

## **Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Medicines Agency on recording of the leave of temporary, auxiliary and contract agents, national experts and trainees**

Brussels, 7 January 2008 (Case 2007-420)

### **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 the recording of the leave of temporary, auxiliary and contract agents, national experts and trainees. No further information was provided with the notification.

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 again for information on 26 October 2007 and this was received on 12 November 2007. The case was suspended again pending comments on the draft opinion from the DPO on 21 November 2007 and these were provided on 30 November and 17 December 2007.

### **2. Facts**

The EMA records all leave taken by temporary, auxiliary and contract agents, national experts and trainees. All leave taken is recorded on an in-house database and in the personal files of the individual staff. Leave record includes:

- annual leave;
- travelling time to/ from place of recruitment/place of origin;
- EMA public holidays;
- special leave<sup>1</sup> (see below);
- leave for training;
- sick leave;
- unpaid leave;
- maternity leave;
- parental leave;
- flexible leave;
- medical and dental appointments;
- antenatal appointments;
- compensatory leave for overtime worked; and
- leave for national service.

Special leave covers the following circumstances:

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<sup>1</sup> cf. Article 57 (2) and Annex V of the Staff Regulations read together with Articles 16, 58 and 91 of the Rules applicable to other servants of the European Communities

- Family reasons:
  - marriage of applicant,
  - marriage of child,
  - birth of a child,
  - serious illness of spouse (up to three days),
  - serious or very serious illness of a dependent child (up to two days),
  - serious illness of a relative in the ascending line (two days)<sup>2</sup>,
  - death of a spouse,
  - death of wife on maternity leave,
  - death of a child,
  - death of a relative in the ascending line,
  - death of a brother or sister,
  - adoption
  - maternity leave, with additional allowances for premature birth, multiple birth and if the child is disabled.
- Other reasons:
  - Court summons as witness in cases involving third parties,
  - short-term military obligations,
  - jury service,
  - annual medical examination,
  - medical consultation abroad,
  - removal at place of employment,
  - training,
  - election,
  - Community examinations/competitions,
  - application for national insurance number, and
  - job-seeking at the end of a contract.

Data subjects therefore will include temporary, auxiliary and contract agents, national experts and trainees. It will also include their families, where information on relatives who are ill or a spouse who is pregnant is provided. In circumstances where an individual is summoned to Court, the third parties may also be data subjects, where they are individuals who are involved in proceedings.

Staff members apply for leave using the Application for Annual Leave and Special Leave Form. The form goes to their Head of Sector/Head of Unit and then to Personnel for storage in the leave database. Categories of data which are collected may include:

- the name of the staff member and personnel number;
- details about their family, including name and health-related data;
- data about the health of the staff member; and
- data concerning the religious beliefs of the staff member.

Staff members are informed about leave arrangements and the recording of leave during the checklist briefing, which is a verbal summary of the rules on leave in the Staff Regulation and the Leave Consolidation Rules<sup>3</sup>, and through a general Data Protection Declaration signed for acknowledgement by each staff member, as well as published on the EMEA website. None

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<sup>2</sup> However, family leave (that can be granted in case of medically certified serious illness or disability of spouse, relatives in ascending and descending line, brothers or sisters for a total period of nine months pursuant to Article 42b of the Staff Regulations read together with Articles 16, 58 and 91 of the Rules applicable to other servants of the European Communities) is being analysed in a separate opinion (EDPS 2007-489).

<sup>3</sup> Consolidation of leave rules and working conditions at EMEA (June 2007 - EMEA/9773/04/4057)

of the other data subjects are provided with any information. The Data Protection Declaration provides information about:

- the identity of the data controller;
- general purposes for which personal data are processed ("*administrative purposes and/or purposes of the tasks pursued by the Agency within Article 57 of Regulation 726/2004<sup>4</sup>*");
- categories of recipients of staff member's personal data;
- the rights of data subjects and how they assert those rights; and
- the right to recourse to the EDPS.

However, there would appear to be no information provided about the specific purpose of the leave related processing operations or the respective storage periods.

Staff members are able to access and rectify their personal data held by EMEA using the on-line request form and can complain about processing of their personal data to EMEA's Data Protection Officer.

The form EMEA has produced for staff to use to request access and rectification of their data (Personal Data Access Request Form) demands 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.

Personal data are held for a period of six years from the date the application for leave is submitted (three years on site and another three years off site). This time period is necessary for auditing purposes. (The initial three years period is necessary for administrative purposes and for business continuity). No further retention for historical or statistical purposes has been notified.

Staff members are able to request a change in EMEA public holidays to a different day which is more appropriate to their own religious or national holidays. Staff members are expected to work on the EMEA public holiday in return for a day off at another point.

(...)

### **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

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<sup>4</sup> Regulation 726/2002 of the European Parliament and the Council of 31 March 2004 laying down procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency

(hereinafter 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 connection with recording of the leave of EMEA staff members 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 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 (EC) 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)(a) *"processing of data relating to health..."*.

In the case of recording leave, processing of personal data concerning health occurs. Thus the respective processing operations 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 operations. In this case however the processing operations have 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) the present opinion must be delivered within a period of two months, that is no later than 8 January 2007 taking into account suspensions for a total of 135 days (19 + 44 + 16 + 25 and the month of August).

### **3.2. Lawfulness of the processing**

Article 5(a) of Regulation EC 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 16, 58 and 91 of the Rules applicable to other servants of the European Communities provide rights to leave for those individuals who are not covered by the Staff Regulations, but are still employed as temporary, auxiliary and contract agents by EMEA. These rights

include rights to leave. It is necessary for effective records to be kept to ensure that staff members are provided with the leave to which they are entitled.

The EDPS is therefore satisfied that the processing of personal data in relation to leave is necessary for the performance of EMEA's obligations to staff as provided by the Rules applicable to other servants of the European Communities and is therefore lawful in accordance with Article 5(a) of Regulation EC 45/2001.

### **3.3. Processing of special categories of data**

Article 10(1) of Regulation 45/2001 states that *"the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, and of data concerning health, or sex life are 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 *"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 addition, pursuant to Article 10(2)(d), sensitive data may be processed *"if the data subject has unambiguously given his or her consent"*.

In this instance, health-related data are processed in connection with sick leave, leave for medical, dental and antenatal appointments, maternity leave, as well as various types of special leave. Data are also processed which could reveal the sexual orientation of that staff member and his/her partner where he/she applies for leave to care for them. The processing of these special categories of data is necessary in order to comply with legal obligations imposed on EMEA with respect to its staff as laid down in Articles 16, 58 and 91 of the Rules applicable to other servants of the European Communities.

Data are also processed which could reveal the religious beliefs of a staff member where he/she asks for the substitution of one EMEA public holiday for one of his/her own religious holidays. The processing of this special data category is based on the consent of the data subject.

In the view of the above, the EDPS is satisfied that the processing of personal data concerning sensitive personal data is in accordance with Article 10 of the Regulation.

### **3.4. Data Quality**

Article 4(1)(c) of Regulation 45/2001 states that personal data must be *"adequate, relevant and non excessive in relation to the purposes for which collected and/or further processed."*

The EDPS is of the opinion that the processing of personal data of third parties involved in court cases for the purpose of recording of the special leave (for court summons as witness in the respective court case) is excessive. The necessity of the processing of these data shall be reconsidered.

In addition, the EDPS does have some recommendations on excessive personal data being provided on the Personal Data Access Request Form. This is dealt with in paragraph 3.9.

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."*

The EDPS is satisfied that the procedure used by EMEA for recording of the leave helps to ensure accuracy of the personal data processed.

In addition, 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.

Article 4(1)(a) provides that personal data must be *"processed fairly and lawfully"*. Lawfulness has been dealt with in 3.2 and fairness will be dealt with in 3.10.

### **3.5. Conservation of data/ 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"*.

EMEA will retain the data for a total period of six years, three years on site and three years off site. The six years period has been set out in accordance with the Community rules applicable to the disposal of records with financial link. In fact, Article 49 of the Implementing Rules to the Financial Regulation<sup>5</sup> states that the original supporting documents are to be kept for up to seven years after the budgetary discharge<sup>6</sup>.

In addition, as regards sick leave related data, the initial three years storage period was established in line with Article 59(4) of the Staff Regulation<sup>7</sup>. (As regards other data, the initial three years storage period was set out in accordance with the EMEA archiving policy to allow the data to be held for administrative purposes and for business continuity purposes.)

The EDPS considers that the sick leave related data can indeed be kept for the initial three years since they are necessary for the establishment of an eventual invalidity on a basis of Article 59(4) of the Staff Regulations.

As to the total storage period of six years, the EDPS recognises the need to keep files for the purposes of a budgetary control. Nevertheless, he would like to bring EMEA's attention to the recently added last paragraph of Article 49 of the Implementing Rules to the Financial Regulation stating that *"personal data contained in supporting documents shall be deleted where possible when those data are not necessary for budgetary discharge, control and audit purposes"*.

### **3.6. Compatible use / Change of purpose**

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<sup>5</sup> Commission Regulation 2342/2002 laying down detailed rules for the implementation of Council Regulation 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities as amended by Commission Regulations 1261/2005, 1248/2006 and 478/2007

<sup>6</sup> Five years provided for in Article 49(d) plus two years by virtue of the fact that *"documents relating to operations not definitely closed shall be kept for longer than provided for in point (d) of the first subparagraph", that is to say, until the end of the year following that in which the operations are closed*" - cf. EDPS Comments on the Draft Common Conservation List of 7 May 2007

<sup>7</sup> Read together with Articles 16, 58 and 91 of the Rules applicable to other servants of the European Communities; cf. EDPS Opinion on conservation periods for medical documents of 26 February 2007

Article 4(1)(b) of Regulation 45/2001 states that personal data must be "*collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes*".

The data processed in connection with leave is processed for the purposes of leave. Further processing as part of the data subject's personal file is compatible with this purpose.

### **3.7. Transfer of data**

Article 7(1) of Regulation 45/2001 states that "*personal data shall only be transferred within or to other Community institutions or bodies if the data are necessary for the legitimate performance of tasks covered by the competence of the recipient*".

In this case, personal data are passed to the Head of Unit or Head of Sector and Personnel. In each of these cases the transfer is necessary for granting requests for leave and recording those requests.

As such, the EDPS is satisfied that, in each case, the transfer of personal data within EMEA is in accordance with Article 7(1) of Regulation 45/2001. However, the EDPS recommends that, in accordance with Article 7(3), each of the recipients is made aware that they shall process the personal data they receive only for the purposes of recording leave.

### **3.8. Processing of personal number or unique identifier**

Each staff member must add their personnel number when making an application for leave. The EDPS considers that the personal number can be used in this context since it allows for the identification of the staff member and facilitates the follow-up in an appropriate way. There is no reason to determine any further conditions in this case.

### **3.9. 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.

As mentioned in point 2.1, EMEA has produced a particular form to be used for all access and rectification requests concerning personal data processed. The EDPS has already made recommendations concerning the need to revise the Personal Data Access Request Form in his Opinion on a notification for Prior Checking received from the EMEA DPO on the public declaration of interests dated of 6 December 2007 (Case number 2007-0419). In particular, the EDPS has requested that the statement on mandatory use of the Personal Data Access Request Form is replaced by a simple recommendation to use the form, as well as that the identification data required on the form are limited to name, surname, telephone and/or fax number, email address and the ID number.

In addition, the EDPS notes that family members whose personal data are processed in the present case are not provided with right of access and rectification. None of the exemptions and restrictions provided for in Article 20(1) of the Regulation 45/2001 applies. The EDPS therefore recommends that EMEA provide these rights where a family member makes an access request or asks for rectification of inaccurate data.

### **3.10. Information to the data subject**

In the present case, both Articles 11 and 12 are applicable since certain personal data processed are provided by the respective data subjects (as regards staff member's own data) and certain personal data are obtained from other sources (as regards personal data of family members).

Article 11 of Regulation 45/2001 requires certain information to be provided when the personal data have been received directly from the data subject. In this instance, EMEA staff members will be informed through the Leave Consolidated Rules and the Data Protection Declaration signed for acknowledgement by each staff member, as well as published on the EMEA website.

The EDPS recommends that the information provided in the Data Protection Declaration to data subjects who are staff members 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 Leave Consolidated Rules and/or to the Application for Annual Leave and Special Leave Form.
- The email address provided in the Data Protection Declaration should correspond with that provided on the Personal Data Access Request Form.

In addition, the EDPS recommends that information about the specific purpose of processing of leave related data, as well as information about the specific time period applicable are added to the Leave Consolidated Rules and/or to the Application for Annual Leave and Special Leave Form.

Article 12 of Regulation 45/2001 requires certain information to be provided to the data subjects when the personal data have been obtained from other source (paragraph 1), unless the provision of such information proves impossible or would involve a disproportionate effort. In such a case, the Community institution or body shall provide for appropriate safeguards (paragraph 2).

The EDPS accepts that providing this information directly to each family member whose personal data are processed in connection with a particular leave would constitute a disproportionate effort on a part of EMEA. Nevertheless, there are other steps EMEA could take which would be appropriate, such as instructing its staff members applying for a leave to inform their respective family members about the processing of their personal data.

### **3.11. Security measures**

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

## **4. Conclusion**

There is no reason to believe that there is a breach of the provisions of Regulation 45/2001 provided the above considerations are fully taken into account. In particular, EMEA should:

- Reconsider the necessity of processing the personal data of third parties involved in court cases for the purposes of recording of special leave;



- Consider the possibility of deleting personal data contained in supporting documents not necessary for budgetary discharge, control or audit purposes;
- Ensure that, in accordance with Article 7(3), each of the recipients of personal data relating to leave is made aware that they shall process the personal data they receive only for the purposes of recording leave;
- Modify the Personal Data Access Request Form in such a way that:
  - the statement on mandatory use of this form is replaced by a simple recommendation to use it,
  - identification data required on the form are limited to name, surname, telephone and/or fax number, email address and the ID number;
- Provide family members whose personal data are processed with a right of access and rectification upon their request;
- Amend the information provided to data subjects in the Data Protection Declaration who are staff members 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 Leave Consolidated Rules and/or to the Application for Annual and Special Leave Form,
  - the email address provided in the Data Protection Declaration should correspond with that provided on the Personal Data Access Request Form;
- Ensure that information about the specific purpose of processing of leave related data, as well as information about the specific time period applicable are added to the Leave Consolidated Rules and/or to the Application for Annual Leave and Special Leave Form;
- Ensure that appropriate measures are put into place in order to inform the family members involved in the processing, such as instructing the staff members applying for a leave to inform their respective family members about the processing.

Done at Brussels, 7 January 2008

Peter HUSTINX  
European Data Protection Supervisor