

Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Medicines Agency on the public declaration of interests

Brussels, 6 December 2007 (Case 2007-419)

1. Proceedings

On 25 June 2007, the European Data Protection Supervisor (EDPS) received from the Data Protection Officer (DPO) at the European Medicines Agency (EMA) a notification for prior checking relating to the processing of personal data in connection with the public declaration of interests.

The case was suspended while further information was sought on 11 July 2007 and this was provided on 15 October 2007. The case was suspended for a second period on 18 October 2007 pending further information which was received on 22 October 2007. The case was suspended again pending comments on the draft opinion from the DPO on 16 November 2007. The comments were provided on 4 December 2007.

2. The facts

The public declaration of interests involves the collection and publishing of personal data related to direct and indirect interests of staff, Management Board, Staff Committee and Working Party members (official observers included), Management Board observers and EU experts which might be incompatible with the EMA mission. Management Board, committee and Working Party members, European experts and staff members (Article 14 of the Staff Regulations) have a primary obligation to disclose at any time the existence of possible conflicts of interests that may place the impartiality of EMA at risk. The individual should state, in particular, the type and nature of interests, and should specify whether they are general or relate to a specific product or tender, recruitment etc. If the conflict is product-related, prior involvement of rapporteurs and experts should also be stated in relation to competing products as well as past and current links with companies. Declarations of interests are updated at least annually.

Classes of data subjects include staff members, Management Board members, Staff Committee and Working Party members (official observers included), EU experts, MB observers. National experts, trainees, interims, visiting experts and conference hosts also sign the declaration of interests. In addition, data about the activities of staff members' families are also collected. Categories of data include data concerning the staff member's career as well as his/her family, partner and private life, in relation to interests of family members which are declared.

Each staff member is informed about the controller's identity and about his/her rights at the time they sign the public declaration of interests. Information will also be provided by the EMEA website via the document *Internal EMEA policy on the practical operation of access to EMEA documents*, which deals specifically with the public declaration of interests. This information includes:

- the identity of the controller;
- the purposes of the processing operation for which the data are intended;
- the recipients of the data; and
- where the public can have access to the declarations of interests.

The EMEA also intends to publish a Data Protection Declaration on its intranet as well as on its external internet page. This declaration provides:

- information on the general purposes for which data are processed by EMEA;
- the classes of recipients of personal data;
- time limits for storing the information;
- details on the rights of access, blocking and erasing data; and
- the right of recourse to the EDPS.

However, there does not appear to be any information provided to other data subjects who are not staff, such as family members or partners of staff who have made a Declaration of Interests. Nor is the right of access, blocking or erasing data provided for these other data subjects. EMEA state that this is due to the large numbers of declarations of interests made each year (over 1000). They claim that providing information and the rights provided for in Regulation EC 45/2001 would constitute a disproportionate effort.

The form that EMEA have produced for staff to use to request access to their data requests the following information:

- name and surname,
- place and date of birth,
- nationality,
- home address,
- postcode
- telephone and/or fax number,
- email address,
- ID number (provided in declaration).

The form also states that a data access request may be refused if it is not made on the form.

The EMEA implementing rules detail procedures for accessing and reviewing the data contained in the declaration of interests. There is an online request form for accessing personal data and a complaints procedure to the Data Protection Officer for unauthorised processing of personal data.

The EMEA Secretariat, under the direct responsibility of the Head of Unit concerned, undertakes the following:

- Remind all parties concerned of their obligation to declare their interests;
- Assess and monitor regularly declarations and make preliminary appraisal of compatibility of interests declared with general or specific office or duties of the individuals concerned;
- Initiate and facilitate dialogue within the appropriate forum (e.g. committee or Working Party).

In accordance with Article 63(2) of Council Regulation (EC) No 726/2004, the EMEA Secretariat ensures, under the responsibility of the Head of Administration in respect of EMEA staff only, the availability of all declarations and updates for public consultation at the EMEA's offices. For Management Board members, all committee, working party members and experts the declarations and updates are available for public consultation at the Agency's offices on contacting the Central Information Group - Post Authorisation for experts and Executive Support Sector for the Management Board.

Declarations of interests are disclosed to the public after personal contact information has been removed.

Declarations of interests must be updated at least annually under Article 63(2) of Council Regulation (EC) No 726/2004 or as soon as an update is required for any new situation arising. As part of the new experts database, electronic updates are available to facilitate exchange of information. Staff members update their declarations at least annually. Management Board members provide a declaration at least at the start of the Management Board mandate of the individual and at the beginning of the official mandate of the Management Board and annually thereafter.

The data are retained and disposed of five years after the financial discharge of the budget of a given year. This is necessary for auditing purposes.

Security measures: All declarations of interest are held in a locked cabinet and access is only granted by authorised request. All EMEA staff sign a confidentiality agreement as part of their contract. This duty of confidentiality is defined in the EMEA Guidance on Confidentiality and Discretion and continues even after a staff member has left employment with EMEA.

3. Legal aspects

3.1. Prior checking

Regulation (EC) 45/2001 of the European Parliament and of the Council on the protection of personal data by Community institutions and bodies and on the free movement of such data (Regulation 45/2001) applies to the processing of personal data by Community institutions and bodies.

Personal data are defined as any information relating to an identified or identifiable natural person. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity. The data processed in the public declaration of interests therefore qualify as personal data according to Article 2(a) of Regulation 45/2001.

The processing of personal data is carried out by EMEA, a Community body whose activities fall within the scope of Community law.

Regulation 45/2001 shall apply to the processing of personal data wholly or partly by automatic means and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system. In this case, the personal data are held as part of a paper filing system and electronically.

Regulation 45/2001 therefore applies.

Article 27(1) of Regulation 45/2001 subjects to prior checking by the EDPS all *"processing operations likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes"*. Article 27(2) of the Regulation contains a list of processing operations that are likely to present such risks. This list includes Article 27(2)(b) *"processing operations intended to evaluate personal aspects relating to the data subject, including his or her ability, efficiency or conduct"*.

In the case of public declaration of interests, the processing of personal data relates to interests which may prove to be incompatible with the work of EMEA. The personal data are used to evaluate the conduct of a natural person. Thus the processing operations defined for each module have to be prior checked by EDPS.

Since prior checking is designed to address situations that are likely to present certain risks, the opinion of the EDPS should be given prior to the start of the processing operation. In this case however the processing operation has already been established. In any case, this is not a serious problem in that any recommendations made by the EDPS may still be adopted accordingly.

The notification of the DPO was received on 25 June 2007. According to Article 27(4) of Regulation 45/2001 the present opinion must be delivered within a period of two months, that is, no later than 22 December 2007 taking into account suspensions for a total of 118 days (96 + 4 + 18 days).

3.2. Lawfulness of the processing

Article 5(a) of Regulation 45/2001 stipulates that personal data may be processed if *"the processing is necessary for the performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof or in the legitimate exercise of official authority vested in the Community institution or body"*.

Article 5(b) of Regulation 45/2001 stipulates that personal data may be processed if *"the processing is necessary for compliance with a legal obligation to which the controller is subject"*.

Article 63(2) of Council Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency states:

"2. Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices."

The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts. Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of

the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public."

Annex 1 of the EMEA Code of Conduct sets out the guidance on conflicts of interests.

The EDPS is satisfied that the processing is legitimate under Article 5(a) and (b) of Regulation 45/2001.

3.3. Processing of special categories of data

Article 10(1) of Regulation 45/2001 states that *"the processing of personal data concerning sex life,[is] prohibited"*.

Article 10(2) of Regulation 45/2001 provides a list of circumstances in which Article 10(1) shall not apply. In particular, Article 10(2)(b) states that the prohibition does not apply when *"processing is necessary for the purposes of complying with the specific rights and obligations of the data controller in the field of employment law insofar as it is authorised by the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof, or, if necessary, insofar as it is agreed upon by the European Data Protection Supervisor, subject to adequate safeguards"*.

In this instance, data concerning the staff member's partner are processed, which could reveal the sexual orientation of that staff member and his/her partner.

The EDPS is satisfied that the processing of these personal data is not prohibited, even where this may reveal the sexual orientation of the persons concerned, as it is necessary for the purposes of the declaration of interests, which is an obligation EMEA is subject to concerning its staff by virtue of Article 63(2) of Council Regulation (EC) 726/2004.

3.4. Data Quality

Article 4(1)(a) requires that personal data must be processed fairly and lawfully. Lawfulness of the processing has been dealt with under Section 3.2 and fairness of the processing shall be dealt with under Section 3.7.

Article 4(1)(c) of Regulation 45/2001 states that personal data must be *"adequate, relevant and not excessive in relation to the purposes for which collected and/or further processed."* In this case the data collected and processed for the purposes of the public declaration of interests are split into four categories and include data concerning the data subject's career as well as his/her family, partner, and private life, in relation to information about the interests of family members which must be declared.

The EDPS does not regard the processing of these personal data as excessive in relation to the identification of the individual or to the measures laid out by the legislative provisions detailed in 2.1. However, the EDPS does have some recommendations on excessive personal data requested on the form provided by EMEA for requesting access to personal data. This is dealt with in Section 3.6.

Article 4(1)(d) of Regulation 45/2001 states that personal data must be *"accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are*

inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified."

Articles 13 and 14 of Regulation 45/2001 provide that the data subject has the right to access and the right to rectify data, so that the file can be as complete as possible. This also makes it possible to ensure the quality of data. However, the members of the staff member's family do not have the right of access to their own personal data, due to the large numbers of declarations of interests made each year. This is dealt with under Section 3.6.

3.5. Data retention

Article 4(e) of Regulation 45/2001 states that personal data must be *"kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. The Community institution or body shall lay down that personal data which are to be stored for longer periods for historical, statistical or scientific purposes should be kept in an anonymous form only or, if that is not possible, only with the identity of the data subjects encrypted. In any event, the data shall not be used for any purpose other than for historical, statistical or scientific purposes"*.

EMEA will retain the data for a period of 5 years after the budget is discharged. This is necessary for audit purposes.

The EDPS is satisfied that the retention of data in a form which permits identification of the data subject is necessary for the five year period stated in the notification and is therefore in accordance with the requirements of Article 4(e) of Regulation 45/2001.

EMEA will keep anonymised data for a period of up to 50 years for statistical purposes. The EDPS is satisfied that this is in accordance with the provisions of Article 4(e) of Regulation 45/2001.

3.6. Right of access and rectification

Article 13 of Regulation 45/2001 grants a data subject the right of access to personal data held about him. Article 14 provides a right of rectification of personal data.

The form which EMEA has produced for staff to exercise their right of access and rectification states that the request for access may be refused if it is not made on the form. Article 13 of Regulation 45/2001 states that *"The data subject shall have the right to obtain, without constraint, at any time within three months from the receipt of the request and free of charge from the controller..."*

While Article 20 of Regulation 45/2001 provides a number of restrictions and exemptions to the right of access and rectification, it does not provide a data controller with the option to restrict the right of access on the basis of whether or not the form provided by the data controller is used.

The EDPS recommends that any statement on the form is amended to remove the provision which states that the request for access may be refused where the form is not used and is replaced by a simple recommendation to use the form, while at the same time making it clear that the usage of the form is by no means obligatory.

The form also asks for the following personal data:

- name and surname,
- place and date of birth,
- nationality,
- home address,
- postcode
- telephone and/or fax number,
- email address,
- ID number (provided in declaration).

The EDPS understands that EMEA need to establish the identity to the individual making the request, but this can be established by use of the personnel number. Any further information on nationality, place or date of birth, home address and postcode is excessive and not in accordance with Article (4)(1)(c) of Regulation 45/2001. The EDPS therefore recommends that the personal data access request form is amended to include only the following information:

- name and surname,
- telephone and/or fax number,
- email address,
- ID number (provided in declaration).

Data subjects who are members of the employee's family are not provided the right of access and rectification. None of the exemptions and restrictions on access and rectification provided for in Article 20(1) of Regulation EC 45/2001 applies. The EDPS therefore recommends that EMEA provide these rights where a family member makes a subject access request or asks for a rectification of inaccurate data.

3.7. Information to the data subject

Article 11 of Regulation 45/2001 requires certain information to be provided to the data subject when the personal data have been received directly from the data subject. In this instance, employees who make a declaration of interest will be provided information through two separate documents:

1. *Internal EMEA policy on the practical operation of access to EMEA documents*; and
2. the *Data protection declaration* on the EMEA website.

The data protection declaration

The EDPS recommends that the information provided to data subjects who are staff members in the data protection declaration is amended as follows:

- There should be an introductory paragraph which states that this is a general data protection statement, and that further information on specific processing operations can be found in the links in an annex to this document.
- An annex should be added to the document with links to the *Internal EMEA policy on the practical operation of access to EMEA documents*.
- The email address provided in the data protection declaration should correspond with that provided on the personal data access request form.

The implementing rules

The EDPS recommends that information on the time periods for retention of the data in connection with the declaration of interests are added to *Internal EMEA policy on the practical operation of access to EMEA documents* or to the declaration of interests form.

Article 12(1) of Regulation 45/2001 provides that information be provided to the data subject when it has been obtained by a third party. Article 12(2) states that this obligation does not apply where to provide such information would be impossible or would constitute a disproportionate effort on the part of the data controller.

EMEA provides no information to data subjects such as family members who are named in staff declarations of interest. EMEA has stated that to provide this information would constitute a disproportionate effort as they will receive over 1000 declarations each year, with at least one family member named in each declaration.

The EDPS accepts that providing this information directly to each individual would constitute a disproportionate effort. However, there are other steps EMEA could take which would not constitute a disproportionate effort.

Therefore the EDPS recommends that EMEA publish an information notice for family members on their website, providing all the information required by Article 12. This could be accompanied by modifying the declaration of interest form with a statement instructing each staff member to inform family members that EMEA will be processing data about them, and that further information is available on the EMEA website.

3.8. Security measures

After careful analysis of the security measures adopted, the EDPS considers that these measures are adequate in the light of Article 22 of Regulation 45/2001.

Conclusion:

There is no reason to believe that there is a breach of the provisions of Regulation 45/2001, provided that the considerations described in Sections 3 above are fully taken into account. These include, among others, the following:

- Any statement on the personal data access request form should be amended to specify that the request for access cannot be refused where the form is not used.
- The EDPS recommends that the personal data access request form is amended to include only the following personal information:
 - name and surname,
 - telephone and/or fax number,
 - email address,
 - ID number (provided in declaration).
- The information provided to data subjects who are staff members in the data protection declaration is amended as follows :

- There should be an introductory paragraph which states that this is a general data protection statement, and that further information on specific processing operations can be found in the links in an annex to this document.
 - An annex should be added to the document with links to the *Internal EMEA policy on the practical operation of access to EMEA documents*.
 - The email address provided in the data protection declaration should correspond with that provided on the personal data access request form.
- Information on the time periods for retention of the data in connection with the declaration of interests should be added to *Internal EMEA policy on the practical operation of access to EMEA documents* or to the declaration of interests form.
 - EMEA should provide these rights where a family member makes a subject access request or asks for a rectification of inaccurate data.
 - EMEA should publish an information notice for family members on their website, providing all the information required by Article 12. This should be accompanied by modifying the declaration of interest form with a statement instructing each staff member to inform family members that EMEA will be processing data about them, and that further information is available on the EMEA website.

Done at Brussels, 6 December 2007

(signed)

Peter HUSTINX
European Data Protection Supervisor