

**REGISTER NUMBER: 1419**

**NOTIFICATION FOR PRIOR CHECKING**

Date of submission: 13/12/2016

Case number: 2016-1144

Institution: EMA

Legal basis: article 27-5 of the Regulation EC 45/2001<sup>(1)</sup>

*(1) OJ L 8, 12.01.2001*

**INFORMATION TO BE GIVEN<sup>(2)</sup>**

*(2) Please attach all necessary backup documents*

**1/ Name and address of the controller**

Agneta Brandt  
Deputy Head of Administration and Corporate Management Division  
European Medicines Agency  
30 Churchill Place Canary Wharf  
E14 5EU London  
United Kingdom

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

It should be noted that contrary to the arrangements held by the European Commission and a number of other EU Institutions, EMA does not have an in-house medical officer. As a result, the provision of medical services is performed by an external medical service provider in accordance with EU public procurement procedures. The EMA medical service provider processes health data of EMA staff on behalf of and under instructions received by EMA with due respect for medical confidentiality and high standards of security. These arrangements are reflected in a contract and a service level agreement between EMA and the medical service provider. (see Annex 1)

Only personal data of an administrative nature concerning sickness (with the exception of medical certificates for sick leaves) is processed by the Staff Relations and Support Department of EMA responsible for the administration and sick leave referral procedure.

**3/ Name of the processing**

Medical data of EMA staff members

**4/ Purpose or purposes of the processing**

The notification is in relation to the processing of personal data for the purpose of ensuring compliance with the requirements laid down in the Staff Regulations for pre-employment medical checks, annual medicals, justifications for sick-related absences, and return to work after illness procedures.

5/ Description of the category or categories of data subjects

Occupational Health Review Data: The concerned data subjects are Temporary Agents and Contract Agents.

Sick Leave Data: The concerned data subjects are Temporary Agents, Contract Agents, National Experts on Secondment and Trainees.

Special leave: The concerned data subjects are Temporary Agents, Contract Agents and National Experts on Secondment.

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

The processing operation relates to the justification for the transmission of medical data of staff members of EMA to a third party medical service provider. The following categories of data are concerned: (i) data concerning health (including disabilities); (ii) data concerning sex life (e.g. name of the partner); (iii) data being used to evaluate personal aspects of the data subject (ability, efficiency, conduct); and (iv) data concerning leave and absences.

7/ Information to be given to the data subject

It should be noted that a data protection statement is notified to staff, including trainees and SNEs on taking up service.

Further, in relation to occupational health reviews, sick leave and special leave, data protection at EMA is explained to staff when they join the service. It forms part of the induction provided by Human Capital Support which includes information available on the data protection website, such as data protection notifications.

The EMA medical service provider discusses with each individual EMA staff the processing of their health data and obtains an informed consent.

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

In accordance with Regulation (EC) 45/2001, data subjects have the right of access to their own data, and under duly justified reasons to rectify, to block, to erase them, or to object, through a direct request to the controller. Both EMA and its medical service provider have in place procedures for guaranteeing the exercise of the rights of the data subject.

9/ Automated / Manual processing operation

The concerned data processing operation involves: (i) automated processing of data: and (ii) manual processing of a structured set of data accessible in accordance with a given criteria.

10/ Storage media of data

Occupational Health Review Data: After closure of the case, data is stored electronically in DREAM following the resignation/expiry of contract/retirement/death of the data subject. Paper files are not maintained. Associated invoices relating to payment are stored on the EMA server, specifically within the finance database (SAP FIN) following discharge with a case number only. There is no identifiable name on the invoice. The link between the invoice with a case number and the associated staff member remains on file and stored confidentially within Human Capital Support.

Sick Leave Data: Sick leave certificates and declaration forms are stored in-house within EMA. These files are specifically held within a secure cabinet by Human Capital Support. This cabinet is locked and can only be accessed by specific Human Capital Support staff. After two years, these files are subsequently transferred to a secure off-site location.

Advance email notifications regarding the start date/extensions of sickness absences are held within the functional inbox of Human Capital Support.

Special Leave Data: No documentation regarding third parties is stored by Human Capital Support. A note that a leave administrator has seen the requested supporting documents is entered under a designated area in SAP HR. Paper files are stored in-house for two years (for the current and previous year). All documents are filed in the same folder where sick leave forms and medical certificates are kept under the staff member's name. Files are stored in locked cabinets which can only be accessed by Human Capital Support. Following this two year period, these files are then transferred to a secure off-site location for archival storage.

It should be noted that electronic filing is password protected. Further, access is strictly limited to a Human Capital Support filing area. This is conducted in accordance with internal filing policy. (see Annex 7)

#### 11/ Legal basis and lawfulness of the processing operation

The processing operation is consistent with a functional need of the service. The legal basis for the transfer of medical data of EMA staff members is provided under the following provisions:

- Article 59 of the Staff Regulations, Article 16 of the Conditions on the Employment of Other Servants;
- Article 1d(4) of the Staff Regulations;
- Article 6 of Annex V of the Staff Regulations;
- Commission Decision of 16.12.2013 on leave; and
- Commission Decision introducing implementing provisions on absences as a result of sickness or accident.

This shall be supplemented by other guidelines and internal discussions for staff in the case of absences as a result of sickness. (see Annexes 2, 8, 9 and 12)

With regard to the processing of health data by the service provider, and in accordance with Article 10(2)(a) of Regulation (EC) No 45/2001 the data subject provides an informed consent to the physician for the processing of health data. It should also be noted that occupational health review reports are submitted by the medical service provider to the data subject for prior approval of the content before being sent to the Staff Relations and Support Department.

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

It should be noted that EMA may request the medical service provider to transfer the medical file of a given staff member to the medical service provider of the new agency/institution following written instructions from HR to the account manager of the medical service provider and with the knowledge of the staff member. The staff member's consent form should be recorded on the template attached to the service level agreement with the medical service provider. (see Annex 13)

A confidentiality statement is signed by all staff on taking up their duties. Further, Human Capital Support staff are informed of their obligations of confidentiality with regard to information that they may receive during the course of the administrative procedures described in this notification.

#### 13/ retention policy of (categories of) personal data

Occupational Health Review Data: After closure of the case, data is stored electronically in DREAM for five years or one year following the resignation/expiry of contract/retirement/death of the data subject. Paper files are not maintained. Associated invoices relating to payment are stored on the EMA server, specifically within the finance database (SAP FIN) following discharge for five years with a case number only. There is no identifiable name on the invoice.

Sick Leave Data: Sick leave certificates and declaration forms are stored in-house within EMA for two years. These files are specifically held within a secure cupboard in the Human Capital Support division. Following this period, these files are then transferred to a secure off-site location for archive storage for two years. Advance email notifications regarding the start date/extensions of sickness absences are held within the functional inbox of Human Capital Support and are deleted after two years.

Special Leave Data: No documentation regarding third parties is stored by Human Capital Support. A note that a leave administrator has seen the requested supporting documents is entered under a designated area in SAP HR. Paper files are stored in-house for two years (for the current and previous year). All documents are filed in the same folder where sick leave forms and medical certificates are kept under the staff member's name. Files are stored in locked cabinets which can only be accessed by Human Capital Support. Following this two year period,

these files are then transferred to a secure off-site location for archival storage where they will be retained for a further two years.

Medical files which are held by EMA's medical service provider and concern staff who have resigned or left the service at the end of their contract are destroyed one year after the date of departure or transfer to another EU body (if applicable). Medical files which are held by EMA's medical service provider and concern retired former staff are destroyed one year after the date of retirement. Medical files which are held by EMA's medical service provider and concern staff in active employment are retained for the duration of their service. Individual medical reports which are more than thirty years old are, however, destroyed.

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)

In line with general policy on processing of data at the EMA – 15 working days.

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,*

It is envisaged that the administrative data concerning absences due to sickness may be, once anonymized through aggregation, further processed for statistical purposes. In relation to occupational health review data, the statistical information which is used is limited to recording the number of cases per year for workload purposes only. Statistical information concerning sick leave data is aggregated to division level and anonymous on the number of days of sick leave per division per year. These statistics are sent to managers and may serve as a basis for discussion at Head of Division/Head of Department or Service/Office regarding a general trend that can be discerned from the table.

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

N/A

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

In accordance with Article 10(1) of Regulation (EC) No 45/2001, the majority of the data to be processed concerns sensitive health data. This processing operation must, therefore, be subject to a prior check by the European Data Protection Supervisor in accordance with Article 27(1) and (2)(a) of Regulation (EC) No 45/2001. In light of the nature of the processing of personal data involved, the handling of medical data will be viewed as sensitive health data.

17/ Comments

Occupational Health Review Data: Medical confidentiality is respected and the staff member is not expected to divulge information of a confidential nature regarding their health. In the event that a staff member is recurrently sick over a given period of time, Human Capital Support may refer the staff member to the EMA medical service provider for an occupational health review. This is intended to determine, for example, whether the absence is justified, when the staff member will be fit to return to work and whether or not any workplace or workload adjustments are required or if other advice or assistance may be required to help the staff member return to work. (see Annexes 3 and 4)

In the event that an occupational health referral is required, a letter is sent to the staff member requesting him/her to book an appointment for an occupational health review with the medical service provider within a given time period. In parallel, a referral letter is sent to the medical service provider with details of the staff member's sick leave records and, where applicable, a copy of the medical certificate provided by the staff member. Also, if the staff member has reported a medical condition to Human Capital Support this information may also be passed onto the medical service provider. The referral letter to the medical service provider requests a report on the outcome of the occupational health review with advice on when the staff member will return to work and if any adjustments need to be taken into consideration, such as, for example, a return to work on medical part-time, the provision of specialised equipment for the workplace or a referral for counselling. (see Annexes 5 and 6)

The report is first sent to the staff member, whose consent is required before the report may be sent to the Head of Human Capital Support. The full report is not copied to the line manager. There may, however, be a partial disclosure of certain information with due respect for medical confidentiality, which may be relevant in assessing

a return to work. Medical reports are password protected electronic files which are stored in the EMA's electronic filing system with strictly limited access to Human Capital Support staff only. Recorded mail delivery is used to send documents to the medical service provider. Human Capital Support only maintains an electronic file of occupational health review cases. After closure of the case, data is stored electronically in DREAM for five years or one year after resignation/expiry of contract/retirement/death. Paper files are stored with the EMA medical service provider.

A follow-up review may be required after a certain period of time and the staff member will be further instructed by letter to book the next appointment. A follow-up report will be provided and acted upon and stored as described above.

Human Capital Support may instruct the medical service provider to conduct an occupational health review by telephone with the staff member if the circumstances so require.

The invoice for payment comes to the Head of Human Capital Support at EMA with the case number only. The invoice is checked by Human Capital Support against the case number list. The number only invoice is attached to the financial processing system (SAP Fin) to be work flowed from the Staff Payments Office to the Verifying Service and then to the Authorising Officer in the Staff Payments Office for approval to issue the payment. The invoice stays in SAP Fin for five years after discharge and it is only the invoice with a case number and no name. The link between the invoice with a case number and the name of the case remains on file, confidentially, in Human Capital Support.

Sick Leave Data: Sick leave (both uncertified and certified) is entered into SAP HR on a daily basis by leave administrators on receipt of an e-mail from the relevant service/department/division. The staff member needs to fill in a sick leave declaration form(s) which is to be signed by their line manager and sent onto Human Capital Support.

A sick leave certificate is necessary if the sick leave exceeds three calendar days. The sick leave certificate needs to state the staff member's name together with the start date and end date of the sickness absence. The certificate must contain the signature and/or stamp of the medical doctor and normally, as is often the practice in the UK, state the reason for the absence. The certificate must be sent to Human Capital Support at the latest by the fifth day of absence. Sick leave certificates are filed together with the sick leave forms in folders under the staff member's name. The folders are kept in locked cabinets accessible only by Human Capital Support. Paper files are stored in house for two years (for the current and previous year) after which files are sent to off-site archives where these are kept for an additional two years.

Special Leave Data: All special leave cases, including special leave to care for a sick relative or child (i.e. of a medical nature) require supporting documentation to be provided within fifteen days after returning to work. The original documents are submitted to the leave administrator by whom documents are copied and certified with the original documents being returned to staff members. All documents are filed in the same folder where sick leave forms and medical certificates are kept under the staff member's name which are stored in locked cabinets and can be accessed only by Human Capital Support. Depending on the specific nature of the document, one may block out irrelevant or superfluous personal data (e.g. medical data not needed by the leave administrator) as long as enough details remain for the person delegated by the appointing authority to establish an entitlement to special leave. The leave administrator makes a note in SAP when a certificate has been provided. No documentation regarding third parties is kept. A note that a leave administrator has seen the requested supporting documents is entered under a designated area in SAP.

PLACE AND DATE:

DATA PROTECTION OFFICER: Alessandro SPINA

INSTITUTION OR BODY: European Medicines Agency