



**Prior Checking Opinion  
regarding the provision of external counselling services  
at European Medicines Agency**

Brussels, 15 October 2015  
(Case 2013-0627)

**1. Proceedings**

On 11 June 2013, the European Data Protection Supervisor ("EDPS") received a notification for prior checking under Article 27(2) of Regulation (EC) No. 45/2001 ("the Regulation") relating to the processing of personal data in the context of external counselling service from the Data Protection Officer ("DPO") of the European Medicines Agency ("EMA"). Upon EDPS request, EMA provided subsequent clarifications.

As this is an **ex-post case**, the deadline of two months for the EDPS to issue his Opinion does not apply. This case has been dealt with on a best-effort basis.

**2. The processing operation**

EMA has contracted a clinic to provide medical services for staff members (hereinafter, "the contractor"), which also include **counselling services**. The latter are the only services subject to the notification sent by EMA. The **purpose** of provisioning such services is to support staff affected by emotional distress during and after a Business Continuity incident. The counselling services are available also for situations such as bullying behaviour, sexual harassment, conflicts at work, or to support staff suffering from stress for other reasons in life, as well as for anxiety, depression, people relationships, court and family disputes, trauma, stress management and psychological assessment.

The legal relationship between EMA and the contractor is governed by a Framework Service Contract ("FSC") and a Service Level Agreement ("SLA").

There are two instances of the data processing operation involved in this procedure: one performed directly by EMA and one performed directly by the contractor with respect to the counselling sessions.

**Personal data** processed directly by EMA are:

- request for counselling sessions made by the data subject,
- a summary report from the contractor stating that the 6 sessions to which the data subject is entitled have been completed - which does not contain any information

- related to the content of the counselling or a diagnosis, but may contain a recommendation for further sessions,
- invoices for the services provided which contain a referral number and the date of birth of the data subject, and
  - "copies of non-medical documents of any staff member from the files" (according to the SLA) .

Personal data processed by the contractor are:

- all of the above, and
- any personal data resulting from, and related to, the counselling sessions.

The Head of Human Resources (HR) and an Authorising Officer have access to the data processed directly by EMA.

An oral and informal meeting between Head of HR and the affected staff member is held before the start of the counselling request. The request for the 6 counselling sessions is then sent by the HR department of EMA to the contractor. The appointments are directly made by the staff member and the service provider. The summary report and the invoice, containing an allocated case number instead of the data subject's name, are sent to EMA after the conclusion of the sessions.

### 3. Legal analysis

#### 3.1. Scope of the Opinion

**Scope.** This Opinion covers the data processing by EMA and its external contractor when providing **counselling services**. It does not cover the processing of personal data by the external contractor when providing medical services *stricto sensu*. Therefore, EMA should send a separate notification in this respect.

**Guidelines.** The processing operation falls within the scope of the EDPS **Guidelines** on the processing of **health data** in the workplace by EU institutions and bodies (the "Guidelines")<sup>1</sup>.

The DPO underlined that the processing operation under review is different than the one related to anti-harassment counselling. The latter was already subject to prior checking by EDPS<sup>2</sup>.

This Opinion focuses on the aspects that do not seem to be fully compliant with the Regulation, as outlined in the above-mentioned Guidelines, need improvement or otherwise merit explanation.

#### 3.2. Grounds for prior checking

As the counselling services may involve the processing of data relating to health, it is subject to prior checking under Article 27(2)(a) of the Regulation.

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<sup>1</sup> *Guidelines concerning the processing of health data in the workplace by Community institutions and bodies*, adopted in September 2009 and available on the EDPS website [https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Guidelines/09-09-28\\_Guidelines\\_Healthdata\\_atwork\\_EN.pdf](https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Guidelines/09-09-28_Guidelines_Healthdata_atwork_EN.pdf)

<sup>2</sup> See Opinion issued in case 2010-0598 (Listening points/Informal procedure at EMA), in February 2011.

### 3.3. Lawfulness

Pursuant to Article 5(a) of the Regulation, the processing is lawful if it 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*".

The legal basis for the processing operation assessed is Article 1e of the Staff Regulations, according to which "*officials in active employment shall have access to measures of a social nature, including specific measures to reconcile working life with family life, adopted by the institutions*". It is also in line with Recital 27 of the Regulation, according to which processing of personal data for the performance of tasks carried out in the public interest "*includes the processing of personal data necessary for the management and functioning of those institutions and bodies*". In addition, the internal memorandum of 19 June 2008<sup>3</sup> mentions that the services are available for situations such as "conflicts at work", "bullying behaviour", "to support staff suffering from stress for other reasons in their life".

Considering the sensitive nature of the data processing operation in question, and that the specific legal basis for staff counselling is detailed only in an internal memorandum note, the EMA should further describe the modalities of the counselling services procedure in more specific rules of normative value (policy, communication, decision), applicable to the their internal staff<sup>4</sup>. Such an act will not only ensure clarity and transparency regarding the procedures, but will also support the staff members in acknowledging the details of this sensitive data processing operation.

The processing implemented by EMA seems necessary to solve employment-related problems and contribute to the overall improvement of the working environment<sup>5</sup> at EMA.

In light of this assessment, the processing operation is lawful under Article 5(a) of the Regulation, provided that the legal basis is strengthened with a policy/decision adopted by EMA.

### 3.4. Processing of special categories of data

Personal data processed by EMA (and by the contractor on behalf of EMA) in the context of the counselling service include data related to health.

Indeed, as it was established by the EDPS in the Guidelines<sup>6</sup>, health data include:

- medical data (e.g. doctor referrals and prescriptions, medical and psychological examination reports) - in the current case, such data are processed by the contractor, and
- administrative and financial data relating to health (e.g. medical appointments scheduling, invoices for healthcare service provision, indication of the number of days of sick leave, sick

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<sup>3</sup> Memorandum (ref.: EMEA/312151/2008 310) sent by the Head of Administration to EMA Secretariat regarding counselling services.

<sup>4</sup> See in this regard *Guidelines concerning the processing of personal data during the selection of confidential counsellors and the informal procedures for cases of harassment in European institutions and bodies*, adopted in February 2011 (available at [https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Guidelines/11-02-18\\_Harassment\\_Guidelines\\_EN.pdf](https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Guidelines/11-02-18_Harassment_Guidelines_EN.pdf)), p. 4.

<sup>6</sup> See *Guidelines on health data*, cited above, p. 2.

leave management) - in the current case, such data are processed by EMA and the contractor.

Processing personal data concerning health or sex life is prohibited unless grounds can be found in Article 10(2) of the Regulation. According to Article 10(2)(b), such an exception is provided for when the processing is necessary for the purposes of complying with the rights and obligations of the controller in the field of employment law. In this case, the justification for processing health related data can be found in the Staff Regulations (Article 1e), which has to be complemented with a policy/decision relating to counselling services, to be adopted by EMA (see Section 3.3 above).

Due to the sensitive nature of the personal data processed in the current case, specific organisational measures should be taken in accordance with Article 22 of the Regulation (see below Section 3.6).

### **3.5. Rights of the data subject**

#### **1) Information**

According to the notification, staff members of EMA are provided with a general data protection notice for all processing operations related to HR procedures, while a general privacy notice is available on the external website. No additional specific data protection notice is provided to staff members. The affected staff member is in copy of the communications between the Head of Human Resources and the external counselling service company.

The "Data Protection Declaration" provided by EMA does not meet the requirements imposed by Articles 11 and 12 of the Regulation. The purposes of the processing operation and the recipients or categories of recipients of the data for instance are not mentioned in the Declaration. EMA should give information to the affected persons through a specific data protection notice on counselling services. The notice should be published on the website or on the intranet<sup>7</sup>.

Moreover, EMA's policy or decision on the counselling services procedure (see above Section 3.3.) should provide that specific information in case of a request for counselling services is provided to the person concerned, during the initial meeting between the Head of HR and the person concerned. In this regard, EMA has already implemented a system of information in the context of the anti-harassment informal procedure, which the EDPS indicated as being a good practice<sup>8</sup>. EMA should implement the same system for the procedure under review.

#### **2) Exercise of their rights by data subjects**

In addition to requiring from its contractor to provide access to data subjects to their personal data (see below Section 3.7.), EMA also has to provide access to the personal data it processes and to provide means for the exercise of the rights to rectification and erasure. In this respect, the data protection notice should provide accurate information on how the data subject can exercise his/her rights vis-à-vis both EMA and the contractor. The notification (section 8) must be updated accordingly.

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<sup>7</sup> See in this regard *Guidelines for anti-harassment procedures*, cited above, point 1.

<sup>8</sup> See Opinion in Case 2010-0598 cited above, point 3.8.

### 3.6. Security

[...]

### 3.7. Outsourcing

According to Article 23(1) of the Regulation, *where a processing operation is carried out on its behalf, the controller shall choose a processor providing sufficient guarantees in respect of the technical and organisational security measures required by Article 22 and ensure compliance with those measures.* In addition, according to Article 23(2) of the Regulation, *the carrying out of a processing operation by way of a processor shall be governed by a contract or legal act binding the processor to the controller stipulating in particular that:*

*(a) the processor shall act only on instructions from the controller;*

*(b) the obligations set out in Article 21 [confidentiality] and 22 [security] shall also be incumbent on the processor, unless, by virtue of Article 16 or Article 17(3) second indent of Directive 95/46/EC, the processor is already subject to obligations with regard to confidentiality and security laid down in the national law of one of the Member States.*

In this case, a contract (FSC and SLA) has been concluded between EMA and the processor.

#### 1) Obligation of the processor to act only on EMA's instructions

The FSC enshrines only one article dedicated to data protection (Article II.7), which does not make reference to the obligation of the processor *to act only on instructions from the controller*, as it is required by Article 23(2)(a) of the Regulation. The mere reference to the Regulation included in the FSC does not suffice to make clear the legal condition under which the data may be processed. Therefore, the contract should be amended to include this obligation.

#### 2) Confidentiality

The contractor is registered in a Member State of the EU (United Kingdom); hence it is subject to the obligations enshrined in Directive 95/46/EC and its transposing law, including the confidentiality and security obligations. The confidentiality clause provided for in the FSC (Article II.9) should also make reference to the applicable national data protection rules<sup>9</sup>.

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<sup>9</sup> See Opinion in Case 2007-0489 (data processed by the Social Counsellor at ECB), 6 December 2007, point 3.9.

### 3) Security measures

[...]

### 4) Exercise of their rights by the data subjects in relation to contractor's processing

In order to ensure the effectiveness of the data subject's right of access, point 14 of the SLA on "Files" should be complemented with provisions making clear that the data subject has access to his or her own file in accordance with Article 13 of the Regulation, and not only with Article 26a of the Staff Regulations (point 14.1 of the SLA). Similarly, point 14.2 of the SLA should be complemented by stating that, the contractor will comply with requests for erasure and rectification submitted by EMA staff members, in accordance with Article 14 of the Regulation.

The EDPS points out that the general rule with regard to the right of access of the data subject to health data processed directly by the contractor remains direct access. However, *ex* Article 20(1)(c) of the Regulation, the access to data of psychological or psychiatric nature can be provided *indirectly*, if an assessment made on a case by case basis reveals that indirect access is necessary for the protection of the data subject, given the circumstances at stake<sup>10</sup>.

Conclusion:

There is no reason to believe that there is a breach of the provisions of Regulation (EC) 45/2001 provided that the considerations in this Opinion are fully taken into account. In particular, EMA should:

- Adopt specific rules of normative value (policy, communication, decision) detailing the modalities of the counselling services procedure;
- Establish and publish an exhaustive privacy statement concerning the processing operation related to counselling services meeting the requirements of Articles 11 and 12 of the Regulation, including information on how the data subject can exercise their rights; the policy/decision on the counselling services should provide that the person concerned receives the privacy statement during the initial meeting with the Head of HR;
- Prepare specific declarations of confidentiality to be signed by the staff in charge for the processing operation performed directly by EMA as to the processing of health data in the context of the counselling services;
- Amend the contract and the SLA with the counselling service provider, which must:
  - include the obligation of the service provider *to act only on instructions from the controller*, required by Article 22(2)(a) of the Regulation;
  - make reference to the applicable national data protection rules in the confidentiality clause;
  - [...];
  - [...];
  - Complement point 16 of the SLA on "Files" in accordance with Articles 13 and 14 of the Regulation, guaranteeing the rights of the data subject;

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<sup>10</sup> See *Guidelines*, point 6.

- include the obligation for the contractor to have signed by each member of its staff a specific declaration of confidentiality in relation to the processing of health data of EMA staff members in the framework of the contract;
- [...]
- Update the notification to insert the procedures for the exercise of the data subjects' rights, both with regard to data processed by the contractor and to data processed directly by EMA;
- Notify with the EDPS the processing of health data by the contractor when providing medical services *stricto sensu*.

15 October 2015

**(signed)**

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