



EUROPEAN DATA PROTECTION SUPERVISOR

WOJCIECH RAFAŁ WIEWIÓROWSKI
ASSISTANT SUPERVISOR

Mr Pierre MEULIEN
Executive Director
Innovative Medicines Initiative
Avenue de la Toison d'Or 56-60
BE - 1060 Brussels

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WW/XK/sn/D(2016)0420 C 2013-0616
Please use edps@edps.europa.eu for all
correspondence

Subject: Prior-check Opinion on the processing of health data at the Innovative Medicines Initiative, case 2013-0616

Dear Mr. Meulien,

We have analysed the notification and the privacy notice you have provided to the European Data Protection Supervisor (EDPS) for prior-checking under Article 27(2)(a) of the Regulation (EC) n° 45/2001 (the Regulation) on the management of health data at the Innovative Medicines Initiative (**IMI**). The purpose of this processing is to ensure compliance with the requirements for recruitment, annual mandatory medicals visits and specific medical check-ups, sick leave and special leave in conformity with the Staff Regulations.

On 20 May 2014, the EDPS requested further information on the processing operations under analysis and a reminder was sent on 7 October 7 2015 due to IMI's silence. IMI has not sent any reply since then, hence the EDPS has decided to issue his Opinion on the basis of the available information. As this is an ex-post case, the deadline of two months for the EDPS to issue his Opinion does not apply.

The notification and the relevant documents are analysed in light of the EDPS Guidelines on health data in the workplace (the Guidelines)¹. The EDPS Joint Opinion related to the processing of health data by 18 agencies² is also applicable in the present case.

¹ Issued in September 2009 and published on the EDPS website.

² Issued on 11 February 2011 and it concerned 18 agencies, case 2010-0071.

The EDPS will identify IMI's practices which do not seem to be in conformity with the principles of the Regulation and the Guidelines, and then provide IMI with relevant recommendations.

1) Lawfulness

Legal basis for special leave

The legal basis is one of the conditions for a processing operation to be lawful under Article 5(a) of the Regulation.

IMI has not stated the relevant legal basis of the processing related to special leave and the requirements that a staff member should fulfill in order to be granted a special leave.

The notification should therefore be updated accordingly.

2) Services of a private practitioner

The notification is silent on the possibility for staff members to have their annual check-up visit carried out by a private practitioner.

The EDPS reminds IMI that a declaration from the staff member's private practitioner should be considered sufficient in terms of the preventive purpose of the annual check-up. This declaration can confirm that the medical exams were carried out and if necessary, it can also specifically mention any special accommodations or working conditions the staff members might need.

IMI should therefore inform staff members of their entitlement to choose the private practitioner who will perform their annual medical check-up and of the practical steps they must take to have the check-up carried out by the private practitioner of their choice.

3) Recipients and processors

IMI lists in the notification the Commission's medical service as recipient.

IMI has concluded a service legal agreement (SLA) with the Commission's medical service for carrying out the pre-recruitment medical visits and annual check-up visits. In light of Article 23 of the Regulation, the Commission's medical service is acting on behalf of the agency and is therefore classed as processor rather than recipient. This is because it is obliged to carry out the processing only on instructions from the controller - IMI (Article 23(2)(a)). Their obligations regarding confidentiality and security measures are also laid down in the SLA (Article 23(2)(b)).

The EDPS therefore recommends that IMI clarify in the notification that the Commission's medical service acts as processor on behalf of IMI in light of the requirements of Article 23 of the Regulation.

4) Quality of data

Staff members are required to send their medical certificates to the HR Department of IMI to justify their absences or special leaves. The notification states that medical certificates

indicate the name and the specialization of the doctor providing the certificate. No information is provided about the diagnosis.

Medical certificates on sick-leave and some on special leave are considered to be data concerning health. Although the exact type of illness or diagnosis is not indicated, staff members can be identified as having been absent due to a short or long term illness on medical treatment or due to special sick leave of a medical nature. Furthermore, the illness of the staff members can also be identified by the doctor's specialization.

The HR Department of IMI should, under Article 4(1)(c) of the Regulation, keep information which is only adequate, relevant and necessary for the purpose of the medical certificates' collection, that is, to be able to manage the absences of the agency's staff members. HR should therefore only collect administrative data related to an absence of a staff member (name, surname and duration of absence) and not the medical certificate as such.

The EDPS recommends that IMI changes its policy and requires its staff members to send their medical certificates directly to the Commission's medical service. The Commission's medical service will then inform the HR Department about the administrative related data, such as the name, surname and duration of absence of the staff member.

5) Retention periods

Both the notification and the privacy notice state that *"the data is stored for 30 years for medical data; 3 years for administrative health data except if a dispute and appeal is underway; and for the period for challenging the data in case of health data of non-recruited candidates."*

The EDPS recalls that **medical data** of the pre-recruitment and annual visits (if the staff member chooses to carry out the medical check-ups with the Commission's medical service) should be kept for a maximum period of **30 years after the last document has been inserted to the medical file**. The underlined sentence, which determines a maximum retention period, should be added to the notification.

IMI should also make reference to the pre-recruitment aptitude certificates. They should be kept in the personal files for **ten years after the end of the period during which a staff member is in active employment or the last pension payment**.

The notification should be updated accordingly.

6) Security measures

IMI's HR officers process personal data related to health, namely aptitude certificates and administrative information on sick leave and special leave.

Due to the sensitive nature of such data, the EDPS recommends that the HR officers sign confidentiality declarations mentioning that they are subject to an obligation of professional secrecy equivalent to that of a health professional. This organisational measure aims at maintaining the confidentiality of personal data and at preventing any unauthorized access to them within the meaning of Article 22 of the Regulation.

7) Information to be given to the data subject

Privacy notices on pre-recruitment and annual check-ups

The privacy notice provided to the EDPS concerns only the management of medical certificates. IMI should prepare two clear privacy notices on the pre-recruitment medical visits and on annual check-ups including all information required under Articles 11 and 12 of the Regulation. All EDPS recommendations in the present opinion should be included.

The privacy notice on pre-recruitment medical visits should be attached to the invitation letter sent to the successful candidate to carry out the pre-recruitment medical visit.

As to the privacy notice on annual check-ups should be easily accessible to all staff members as soon as they request to carry out their annual check-up either with the Commission's medical service or with a private practitioner.

Legal basis of the processing operation

On the basis of Articles 11(1)(f)(i) and 12(1)(f)(i) of the Regulation, IMI should indicate to all privacy notices the specific legal basis of all processing operations including the EDPS recommendation on point 1).

The recipients of the data

In light of Articles 11(1)(c) and 12(1)(d), IMI should list the medical service as a processor (see point 3 above).

Rights of access and rectification

On the basis of Articles 11(1)(e) and 12(1)(e), IMI should provide more specific information as to the meaning of the rights of access and rectification in the context of the processing operations under analysis, so that affected individuals fully understand their rights.

IMI should indicate that staff members can have indirect access - instead of direct access - to their psychiatric and psychological reports via a doctor appointed by them³.

As to the right of rectification, IMI should mention that staff members are entitled not only to correct administrative errors in their medical file but also to supplement it by adding opinions of other doctors to ensure completeness of the file.

The time-limits for storing the data

In light of Articles 11(1)(f)(ii) and 12(1)(f)(ii), IMI should clearly indicate in the relevant privacy notices the different retention periods of medical data and of pre-recruitment aptitude certificates (see point 5 above).

The right to recourse to the EDPS

In light of Articles 11(1)(f)(iii) and 12(1)(f)(iii), IMI should indicate in all privacy notices that affected individuals have a right to recourse to the EDPS at any time. The mere reference to its contact information is not sufficient.

IMI should revise both the privacy notices and the notification accordingly including all the above recommendations.

³ In that regard, IMI should refer to the Conclusion 221/04 of the Board of Heads of Administration of 19 February 2004.

The EDPS regrets the lack of cooperation from IMI and expects that IMI adopt all EDPS recommendations in order to comply with the Regulation. In the context of the follow-up, IMI should send all updated relevant documents (notification and privacy notices) within a period of three months, to demonstrate that IMI has implemented the above recommendations.

Yours sincerely,

(signed)

Wojciech Rafał WIEWIÓROWSKI

Cc: Mr. Jerome CHAMBON, Head of HR Team.
Ms. Estefania RIBEIRO, Data Protection Officer.