

Opinion on the notification for prior checking from the Data Protection Officer of the European Commission concerning the selection procedure for the position of a member of the Management Board of the European Medicines Agency (EMA) and for the position of a member of the following scientific committees of EMA: Committee for Advance Therapies, Committee for Orphan Medicinal Products, Paediatric Committee and Pharmacovigilance Risk Assessment Committee

Brussels, 26 November 2012 (Case 2011-1166)

1. Proceedings

On 20 December 2011, the European Data Protection Supervisor (EDPS) received a notification for prior checking from the Data Protection Officer (DPO) of the European Commission (EC) concerning the selection procedure for members of the Management Board of the European Medicines Agency (EMA) and members of the following scientific committees of EMA: Committee for Advance Therapies, Committee for Orphan Medicinal Products, Paediatric Committee, Pharmacovigilance Risk Assessment Committee (hereinafter scientific committees).

Request for additional information was sent on 7 February 2012. Additional information and documents were submitted on 24 October 2012. The draft Opinion was sent to the DPO for comments on 26 October 2012. These were received on 15 November 2012.

2. Facts

This prior check Opinion deals with the selection procedures for the position of members of the Management Board of EMA and members of scientific committees of EMA carried out by the European Commission on the basis of Calls for expression of interest.

Members of the Management Board of EMA are appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission¹, while members of the above mentioned scientific committees of EMA are appointed by the Commission only with the exception of some appointments that require consultation with the European Parliament (patient and healthcare professionals appointed to the Committee of Advanced Therapies, the Paediatric Committee and the Pharmacovigilance Risk Assessment Committee)².

The **controller** is the European Commission, represented here by the Head of Unit DDG1.D of Directorate-General for Health and Consumers (DG SANCO).

¹ See Article 65(1) of Regulation No 726/2004.

² See Article 21(1) of Regulation (EC) No 1394/2007; Article 61a(1) of Regulation (EC) No 726/2004 and Article 4(1) of Regulation (EC) No 1901/2006.

The **purpose** of the processing operation is to organize and manage the selection procedure of members of the Management Board of EMA and members of scientific committees of EMA.

Data subjects are natural persons who express their interest to be selected as members of the Management Board of EMA or its scientific committees and submit their application pursuant to a Call for expression of interest.

Recipients of data are members of the Selection Committees (staff members of DG SANCO and other DGs concerned), staff members of EMA involved in the screening of the declaration of interest forms, staff members of DGT involved in the translation of documents when needed, and Members of the European Commission. Data are transferred also to the European Parliament and the Council of the EU according to their role in the respective selection procedure, and to other EU institutions and bodies according to their respective monitoring or supervisory tasks such as the European Court of Auditors, the Internal Audit Service, OLAF, the European Ombudsman and the European Data Protection Supervisor.

The following **categories of data** are processed:

- *Application form*: identification data and contact information of applicants, current employment, qualifications and professional experience, data on the applicants' language knowledge;
- *Declaration of interests form*: data concerning the applicants' professional career (e.g. activities as a member of a scientific advisory body, employment, consultancy or advisory activities), personal (private) interests (e.g. financial interests in pharmaceutical companies or ownership of patents). This data are collected to safeguard the independence of EMA, in line with the aim of Article 63(2) of Regulation (EC) No 726/2004 according to which members of the Management Board are to act in the public interest and in an independent manner;
- *Other application documents*: CV and motivation letter (both attached to the application file), supporting documents (if requested at a later stage of the selection procedure).

The following **retention policy** applies:

- Electronic files are kept for 3 months after the end of the selection procedure and are then archived. Archived files are destroyed after 3 years from the end of the selection procedure;
Paper files are kept for 3 years after the end of the selection procedure and are then destroyed;
- Data concerning appointed candidates are kept for the entire period of their appointment, if it is longer than the abovementioned period of 3 years.

The following **information to data subjects** is provided in the Calls for expression of interest and the Privacy statements accompanying each specific call:

- information on the controller and the persons responsible for the processing operations;
- legal basis and purpose of the processing;
- eligibility and selection criteria;
- recipients of the data processed;
- categories of data processed;
- time-limits for storing the data;
- existence of the right to request access to the evaluation results;
- existence of the right of data subjects to access and rectify their data;
- existence of the right of data subjects to contact the controller and to have recourse to the EDPS.

The data subjects are granted **rights of access to and rectification of data processed** that they can exercise by mail or email sent to DG SANCO. The applicants may request the rectification of their identification data at any time. However, in order to ensure fair and equal treatment of data subjects, data demonstrating compliance with the evaluation criteria set out in the call for applications may not be rectified or updated after the closing date for the call. The controller has the obligation to reply within 15 working days to any legitimate request.

Applicants may request access to their evaluation results once the decision on appointment has been taken. However, where necessary to protect the confidentiality and independence of the deliberations of the selection committee, and the rights and freedoms of other persons, access may be denied to (1) the comparative data concerning other applicants; (2) the individual opinions of the evaluators involved in the selection procedure.

As regard **security measures**, (.....)

3. Legal aspects

3.1. Prior checking

The processing of personal data relating to the management and administration of Calls for expression of interest falls within the scope of Regulation (EC) No 45/2001 (hereinafter the Regulation). It is subject to prior checking by the EDPS pursuant to its Article 27(2) (b) since it is clearly intended to evaluate personal aspects of each applicant and their capacity to perform specific tasks and obligations as members of the Management Board of EMA or its scientific committees.

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, the EDPS regrets that the processing operations have already been established prior his prior-checking Opinion. However, the EDPS underlines that all his recommendations made in the present Opinion should be duly implemented and the processing operations adjusted accordingly.

The notification was received by email on 20 December 2011. According to Article 27(4) of the Regulation, the EDPS Opinion must be delivered within a period of two months. Taking into account that the deadline was suspended for 300 days to allow for the submission of additional information and comments on the draft Opinion, the present Opinion must be delivered no later than 26 November 2012.

3.2. Lawfulness of the processing

Under Article 5(a) of the Regulation, personal data may be processed "*if 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 (...)*".

In the present case, the selection procedures are organised pursuant to the following legal acts:

- The Call for expression of interest for the selection of members of the Management Board of EMA is based on Article 65(1) of Regulation (EC) No 726/2004, according to which members of EMA Management Board are appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission;

- The Call for expression of interest for the selection of members of the Committee for Advanced Therapies is based on Article 21(1) of Regulation (EC) No 1394/2007, according to which members of this committee representing clinicians and patients' organisations are appointed by the Commission after consulting the European Parliament;
- The Call for expression of interest for the selection of members of the Committee for Orphan Medicinal Products is based on Article 4 (3) of Regulation (EC) No 141/2000, according to which three members of this committee are appointed by the Commission to represent patients' organisations on the basis of a public call for expression of interest;
- The Call for expression of interest for the selection of members of the Pharmacovigilance Risk Assessment Committee is based on Article 61a(1) of Regulation (EC) No 726/2004, according to which members of this committee are appointed by the Commission on the basis of a public call for expression of interest and in case of healthcare professionals and patient organisation representatives after consulting the European Parliament;
- The Call for expression of interest for the selection of members of the Paediatric Committee as representatives of health professionals or patient associations is based on Article 4(1) of Regulation (EC) No 1901/2006, according to which members of this committee are appointed by the Commission on the basis of a public call for expression of interest and in case of health professionals and patient association's representatives after consulting the European Parliament.

Therefore, the data processing under review is lawful within the meaning of Article 5(a) of the Regulation as it is necessary for the performance of tasks carried out in the public interest on the basis of the above mentioned regulations.

3.3. Data quality

Pursuant to Article 4(1)(a), (c) and (d) of the Regulation, personal data must be processed fairly and lawfully, be adequate, relevant and not excessive in relation to the purpose for which they are collected or further processed, as well as accurate and kept up to date.

The accuracy of the data processed is facilitated by the fact that data are provided by the respective data subjects who can also make use of their right of access and rectification (see point 3.6).

Lawfulness of the data processing has been already discussed (see point 3.2), whereas fairness has to be assessed in the context of information provided to data subjects (see point 3.7).

The EDPS notes that data requested in the application form and the declaration of conflict of interest form are adequate, relevant and not excessive in relation to the purpose of the selection procedure. The applicants may however submit in their application forms, declarations of conflict of interest, CVs and motivation letters information that may not be necessary or is excessive to what is requested. This information should not be further processed.

3.4. Data retention

According to Article 4(1)(e) of the Regulation, personal data may be kept in a form enabling 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 EDPS notes that data concerning unsuccessful candidates will be kept in paper files for three years after the end of the selection procedure and respective data in electronic format - three years and three months after the end of the selection procedure.

As regard to successful and appointed candidates, the EDPS would like to point out that according to Article 49(1)(d) of the Implementing Rules to the Financial Regulation, supporting documents relating to the budget implementation measures should be kept for *"at least five years from the date on which the European Parliament grants discharge for the budgetary year to which the documents relate"*. Further, according to Article 49(2) of the Implementing Rules, *"documents relating to operations not definitively 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"*. In any case, *"personal data contained in supporting documents [relating to the budget implementation measures] shall be deleted where possible when those data are not necessary for budgetary discharge, control and audit purposes"* as provided by Article 49(3) of the Implementing Rules. Against this background, the EDPS welcomes that the European Commission intends to keep personal data of successful and appointed applicants for only three years after the end of the selection procedure, respectively after the end of their mandate if it is longer, but he would like also to invite the European Commission to reconsider the data retention period for data with financial/budget implications (supporting documents relating to the budget implementation measures) in line with the requirements of Article 49 of the Implementing Rules to the Financial Regulation.

3.5. Transfer of data

The internal and inter-institutional data transfers mentioned above are subject to Article 7 of the Regulation. They should be necessary for the legitimate performance of tasks covered by the competence of the particular recipient who can process the data only for the purposes for which they were transmitted.

In the present case, the transfers of personal data to the members of the Selection Committees, staff members of DGT, staff members of EMA and Members of the European Commission are in principle considered as necessary for the accomplishment of the respective selection procedures. Further, the transfers to the European Parliament and the Council of the EU are also necessary due to the specific role of these institutions in the selection procedures on the basis of legal acts mentioned above (section 3.2). Finally, the data transfers to the European Court of Auditors, the Internal Audit Service, OLAF, the European Ombudsman and the European Data Protection Supervisor may be regarded as being necessary for the performance of respective monitoring or supervisory tasks in accordance with EU law.

As stated in point 3.3, despite the guidance provided in the Calls for expression of interest and other supporting documents the applicants may provide in their application forms, declarations of interest, CVs, motivation letters and other documents information that may not be necessary for the respective selection procedure.

In order to ensure compliance with Article 7 (1) and (3) of the Regulation, the EDPS considers that the controller should ensure that 1) data supplied by applicants but irrelevant or excessive to the purpose of the selection procedure are not transferred; and 2) intra- and inter-institutional recipients of data are always reminded of their obligation to process data only for the purposes for which they were transmitted.

3.6. Rights of access and rectification

Article 13 of the Regulation provides for a right of access and sets out the modalities of its application following the request of the data subject concerned. Article 14 of the Regulation provides that *"the data subject shall have a right to obtain from the controller the rectification without delay of inaccurate or incomplete personal data"*.

In the case at hand, access and rectification of data processed can be granted upon a request sent to DG SANCO at any time, whereby the right of rectification of data demonstrating compliance with the evaluation criteria is precluded after the expiry of the application deadline. This restriction can be deemed necessary to ensure the fairness of the selection procedure, i.e. safeguard the protection of rights of other applicants in terms of Article 20(1)(c) of the Regulation.

The EDPS takes good note that the applicants have the right to access their evaluation results once the decision for the appointment has been taken. In line with Article 20(1)(c) of the Regulation access may be denied to (1) the comparative data concerning other applicants; (2) the individual opinions of the evaluators involved in the selection procedure only where necessary to protect the confidentiality and independence of the deliberations of the selection committee, and the rights and freedoms of other persons,

3.7. Information to the persons concerned

Articles 11 and 12 of the Regulation provide that data subjects must be informed of the processing of data relating to them and list a range of general and additional items. The latter apply insofar as they are necessary in order to guarantee fair processing in respect of the data subject having regard to the specific circumstances of the processing operation.

The EDPS notes that the Calls for expression of interest and the Privacy statements provide for all information as required in terms of Articles 11 and 12 of the Regulation.

3.8. Security measures

On the basis of the available information, the EDPS has no reason to believe that the security measures implemented by the Commission are not adequate in light of Article 22 of the Regulation.

4. Conclusion

The proposed processing operation does not appear to involve any breach of the provisions of Regulation (EC) 45/2001, provided that the recommendations made above are taken into account. This means, in particular, that:

- the controller should ensure that intra- and inter- institutional recipients of data are reminded of their obligation to process data only for the purposes for which they were transmitted;
- the controller may need to reconsider the data retention period for data with financial/budget implications regarding successful applicants in light of Article 49(1)(d) of the Implementing Rules to the Financial Regulation as stated in point 3.4 of the present Opinion.

Done at Brussels, 26 November 2012

(signed)

Giovanni BUTTARELLI
Assistant European Data Protection Supervisor