

REGISTER NUMBER: 561

NOTIFICATION FOR PRIOR CHECKING

Date of submission: 19/1/2010

Case number: 2010-047

Institution: European Medicines Agency

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

Surname: Pott First Name: Andreas

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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

Head of Administration

Place of work: 7 Westferry Circus, E14 4HB, London, UK

3/ Name of the processing

Administrative inquires / Disciplinary procedures

4/ Purpose or purposes of the processing

The main purpose of the data processing is to put together relevant information into files, in order to enable the Disciplinary Board to carry out administrative inquires to determine whether an agent, a servant or other person working for the European Medicines Agency, has failed to fulfill his/her obligation under the Staff Regulations of officials of the European Communities (Staff Regulations) and the Conditions of Employment of other servants and, where appropriate, impose a disciplinary penalty.

The European Medicines Agency prepared a draft of the rules on the conduct of administrative inquiries and disciplinary procedures (See Annex 1). Under Article 4(4) of these rules "All relevant documents to the Administrative inquiry should be stored in paper form and in an electronic version, in a disciplinary file".

5/ Description of the category or categories of data subjects

- Agents and former agents;
- Servants and former servants;
- Other persons working for the European Medicines Agency, such as persons employed under private law contracts, experts on secondment, trainees or other relevant persons;
- Individuals who participate in an administrative enquiry and disciplinary procedures in a role than that of the staff member concerned (e.g. witness and whistleblowers).

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)
- Revealing political opinions (e.g. external activities)
- Revealing religious or philosophical beliefs (e.g. switch of holiday)
- Revealing trade-union membership
- Concerning health (including disabilities)
- Concerning sex life (e.g. name of partner)
- Relating to health and suspected offences, offences, criminal convictions or security measures (e.g. police certificates)
- Being used to evaluate personal aspects of the data subject (ability, efficiency, conduct)

Other categories of personal data:

- in the form of personal identification numbers;
- concerning the physical characteristics of persons as well as the image, voice or fingerprints;
- concerning the data subject's private sphere;
- concerning pay, allowances and bank accounts;
- concerning recruitment and contracts;
- concerning the data subject's career;
- concerning leave and absences;
- concerning missions and journeys;
- concerning Social Security and pensions;
- concerning expenses and medical benefits;
- concerning telephone numbers and communications (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 European Medicines Agency ensures that the personal data of all the persons involved in an administrative enquiry and disciplinary procedures are processed as required by Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals, with regard to the processing of personal data by the European Union institution and bodies and on the free movement of such data.

It is foreseen that the Data Subjects will be informed of their rights in terms of data protection, as soon as it is feasible.

8/ Procedures to grant rights of data subjects

(rights of access, to rectify, to block, to erase, to object)

- Under Article 5(6) of Annex 1, "The Staff member concerned shall have the right to access his/her complete disciplinary file and take copies of the documents which may be important to a proper defence during the disciplinary procedure. When information refers to others individuals, the right to access and take copies of his/her disciplinary may be limited to the information that relates uniquely to the staff member concerned."

- According to Article 5(11) of Annex 1, "The Executive Director shall inform the staff member concerned of the conclusion of the inquiry together with the conclusions of the inquiry report and, on request, all documents directly linked to the allegations made, subject to the protection of the legitimate interests of third parties."

9/ Automated / Manual processing operation

Both automated and manual processing operation.

10/ Storage media of data

The personal data are stored both in paper form and in an electronic version. The data are stored under the name and European Medicines Agency reference number of the data subject.

11/ Legal basis and lawfulness of the processing operation

The legal basis for the processing is provided by:

- (i) the Staff Regulations, in particular Article 22, 86 and 110 and Annex IX thereto;
- (ii) the Articles 49, 50 and 119 of the Conditions of Employment of other servants;
- (iii) the European medicines Agency implementing rules on the conduct of administrative inquiries and disciplinary procedures, when they enter into force.

An European Medicines Agency agent, servant or other person working for it who does not comply with his obligations under the Staff Regulations may become the subject of an administrative inquiry and, where appropriate, a disciplinary procedure.

The processing meets a functional need of the service.

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

- Data subjects;
- Head of Administration;
- Executive Director
- Disciplinary Board;
- Investigator.

13/ Retention policy of (categories of) personal data

Disciplinary files are stored for a maximum period of 20 years if, following an administrative inquiry, a charge is brought against the staff member concerned, and for a minimum period of five years for administrative inquiries without disciplinary follow-up.

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

In accordance with Article 27 of Annex of the Staff Regulation, "An official against whom a disciplinary penalty other than removal from post has been ordered may, after three years in the case of a written warning or reprimand or after six years in the case of any other penalty, submit a request for the deletion from his personal file of all reference to such measure. The Appointing Authority shall decide whether to grant this request."

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,

Further processing for historical, statistical or scientific purposes is not envisaged.

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

The following transfers may occur:

- if the staff member concerned contests the disciplinary decision, the disciplinary file may be referred to the Court of Justice of the European Union;
- to the European Ombudsman, if the staff member concerned addresses a complaint;
- after receiving an inquiry report from the European Anti-Fraud Office (OLAF), the Executive Director may, if appropriate, ask OLAF to supplement the report himself (See Article 5(12) of Annex 1).

We would like to point out that if the above mentioned transfers occurs:

- The data will be transferred following a request from the above mentioned recipients;
- The data controller has to verify the competence of the above mentioned recipients and make a provisional evaluation of the need for the transfer of the data;
- The above mentioned recipients will be informed of his obligations in respect of this transfer.

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

AS FORESEEN IN:

Article 27.2.(a)

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

Article 27.2.(b)

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

Reason:

The processing of personal data on administrative inquiries and disciplinary procedures implies the collection, recording, organisation, storage, consultation and use of data of persons involved in an administrative enquiry and disciplinary procedures. These files may also contain data on suspected offences, offences, criminal convictions or security measures. The documents are also used to evaluate aspects of the personality of those involved, particularly their behaviour.

Article 27.2.(c)

Processing operations allowing linkages not provided for pursuant to national or European Union 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

We would like to emphasize that:

(i) Until the present moment, the rules on the conduct of administrative inquiries and disciplinary procedures were not formally adopted. When adopted the final text will be made available to all the EMA Staff on the intranet.

(ii) In accordance with a specific provision of Annex 1, the investigator is made aware of the implications that the investigation could have in terms of data protection and he is given instructions with respect to collecting evidence or data, in order to protect the rights of the Data Subjects.

PLACE AND DATE:

DATA PROTECTION OFFICER:

INSTITUTION OR BODY: