

REGISTER NUMBER: 1406

NOTIFICATION FOR PRIOR CHECKING

Date of submission: 24/10/2016

Case number: 2016-0953

Institution: EMA

Legal basis: article 27-5 of the Regulation EC 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

Melanie Carr
Head of Stakeholder and Communication 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

The concerned division is the Stakeholder and Communications division.

The place of processing of personal data will be 30 Churchill Place, Canary Wharf, London E14 5EU, UK.

3/ Name of the processing

Public hearings

4/ Purpose or purposes of the processing

The notification is in relation to the processing of personal data for the purpose of the conduct of public hearings by the Pharmacovigilance Risk Assessment Committee (hereafter, "PRAC").

The PRAC is one of the scientific committees of the European Medicines Agency. Pursuant to Article 20 of Regulation (EC) 726/2004, Article 31 or Article 107i of Directive 2001/83/EC, the PRAC may hold public hearings in the context of safety referral procedures.

A public hearing is a forum to which the public is invited to express its views, guided by a pre-defined set of questions, on issues related to the safety of a particular medicinal product, a medicinal substance or a therapeutic class.

Public hearings give the PRAC a channel to hear the public's views and concerns and take them into account in its opinion-making, particularly where options for regulatory actions to manage and/or minimise risks will need to be considered in a wider public health context.

Public hearings are open to all members of the public; they can participate as speakers (in person or via telephone conference) or as observers.

All members of the public who wish to attend a public hearing are required to register in advance. Participation requests are submitted to the Agency within a dedicated application form and include the following information:

- Full name of the individual;
- Capacity (i.e. whether the person is a patient/consumer representative or carer, a healthcare professional; academic or pharmaceutical industry representative);
- Affiliation (i.e. name of the organisation/ company the individual represents), if applicable;
- Contact information (postal address, e-mail address, telephone number);
- Country of residence; and
- For speakers: a brief outline of their planned intervention and specifically how it addresses the questions on which the PRAC is seeking public opinion.

The Agency will need to be informed on the registration form of details of any special assistance that may be required and if a registered carer will also attend.

The information submitted to the Agency will be made public for all participants who make an intervention at the public hearing (with the exception of personal contact details)

The proceedings of the public hearing are broadcast and can be viewed live on the Agency's website. A recording of the hearing, the list of all participants, including their affiliation and any declared interests, as well as a summary of the conclusions, will be published on the EMA website after the hearing.

The information included within the application form will be used by the Agency to:

- Review requests to speak / observe at the public hearing (depending on the number of requests received, the Agency may not be able to accommodate all requests. The Agency will decide on the list of participants based on their appropriateness to the subject matter of the public hearing and/or the geographical spread of the requesters); and
- Advise the PRAC / public who is speaking / attending the hearing.

Individuals who have not been admitted as speakers are given the option to submit a written contribution to the PRAC for their consideration, prior to the public hearing.

The Agency will prepare an agenda and a list of confirmed speakers, including the time allocated to each speaker, which is published in advance of the hearing on its website.

A Guidance document with detailed information about the participation to public hearings will be also made available by EMA (Annex I)

5/ Description of the category or categories of data subjects

The data subjects concerned include members of the public, i.e. a patient/consumer representative or carer, a healthcare professional, academic or pharmaceutical industry representative, who wish to participate in the public hearings held by the PRAC.

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 mainly relates to the justification for the individual application for participation in the public hearings and the contact details of the applicants. Therefore, the processing operation relates to:
: (i) data concerning health (including disabilities); and (ii) data concerning telephone numbers and communications.

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

The data subject may request access to his/her personal data at any time within three months from the receipt of the request and free of charge. This principle governing right of access is provided under Article 13 of Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

The data subject may obtain from the controller rectification of his/her personal data where there the concerned data is deemed to be inaccurate or incomplete. This right is provided under Article 14 of Regulation (EC) 45/2001.

In certain cases, the data subject may obtain from the controller the blocking of his/her personal data. This right is provided under Article 15 of Regulation (EC) 45/2001.

If the processing of the data subject's personal data is deemed to be unlawful, recourse to the erasure of that data may be permitted. This right is provided under Article 16 of Regulation (EC) 45/2001.

Finally, in certain cases the data subject has the right to object to the processing of his/her personal data on the basis of compelling legitimate grounds. This right is provided under Article 18 of Regulation (EC) 45/2001.

Information concerning processing and the rights of the data subjects is provided in the application form in the specific data protection section. (see Annex II)

9/ Automated / Manual processing operation

For present purposes, data processing will be automated wholly or in part.

10/ Storage media of data

The data of the participants to the PRAC public hearings will be stored on the EMA server. They will be kept in a dedicated folder (entitled "Public hearings") sub-divided by public hearing; situated within DREAM web-top application, which is password protected and only available to EMA staff members, based on need to know and justified basis.

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 conduct of public hearings is laid down in Article 20 of Regulation (EC) 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 a European Medicines Agency and Articles 31 and 107i of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

In accordance with Article 10(2)(a) of Regulation (EC) No 45/2001 the data subject has unambiguously consented to the processing of health data. By submitting the application for participation in the public hearing, the applicant has unambiguously consented to the processing of his/her health data.

The EMA has adopted *Rules of procedure on the organisation and conduct of public hearings* on the 13 April 2016 (Ref. EMA/363479/2015) (Annex III).

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

Staff at the EMA, on a need to know basis, will have access to the concerned data. Certain members of the PRAC, such as the Chairs and Rapporteurs, may also have access to the data for the purpose of determining its appropriateness to the subject matter of the public hearing and/or the geographical spread of the requesters.

It should be noted that natural or legal persons employed by or under contract to the EMA have received instructions about confidentiality in processing personal data.

It is recalled that Article 76 of Regulation (EC) No 726/2004 sets out a duty of confidentiality for members of the Management Board and Scientific Committees, rapporteurs, experts and EMA staff. The protection of personal data and respect of confidential information is an essential part of the relationship between the EMA, European institutions, Member States, pharmaceutical companies and patients. Moreover, the specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMA policy on the handling of conflicts of interests of Scientific Committee members and experts are applicable to members of the PRAC.

Further, Article 17 of the Regulations and Rules applicable to officials and other servants of the European Union (Staff Regulations) binds staff members to a general duty of confidentiality. Interim staff, national experts on secondment, visiting experts, and persons participating in a work experience programme (trainees) are all required to sign a confidentiality undertaking.

13/ retention policy of (categories of) personal data

Personal data of participants to the PRAC public hearings will be kept for a period of 2 years after the end of the PRAC meeting during which the public meeting was held.

Personal data of members of the public whose requests to speak at the PRAC public hearing were declined will be kept for a period of 2 years after the end of the PRAC meeting in which the public hearings were conducted.

An exception will apply in relation to the personal data of speakers (excluding industry representatives) for which the Agency will cover the travel costs. In this case, the data will be stored for the duration necessary to comply with the provisions of the Financial Regulation, for auditing purposes, namely 5 years after discharge of the budget by the European Parliament.

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 not envisaged that the concerned data will be handled for historical, statistical or scientific purposes.

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

It is not intended that the concerned data will be transferred to third countries or international organisations.

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.

Given the nature of the public hearings which concern safety issues regarding the medicinal product(s), it is likely that applicants might present personal experiences with the use of the medicinal product(s) and therefore data to be processed will concern sensitive health data.

17/ Comments

N.A.

PLACE AND DATE:

DATA PROTECTION OFFICER: Alessandro SPINA

INSTITUTION OR BODY: European Medicines Agency

Annex I – Draft Guidance Note for Public Participants

Annex II – Application form

Annex III – Rules of procedure on the organisation and conduct of public hearings