission is to promote an innovative and dynamic biotechnology-based industry in Europe. EuropaBio represents 62 corporate and 7 associate members operating worldwide, 2 Bioregions and 18 national biotechnology associations who in turn represent some 1800 small and medium sized biotech companies in Europe. Further information is available at http://www.europabio.org.

- The **International Pharmaceutical Privacy Consortium** (IPPC). The IPPC promotes responsible privacy and data protection practices in the research-based, global pharmaceutical industry. The IPPC seeks to increase awareness of privacy and data protection issues and to engage government in a dialogue about the need for data to support cutting edge biomedical research and public health activities. Further information is available at http://www.pharmaprivacy.org.

- The **Association of Clinical Research Organizations** (ACRO). ACRO represents the world's leading clinical research organizations. ACRO members provide specialized services that are integral to the development of drugs, biologics and medical devices. Each year, ACRO's members conduct thousands of clinical trials and provide related drug development services in more than 115 countries while ensuring the safety of nearly 2 million research participants. Further information is available at http://www.acrohealth.org.

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BRE-JBZ

From: Kaai, Geran
Sent: vrijdag 3 april 2015 15:57
To: Verweij, Ellen
Subject: FW: Data Protection Regulation
Attachments: EFPIA Letter re LIBE report assessment on Data Protection Regulation (MS....docx

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From: [redacted] [mailto[redacted]]
Sent: vrijdag 7 februari 2014 12:50
To: Kaai, Geran
Cc: Kuiper, Elizabeth; Pieters, Davy; Stieger, Nathalie
Subject: Data Protection Regulation

Geachte Heer Kaai,

Mijn Roche collega [redacted]en ik hadden al eerder de gelegenheid, over dit thema met u van gedachten te wisselen. Nu het Parlement, naar verwacht, het LIBE rapport onverkort in plenaire zitting gaat goedkeuren, wouden wij onze bezwaren m.b.t. de LIBE amendementen op artikels 81 en 83 nog eens onder uw aandacht brengen. Bijgaande brief van EFPIA President [redacted]gaat hier uitvoerig op in. U bent ondertussen ongetwijfeld reeds vertrouwd met onze standpunten, maar indien u dit wenst, zitten mevrouw Stieger en ik graag nog eens met u samen. Voor ons zou dit kunnen op 26 februari vanaf 14 uur of op 27 februari vóór 15 uur.

Wij hopen stellig dat de Raad de tekst van artikels 81 en 83 in de door ons gewenste zin kan corrigeren en danken u bij voorbaat voor de steun die Nederland op dit punt kan geven.

Vriendelijke groet,

[redacted]

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European Federation of Pharmaceutical Industries and Associations

Mr. Geran KAAI
Counsellor
Permanent Representation of the Netherlands
Brussels

6 February 2014

Dear Mr. Kaai,

I am writing to you on behalf of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Pharmaceutical Privacy Consortium (IPPC) to raise, ahead of trialogue negotiations, concerns with the 21 October European Parliament Civil Liberties Committee (LIBE) report on the Commission's proposal for a General Data Protection Regulation.

We have had fruitful discussions with legislators about EU data protection legislation and its potential impact on medical research in Europe. Although we welcome the Commission's proposal for a regulation that harmonises data protection requirements in the EU and the recognition that the public interest in advances in medical science warrants special rules on the collection and use of personal data for medical research purposes, we write to express concerns, shared by others in the research community, about the amendments adopted by the LIBE Committee to Articles 81 and 83. These amendments may impede important biomedical research.

Even without new limitations on a data subject's ability to consent to future research, data subjects remain protected by existing standard practices, regulations, and laws, including the Clinical Trials Directive (2001/20/EC) and international medical research standards that highlight the importance of seeking voluntary and informed consent and of protecting individuals' privacy and the confidentiality of their personal data. Ethics Committees also review and approve research protocols and informed consent forms. In addition to medical researchers' contractual and legal confidentiality obligations, the standard practice of "key-coding" research data further protects participants' identities. Key-coding replaces identifying information in a data set with a code or pseudonym, and the "key" to the code is then kept separately from the data to prevent unauthorized re-identification. Unlike the Commission's 2012 Proposal, the versions of Articles 81 and 83 adopted by the LIBE Committee could be interpreted as adding an additional layer of potentially conflicting regulation to this existing structure, which already guarantees high standards of patient privacy.

The amendments to Article 81 could be read as limiting a research participant's ability to give informed consent to participate in medical research. The clause limiting consent to "one or more specific and similar researches" implies that participants who wish to allow their health information to be used for a broad set of research purposes may be prevented from doing so. Accordingly, we are asking that this section be clarified to make it clear that a data subject can give consent to future medical research so long as that research can be appropriately described.

Moreover, the LIBE Committee's amended language of Article 81 would require Member States to adopt potentially differing and inconsistent "high public interest" exemptions to enable research in circumstances where a patient's consent cannot be

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obtained. This reduces the beneficial effect of a single, Union-wide regulation, contradicts the Commission's efforts to harmonise data protection requirements across the EU, and would place certain types of research on hold until Member States made exemptions.

The amendments to Article 83 also contain language which would impede medical research in circumstances where participants are necessarily either identified or identifiable. Article 83 of the LIBE report currently stipulates that research using personal data is permissible only if "data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information." The LIBE Committee has removed the important qualification from the original Commission wording: "as long as these purposes can be fulfilled in this manner." EFPIA suggests reinserting this qualification from the original Commission draft, thereby requiring separation of information identifying a data subject only when it would not prevent the research from occurring.

EFPIA proposes a more straightforward approach, harmonised across EU Member States, to protecting data privacy in the medical research context. Ahead of the trialogue negotiations, EFPIA calls on the Member States to permit data processing for appropriate medical research when obtaining a participant's consent is impossible or would require disproportionately difficult effort. As discussed above, ethics committee review, key-coding of data, and other protections appropriately protect participants' rights and interests in these circumstances. In the alternative, if necessary to accommodate specific member state concerns or cultural differences, this standard could be adopted with the additional caveat that Member States would be permitted to impose additional requirements for research within their borders, if deemed necessary.

Thank you for your time and consideration of these issues. Please do not hesitate to contact our organisations if you have any questions or would like additional information.

Sincerely,

[redacted]
[redacted] EFPIA

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