To be filled out in the EDPS' office

REGISTER NUMBER: 548

NOTIFICATION FOR PRIOR CHECKING

Date of submission: 9/11/2009

Case number: 2009-740

Institution: EMEA

Legal basis: article 27-5 of the regulation CE 45/2001(1)

(1) OJ L 8, 12.01.2001

INFORMATION TO BE GIVEN (2)

(2) Please attach all necessary backup documents

1/ Name and adress of the controller

Surname: Pott First Name: Andreas
E-mail: andreas.pott@emea.europa.eu
Function: Head of Administration Unit
Administrative Address: 7 Westferry Circus, E14 4HB, London, UK

2/ Organisational parts of the institution or body entrusted with the processing of personal data

Pharmacovigilance and Risk Management/Data Collection and Management
Place of work: 7 Westferry Circus, E14 4HB, London, UK

3/ Name of the processing

EudraVigilance Data Quality Management

4/ Purpose or purposes of the processing

This notification regards a processing activity referred to as EudraVigilance Data Quality Management.

The main purpose of this processing is the assessment of quality of the data already contained or to be included in EudraVigilance, a database managed by EMEA in order to operate an EU-wide pharmacovigilance system. The EudraVigilance Data Quality Management is a complementary and independent technical activity undertaken within the broader context of the EudraVigilance database. It must be borne in mind that the EDPS has already issued an Opinion for prior checking on the EudraVigilance database on the 7th of September 2009 (Case 2008/402).

EudraVigilance is the European Community's system monitoring the safety of medicines through safety reports. It is designed to receive, process, store and make available information submitted electronically using the E2B format agreed at ICH, referred to as Individual Case Safety Reports or ICSRs. Reports are received via the gateway.

5/ Description of the category or categories of data subjects

The data subjects are the patients who have experienced adverse reactions resulting of the use of medicinal products.
Data contained in the Eudravigilance database and processed in this service do not provide a direct identification of data subjects. However, the information contained in the ICSRs might lead to personal identification in exceptional circumstances.

6/ Description of the data or categories of data
(including, if applicable, special categories of data (article 10) and/or origin of data)

Revealing racial or ethnic origin (e.g. photos)
The ICSRs have no specific field for racial or ethnic origin although it could be mentioned in free text areas. It is important to point out that the indication of the ethnic origin of the patients might be useful in order to better understand certain metabolic reaction connected with the assumption of drugs, although, in the cases of data referring to patients, no photo is included.

Data concerning health (including disabilities)
Information contained in ICRSs concerning health can be held in structured fields and also in free text areas.

Concerning sex life (e.g. name of partner)
There is no specific field although this may be mentioned in the free text area, for example where the medical history concerns HIV status. However the name of the partner is not included.

Data relating to suspected offences, offences, criminal convictions or security measures (e.g. police certificates)

7/ Information to be given to data subjects

The personal data are not provided directly by the data subject. The recommendations of the EDPS in the prior check opinion concerning EudraVigilance (Case 2008/402) are being considered.

8/ Procedures to grant rights of data subjects
(rights of access, to rectify, to block, to erase, to object)

Same as above.

9/ Automated / Manual processing operation

- processing automated wholly or in part
- manual processing of a structured set of data accessible according to given criteria

10/ Storage media of data

- Physical security (access to computer systems, quality of the file supports, public access or restricted access to locations, storage, transport of equipment, etc). The service provider will put in place all the security measures detailed in art. 5.3 and 5.6 of the Service Level Agreement (see Annex 3).

- Logical security (coding control, undue removal or transmission of data, passwords, encrypted directories, backup, audit trails for data processing and communication, etc). The service provider will put in place all the security measures detailed in art. 4.4, 4.5 and 5,4 of the Service Level Agreement (see Annex 3).

- Staff security (restricted access codes, conditions of subcontracting, etc) The Technical Specifications of the Contract (see Annex 4), art. 3.6.1, include a section on the security measures of the service provider's staff requested by EMEA.

11/ Legal basis and lawfulness of the processing operation

11.1 Indicate any legal basis (Treaty, Regulation, Decision, etc.) for this processing operation:

The processing operations are necessary to ensure a high level of data quality contained in the EU pharmacovigilance network the EudraVigilance database.

The legal basis of the operation of EudraVigilance are Title II, Chapter 3, Article 22, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and Article 105 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

Reporting obligations related to post authorisation are in accordance with article 24 and article 25 of Chapter 3, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Volume 9A of the Rules Governing Medicinal Products in the European Union: Pharmacovigilance for medicinal products for human use (Part I and III).

Reporting obligations related to Clinical trials fall under Article 17 of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and chapter II of Volume X of the rules governing medicinal products in the European Union.

11.2 Legal basis: indicate
x if the processing meets a functional need of the service
□ if the data subject has unambiguously consented to the processing
□ any other basis

12/ The recipients or categories of recipient to whom the data might be disclosed

The staff members employed by the processor in the provision of services requested.

Additional information: Natural or legal persons employed by or under contract to the EMEA have received instructions about confidentiality in processing personal data (See above under 4).

13/ retention policy of (categories of) personal data The period of storage is indefinite to allow full and complete scientific evaluation of the information.

The retention policy of those data processed within EudraVigilance Data Quality Management does not differ from EudraVigilance policy database (Case 2008/402) as it is based in the same rationale.

13 a/ time limits for blocking and erasure of the different categories of data (on justified legitimate request from the data subject)

Non applicable.

(*Please, specify the time limits for every category, if applicable)*

14/ Historical, statistical or scientific purposes

If you store data for longer periods than mentioned above, please specify, if applicable, why the data must be kept under a form which permits identification,

The data is often processed for statistical / scientific purposes.

15/ Proposed transfers of data to third countries or international organisations

The transfer of data involved in the processing operations would be governed by contractual agreements between the controller and the processors that introduce specific obligations with regard to confidentiality and data protection (see Annex 1).
As an open procedure any interested economic operator may submit a tender. As a result the legal status of the processor of the data, whether falling under art. 8 or art. 9 of Regulation 45/2001, will only be known at the end of the tender procedure. However, pursuant art. 9 (7) of Regulation 45/2001, the obligations in respect of data protection foreseen by the Directive 95/46 and the Regulation 45/2001 will be legally binding for the processor on the basis of art. II.10.5 of the Framework Service Contract (See Annex 3).

16/ The processing operation presents specific risk which justifies prior checking (*please describe*):

Most of the data processed in EudraVigilance constitutes health data, including medical histories of patients, reactions to medicines, etc. Therefore the processing operations must be prior checked by the EDPS.

AS FORESEEN IN:

x Article 27.2.(a)

Processing of data relating to health and to suspected offences, offences, criminal convictions or security measures (e.g. police certificates),

x Article 27.2.(b)

Processing operations intended to evaluate personal aspects relating to the data subject,

□ Article 27.2.(c)

Processing operations allowing linkages not provided for pursuant to national or Community legislation between data processed for different purposes,

□ Article 27.2.(d)

Processing operations for the purpose of excluding individuals from a right, benefit or contract,

□ Other (general concept in Article 27.1)

17/ Comments

PLACE AND DATE:

DATA PROTECTION OFFICER:

INSTITUTION OR BODY: