BRE-JBZ [redacted]

From: Kaai, Geran
Sent: vrijdag 3 april 2015 16:02
To: Verweij, Ellen
Subject: FW: EFPIA request for a meeting on Data Protection Regulation
Attachments: FINAL EFPIA position paper Data Protection 13 June 2012.pdf [redacted]

From: BRE-JUS
Sent: woensdag 24 oktober 2012 16:56
To: Kaai, Geran
Subject: FW: EFPIA request for a meeting on Data Protection Regulation

From: [redacted] [mailto:[redacted]
Sent: woensdag 24 oktober 2012 15:40
To: BRE-JUS
Subject: EFPIA request for a meeting on Data Protection Regulation

Dear Mr Geran Kaai,

I am writing to you on behalf of the European Federation of Pharmaceutical Industries and Associations (EFPIA) with regard to the Personal Data Protection proposal. EFPIA has been following the development of this file with great interest and welcome the Commission's efforts to further harmonise data protection requirements in the EU.

We would be delighted to meet with you in the next couple of weeks to learn your perspective on this and how you see the Council approach develop. We would also like to share some concerns that we have regarding requirements to key-coded data, the definition of "genetic data" and the prospects of delegated acts.

For your information and background, I attach our position paper. I will follow-up with a phone call tomorrow to see if we can arrange a meeting.

In the meantime, please do not hesitate in contacting me should you have any initial questions or comments.

Sincerely yours,

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[redacted]
Assistant Manager Government Affairs
EFPIA
Rue du Trône, 108
1050 Brussels
Tel: +32 [redacted]
Fax: +32 [redacted]

Working together for 2D-coding to fight counterfeit medicines

[redacted]

efpia

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]
Director – Government Affairs
[redacted]
Tel: +32 (0)[redacted]

Or visit the EFPIA website:
www.efpia.eu

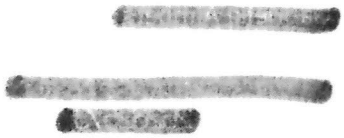
The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 35 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,000 companies committed 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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