

REGISTER NUMBER: 816

NOTIFICATION FOR PRIOR CHECKING

Date of submission: **20/12/2011**

Case number: **2011-1166**

Institution: **EC, DG SANCO**

Legal basis: article 27-5 of the regulation CE 45/2001⁽¹⁾

(1) OJ L 8, 12.01.2001

INFORMATION TO BE GIVEN⁽²⁾

(2) Please attach all necessary backup documents

1/ Name and address of the controller

2) Name and First Name of the Controller: BRUNKO Patricia

3) Title: Head of Unit

4) Directorate, Unit or Service to which the Controller is attached: DDG1.D

5) Directorate General to which the Controller is attached: SANCO

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

26) External Company or Directorate General to which the Processor is attached:

25) External Company or Directorate, Unit or Service to which the Processor is attached:

3/ Name of the processing

Selection procedure for the position of Member of the Management Board of the European Medicines Agency (EMA) and for the position of Member of the following scientific committees of EMA: Committee for Advance Therapies, Committee for Orphan Medicinal Products, Paediatric Committee, Pharmacovigilance Risk Assessment Committee

4/ Purpose or purposes of the processing

Processing is carried out for the purpose of managing an open procedure for the selection of the best-suited candidates to fill the position of Members of EMA Management Board and position of Members of certain scientific committees of EMA.

5/ Description of the category or categories of data subjects

14) Data Subject(s) concerned:

Data subjects are all the applicants in the Call for expressions of interest.

16) Category(ies) of Data Subjects:

See point 14.

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

17) Data field(s) of Data Subjects:

Attention: Please indicate and describe in the answer to this question also data fields which fall under article 10

Application form: identification data and contact information of applicants, data on the applicants' language knowledge, current employer, qualifications and professional experience;

Declaration of interests form (see comments under point 37): data concerning the applicants' professional career (e.g. activities as a member of a scientific advisory body, employment, consultancy or advisory activities), private interests (e.g. financial interests in pharmaceutical companies or ownership of patents);

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)

Evaluation of qualifications: evaluation grids and other data relating to applicants generated as a result of the assessment carried out by the selection committees with regard to the matching of applications against the

18) Category(ies) of data fields of Data Subjects:

Attention: Please indicate and describe in the answer to this question also categories of data fields which fall under article 10

See point 17.

7/ Information to be given to data subjects

15a) Which kind of communication(s) have you foreseen to inform the Data Subjects as described in articles 11 - 12 under 'Information to be given to the Data Subject'

The Call for expressions of interest, the Application form and the Declaration of interests form all contain a specific Section on personal data protection and the invitation to consult the Specific Privacy Statement published on the Call webpage.

The specific privacy statements to be annexed to the Call for expressions of interest for the position of member of EMA Management Board and to the various Calls for expressions of interest for the position of member of EMA scientific committees are attached under point 15).

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

15b) Which procedure(s) did you put in place to enable Data Subjects to exert their rights: access, verify, correct, etc., their Personal Data as described in articles 13 - 19 under 'Rights of the Data Subject' :

The procedure, together with the Controller's contact information, is provided in the Specific Privacy Statements (see attachments under point 15 a) above).

9/ Automated / Manual processing operation

7) Description of Processing:

Attention: Please describe in the answer to this question if you process personal data falling under article 27 "Prior-Checking (by the EDPS - European Data Protection Supervisor)"

For the Management Board:

In order to draw up a short-list of the most suitable candidates for the position of Members of EMA Management Board, on the basis of which the Council will take its decision on appointment, the Commission launches and manages an open Call for expressions of interest thereby processing a certain amount of personal data of applicants in the Call.

The data submitted by applicants are handled by different actors in the selection process: DG SANCO (Unit D3), the Selection Committee and Commission Members adopting the final decision on the Commission's list.

Once adopted by the Commission, the list, accompanied by the relevant documentation, is then transmitted to the Council which in turn transmits it to the EP, in view of the final decision on appointment.

For a detailed description of data processing operations carried out in the context of the selection procedure,

8) Automated Processing operation(s):

See Table attached under point 37 (column on "Description of processing").

9) Manual Processing operation(s):

See Table attached under point 37 (column on "Description of processing").

10/ Storage media of data

Selection files are stored both electronically and physically (in paper form).

Electronic files are stored in a separate and secure network drive accessible only to a well-defined population of authorised users in DG SANCO and, if appropriate, in other DGs involved in the selection procedure. Archived files are kept in an electronic medium in a physically secure location with restricted access. For further details, see the Table attached under point 37 (column on "Data protection measures").

Paper files are locked in secure cabinets of DG SANCO with access limited to designated staff members of SANCO.D3 on a need-to-know basis.

11/ Legal basis and lawfulness of the processing operation

11) Legal basis of Processing:

For the Management Board:

Processing is based on Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency.

According to Article 65(1) second subparagraph of that Regulation, members representing patients' organisations, doctors' organisations and veterinarians' organisations of the EMA Management Board are appointed by the Council in consultation with the European Parliament from a short-list drawn up by the Commission.

Additionally, Article 63(2) of the same Regulation requires that members of the Management Board undertake to act in the public interest and in an independent manner and to disclose at any time the existence of possible conflicts of interest in the pharmaceutical industry which may affect their impartiality.

For the scientific committees:

See the Annex to the Table attached under point 37.

12) Lawfulness of Processing:

Answering this question please also verify and indicate if your processing has to comply with articles 20 "Exemptions and restrictions" and 27 "Prior checking (by the EDPS)"

Processing is lawful in accordance with Article 5(a) and (b) of Regulation (EC) No 45/2001, since it is necessary for the performance of a task carried out in the public interest on the basis of a legal instrument adopted according to the Treaties and for compliance with a legal obligation to which the Controller is subject under Article 65 of Regulation (EC) N° 726/2004, Article 21 of Regulation (EC) No 1394/2007, Article 4 of Regulation (EC) No 141/2000, Article 4 of Regulation (EC) No 1901/2006 and Article 61a of Regulation (EU) No 1235/2010.

Article 27 "Prior checking" of Regulation (EC) No 45/2001 is applicable.

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

20) Recipient(s) of the Processing:

See Table attached under point 37 (column on "Recipients").

21) Category(ies) of recipients:

Staff/members of EU institutions and agencies

13/ retention policy of (categories of) personal data

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 as from the end of the selection procedure.

Selection dossiers in paper format are kept in locked cabinets of the DG for 3 years after the end of the selection procedure and are then destroyed. Commission's documents containing personal data will be archived in accordance with the relevant Commission's legal framework.

However, personal data of appointed candidates are kept for the entire period in which these candidates are on duty, if longer than the abovementioned period of 3 years.

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)
(on justified legitimate request from the data subject)
(Please, specify the time limits for every category, if applicable)

22 b) Time limit to block/erase data on justified legitimate request from the data subjects

Legitimate requests from data subjects to have their data blocked or erased in accordance with Articles 15 and 16 of Regulation (EC) No 45/2001 will be replied by the Controller within 15 working days as from receipt of the request.

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,

22 c) 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

n/a

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

27) Legal foundation of transfer:

Only transfers to third party countries not subject to Directive 95/46/EC (Article 9) should be considered for this question. Please treat transfers to other community institutions and bodies and to member states under question 20.

Only transfers to other EU institutions or bodies (Article 7 of Regulation (EC) No 45/2001) take place.

28) Category(ies) of Personal Data or Personal Data to be transferred:

n/a

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

7) Description of Processing:

Attention: Please describe in the answer to this question if you process personal data falling under article 27 "Prior-Checking (by the EDPS - European Data Protection Supervisor)"

For the Management Board:

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Once adopted by the Commission, the list, accompanied by the relevant documentation, is then transmitted to the Council which in turn transmits it to the EP, in view of the final decision on appointment.

For a detailed description of data processing operations carried out in the context of the selection procedure, 12) Lawfulness of Processing:

Answering this question please also verify and indicate if your processing has to comply with articles 20 "Exemptions and restrictions" and 27 "Prior checking (by the EDPS)"

Processing is lawful in accordance with Article 5(a) and (b) of Regulation (EC) No 45/2001, since it is necessary for the performance of a task carried out in the public interest on the basis of a legal instrument adopted according to the Treaties and for compliance with a legal obligation to which the Controller is subject under Article 65 of Regulation (EC) N° 726/2004, Article 21 of Regulation (EC) No 1394/2007, Article 4 of Regulation (EC) No 141/2000, Article 4 of Regulation (EC) No 1901/2006 and Article 61a of Regulation (EU) No 1235/2010.

Article 27 "Prior checking" of Regulation (EC) No 45/2001 is applicable.

Article 27.2.(a) Processing of data relating to health and to suspected offences, offences, criminal convictions or security measures,

n/a

Article 27.2.(b) Processing operations intended to evaluate personal aspects relating to the data subject,

Article 27.2.(b) Processing operations intended to evaluate personal aspects relating to the data subject,

Article 27.2.(c) Processing operations allowing linkages not provided for pursuant to national or Community legislation between data processed for different purposes,

n/a

Article 27.2.(d) Processing operations for the purpose of excluding individuals from a right, benefit or contract,

n/a

Other (general concept in Article 27.1)

n/a

17/ Comments

1) Date of submission:

10) Comments if applicable:

No assessment of the candidates' skills, capacity or suitability for the position derived from the candidates' performance during interviews or tests is carried out.

Evaluation of candidates is limited to a comparative analysis of qualifications and competences (based exclusively on the declarations made by each candidate in the application documents) and to the objective attribution of ranking points to candidates in result of this comparison of "merits". The evaluation is conducted against the objective criteria on qualifications for the position laid down in the Call for expressions of interest. These criteria relate in particular to the areas of competence and the number of years of relevant professional experience, as well as to the ability to work in a multicultural and multidisciplinary environment derived solely from the candidate's declared experience. The criterion of the broadest possible geographic distribution within the EU also applies.

36) Do you publish / distribute / give access to one or more printed and/or electronic directories?

Personal Data contained in printed and/or electronic directories of users and access to such directories shall be limited to what is strictly necessary for the specific purposes of the directory.

If Yes, please explain what is applicable.

no

37) Complementary information to the different questions if applicable, including attachments to this notification which should not be public :

Complementary information to point 7: a detailed description of the data processing is provided in the Table attached below.

Complementary information to point 17: the Declaration of interests forms annexed to the Call for expressions of interest are the forms which are used at EMA for annual declarations of interest of members of the Management Board and of the Scientific Committees (EMA has recently introduced new forms for the latter, whereas the members of the Management Board still use the 'old' forms). The processing of personal data by EMA in the context of Public Declarations of Interest has been assessed by the EDPS (prior checking procedure case ref. 2007-419).

PLACE AND DATE:20/12/2011

DATA PROTECTION OFFICER: MANOLESCU Dan

INSTITUTION OR BODY:European Commission