REGISTER NUMBER: 381

NOTIFICATION FOR PRIOR CHECKING

Date of submission: 25/06/2008

Case number: 2008-402

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 address of the controller

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

Post Authorisation Unit, Pharmacovigilance, Safety & Efficacy Sector
Place of work: 7 Westferry Circus, E14 4HB, London, UK
the filing system is available on a network, and the server is located at the 8th Floor Data Centre

3) Name of the processing

EudraVigilance

4) Purpose or purposes of the processing

The main puropse of the processing is the protection of public health within EEA countries.

EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA). The first operating version was launched in December 2001.

EudraVigilance supports in particular the:

Electronic exchange of suspected adverse reaction reports (referred to as Individual Case Safety Reports) between the European Medicines Agency (EMEA), national Competent Authorities, marketing authorisation holders, and sponsors of clinical trials in the EEA;
Early detection of possible safety signals associated with medicinal products for Human Use;

Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions;
Decision making process, based on a broader knowledge of the adverse reaction profile of medicinal products especially in the frame of Risk Management.
Taking into account the pharmacovigilance activities in the pre- and post- authorisation phase, EudraVigilance provides two reporting modules:

The EudraVigilance Clinical Trial Module (EVCTM) to facilitate the electronic reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) as required by Directive 2001/20/EC.
The EudraVigilance Post-Authorisation Module (EVPM) designed for post-authorisation ICSRs, Regulation (EC) No 726/2004, Directive 2001/83/EC as amended, and Volume 9A of the "Rules Governing Medicinal Products in the European Union: Pharmacovigilance for medicinal products for human use".
EudraVigilance is also one of the main pillars of the European Risk Management Strategy, a joint effort between the EMEA and national Competent Authorities to strengthen the conduct of pharmacovigilance in the EEA. EudraVigilance facilitates the process of risk management at several levels including aspects of risk detection, risk assessment, risk minimisation and risk communication. Consequently, EudraVigilance contributes to the protection and promotion of public health in the EEA and provides a powerful tool for the EMEA and national Competent Authorities in monitoring the safety of medicinal products and in minimising potential risks related to suspected adverse reactions.

The reporting obligations of the various stakeholders are defined in the Community legislation, in particular Regulation (EC) No 726/2004, Directive 2001/83/EC as amended and Directive 2001/20/EC.

NOTE:

Please see Annex 1 for a description of the system. Annex II describes the personal data which may be held for the EudraVigilance registration process, Annex III lists the personal data which may be contained in an Individual Case Safety Report (ICSR), and Annex IV relates to personal data captured in the EU Risk Management Plans. Annex V is the draft EudraVigilance Access policy (Doc Ref EMEA/216166/2008). Annex VI is the Memorandum Of Understanding on the sharing of confidential data and/or information within the EU Regulatory System in the field of safety of medicines for human use (Doc Ref EMEA/216166/2008).

5) Description of the category or categories of data subjects

1) The EudraVigilance registration process includes data on worldwide citizens (please refer to Annex II).

The EudraVigilance registration process is necessary to identify and mange the business partners of the EMEA in the European Economic Area (EEA) for the secure electronic transmission of Individual Case Safety Reports (ICSRs) in the pharmacovigilance pre- and post-authorisation phase.

Only registered organisations are permitted to exchange Safety, Acknowledgement and Medicinal Product Messages through the EudraVigilance Gateway, the European data-processing network as defined in Community legislation. A list of registered organisations, which are part of the EudraVigilance User Community, is maintained by the EMEA and is accessible for all registered partners in the restricted area of the EudraVigilance web site.

2) ICSR (individual case safety reports) data relates to Patients, Healthcare professionals and Lawyers. Some National Competent Authorities also collect data from consumers, whose reports may be submitted to EudraVigilance.

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 EudraVigilance registration process will hold paper copies of identification including photographs (of persons registered with EudraVigilance).
The ICSRs have no specific field for racial or ethnic origin although it could be mentioned in free text areas. 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 ICSRS 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. Although the name of the partner is not included.

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

There is no specific field although this may be mentioned in the free text area, where social history may include criminal offences.

Data being used to evaluate personal aspects of the data subject (ability, efficiency, conduct)

There is no specific field although this may be mentioned in the free text area, for example mental status.

Other categories of personal data:

- in the form of personal identification numbers

- concerning the physical characteristics of persons

- concerning the data subject's private sphere

- concerning the data subject's family (For example family history of a certain disease)

- concerning telephone numbers and communication (NB of primary source such as Healthcare professional and possibly in rare instances of the consumer)

- other Identifiers such as Initials, date of birth, medical history details

7) Information to be given to data subjects

the personal data are not provided directly by the data subject, there is no policy as yet but is under development.

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

the EMEA has developed a procedure to allow data subject to exercise their rights. They can make request directly by contacting the EMEA Data Controller. the eMEA is currently working to publish the acces request form (al already notified in the other procedures for ex-post prior check) on line.

9) Automated / Manual processing operation

As far as data regarding person registered with EudraVigilance, the data are collected from the data subjects for the EudraVigilance registration process.

ICSRs (individual case safety reports) are instead collected from healthcare professionals, Marketing Authorisation Holders, Sponsors of Clinical trials, National Competent Authorities (NCAs) and Lawyers. Some NCAs also collect reports from consumers which may be submitted to EudraVigilance.

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.)
Based on user ID and password following the EudraVigilance registration process. Users of the system are also required to sign a user declaration if their details should change (information can be found at eudravigilance.emea.europa.eu/human/How to register) (Access is also restricted according to the draft EudraVigilance access policy (Annex V)

- Logical security (coding control, undue removal or transmission of data, passwords, encrypted directories, backup, audit trails for data processing and communication, etc.)

Please refer to C&N unit, (Oliver Simoen)

- Staff security (restricted access codes, conditions of subcontracting, etc.)
According to EMEA policy

11) Legal basis and lawfulness of processing operation

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

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.

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

Please see annex V “EudraVigilance Access Policy” and point 15 of the notification

13) Retention policy of (categories of) personal data

The period of storage is indefinite. The data must be store indefinitely to allow for a full and complete scientific evaluation of the data. Data should not be deleted in case an evaluation of it is required at a future date. Also, removal of any data changes the context in which other data is evaluated.

Some form of anonymisation (such as initials filed may be completed with 'PRIVACY'). However, there is variation amongst the sources of the data as to whether it is anonymised or not. A project is currently underway to seek harmonisation of the level of anonymisation across all data sources in the EEA.

Data can only be accessed in line with the draft EudraVigilance access policy (Please see Annex V)

EudraVigilance was established in December 2001, although post authorisation data is collected retrospectively back until 01/01/1995

13.a) time limits for blocking and erasure of the different categories of data (on justified legitimate request from the data subject)
(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 further processed for statistical / scientific purposes.

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

- transfer within or between Community institutions or bodies: Data is transferred on routine and ad-hoc basis.

- the recipient is always informed about his obligation in respect of the transfert: Obligations are in accordance with legislation named in section 2.2 and also in the Memoranda of Understanding on the sharing of confidential data and/or information within the EU Regulatory System in the field of safety of medicines for human use (Annex VI). Data is made accessible according to Access policy (See Annex V).

Sometimes data are also transferred outside the EU insititution but only within non EU Regulatory bodies with whom the EMEA has signed confidentiality agreements and memoranda of understanding, that is to say USA (FDA), Canada (Health canada) and Japan (ministry of Health, Labour and Welfare):

If for example there is a request for information from the FDA, there is an agreement between the EMEA and FDA (this is also true for MHLW and Health Canada and Japan) regarding data confidentiality which can be found on the EMEA website general reporting /executive/international.

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

As you can infer form the description of the process data collected in the framework of EV fall within the hypothesis foreseen by Article 27 Reg. (EC) 45/2001

AS FORESEEN IN:

- **Article 27.2.(a) YES**

Processing of data relating to health and to suspected offences, offences, criminal convictions or security measures,

- **Article 27.2.(b) PARTLY**

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: London, 25 June 2008

DATA PROTECTION OFFICER: Vincenzo Salvatore

INSTITUTION OR BODY: European Medicine Agency