



"Public Hearings at EMA"

Prior Checking Opinion

Case 2016-0953

Public hearings enable EMA to engage EU citizens in the supervision of medicines and to listen to their views and experiences. These public hearings are part of certain safety reviews of medicines, particularly in relation to their therapeutic effects and available therapeutic alternatives. Contributions made by the public in this context will be considered by the EMA scientific committee in charge and will inform its opinion-making. Public hearings are open to all members of the public who can justify a specific interest in the subject matter concerned. Since some members of the public will attend in their capacity of patients or consumers, it may be necessary to collect their health data for the purpose of organising these public hearings.

It is important that the members of the public who submit an application to attend a public hearing are properly informed of how their data will be processed and that their data are not kept for longer than necessary.

Brussels, 17 January 2017

1) The facts

Public hearings

Public hearings are a new tool for the European Medicines Agency ("EMA") to engage EU citizens in the supervision of medicines and to listen to their views and experiences. The Pharmacovigilance Risk Assessment Committee ("PRAC") is one of the scientific committees of EMA, which has been enabled to hold public hearings as part of certain safety reviews of medicines, particularly in relation to their therapeutic effects and available therapeutic alternatives. Public hearings give the PRAC a channel to hear the public's view and concerns and take them into account in its opinion-making, in particular where options for regulatory actions and to manage and/or minimise risks will be considered in a wider public health context.

EMA has issued a document entitled "Public hearings guidance for public participants" ("Guidance document"), intended to provide practical information and answer questions about how the public may participate in hearings convened by the PRAC. Further details can be found in the "Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee 'PRAC'" ("RoP").

Application to participate as observer or speaker

Public hearings are open to all members of the public¹; they can participate as speakers or as observers. Members of the public who wish to attend a public hearing must register via an application form on EMA's website. The data collected include: contact details, nationality and country of residence, in what capacity the individual wants to attend (i.e. whether the person is a patient, healthcare professional, pharmaceutical industry representative, etc.), affiliation (i.e. what company or patient association etc., the person represents), and, for speakers, a brief outline of their planned intervention. In the application form, applicants with any disability or mobility impairment should also submit details of any special assistance (including an accompanying carer) that may be required.

The fact that applicants must submit a justification for their participation in the public hearings entails that data concerning health may be collected and further processed. Furthermore, for practical reasons, data relating to disabilities or mobility impairments may also be processed.

Selection of the participants in public hearings

EMA will use the information included in the application form to decide on the list of participants and to advise PRAC and the public on the speakers/observers attending the hearing. Speakers will be selected on the basis of the appropriateness of their intervention, considering the questions to be addressed at the public hearing, the stakeholder group and the geographical spread.² Observers will be admitted on a first come-first served basis taking into account affiliation, experience and location, etc.³

Publication of information about participants

According to the notification, the information submitted to EMA "*will be made public for all participants who make an intervention at the public hearing (with the exception of personal contact details)*"⁴. The application form states that "*a recording of the hearing, the list of all*

¹ E.g. patient/consumer representatives, healthcare professionals, academic or pharmaceutical industry representatives.

² See points 6 and 9 of the Guidance document and point 3.5 of the RoP.

³ See point 6 of the Guidance document.

⁴ See also point 3.3 of the RoP.

participants, including their affiliation and any declared interests and a summary of the conclusions of the meeting will be published on the EMA website”.⁵ The application form also indicates that “*personal data may be published on the EMA’s website for transparency purposes*”, with the exception of contact details.

Furthermore, the proceedings of the public hearing are broadcast and can be viewed live on EMA’s website.

2) Legal analysis

This prior checking Opinion⁶ under Article 27(2) of Regulation (EC) 45/2001⁷ (the Regulation) will focus on those aspects which raise issues of compliance with the Regulation or otherwise merit further analysis. For aspects not covered in this Opinion, the EDPS has, based on the documentation provided, no comments.

a) Grounds for prior checking

EMA correctly states in the notification that the processing operation is subject to prior checking under Article 27(2)(a) of the Regulation since it includes the processing of health data. However, the EDPS finds that the processing operation is subject to prior checking also on the grounds of Article 27(2)(b) of the Regulation, since there will be an evaluation of applications of both speakers and observers in order to select those that will be able to speak/attend.⁸

b) Legal basis and lawfulness

The legal basis for the processing operation is laid down in Regulation (EC) 726/2004 and in Directive 2001/83/EC.

According to the notification, the processing operation is lawful since data subjects have unambiguously given their consent to the processing of their health data in accordance with Article 10(2)(a) of the Regulation. Such consent is specific to the processing of health data, which is prohibited unless one of the exceptions laid down in paragraphs 2-4 of Article 10 apply. However, the EDPS considers that lawfulness of the entire processing operation, i.e. collection and further processing of the data, is based also on Article 5(a) (processing necessary for the performance of a task carried out in the public interest), and 5(d) (data subject’s unambiguous consent), of the Regulation.

⁵ See also point 1 under “After a public hearing” of the Guidance document, and point 5.1 of the RoP.

⁶ According to Article 27(4) of the Regulation, the EDPS has to provide his Opinion within two months of receiving the notification, not counting suspensions. The notification was received on 21 October 2016. It was suspended from 4 November to 7 November 2016; from 15 November to 18 November 2016 and from 15 December 2016 to 13 January 2017. The EDPS shall thus render his Opinion by 25 January 2017.

⁷ OJ L 8, 12.1.2001, p. 1.

⁸ C.f. Point 6 and 9 of the Guidance document and point 3.5 of the RoP.

c) Information to be given to data subjects and data quality

Pursuant to Article 11 of the Regulation the controller must provide the data subjects with certain information on the processing of their data, such as the purpose of the processing, the recipients of the data, the existence of a right of access, the retention period, etc.

This information can for instance be given in a data protection notice, which should be specific to the processing operation at hand and readily accessible for the data subject.

EMA has included some of the required information in the application form: the purpose, the publication of certain data on the EMA website, the possibility to contact the data protection officer of EMA or the EDPS, and the fact that the data will be stored “*for the duration necessary for organising the public hearing*”. The application form also includes a link to a general privacy statement on EMA’s website. The privacy statement provides useful information relating to the processing of personal data carried out by EMA in general terms, but it is not specific to the processing of data within the framework of public hearings. The Guidance document also includes a link to the same general privacy statement. In addition to the above, EMA also refers to the RoP.

The EDPS is of the opinion that the information included in the application form is not sufficient since it does not address all points in Article 11. In particular, data subjects are not informed of the actual retention period of their data. In the same vein, the general privacy statement is not sufficiently specific to the processing operation at hand. Furthermore, information cannot be considered readily accessible if the data subject must refer to no less than three different documents, in addition to the application form, in order to receive information on the processing of their data.

As regards the publication of data, the notification and the annexes (application form, Guidance document and RoP) are not clear nor coherent as to what data will be published on the EMA website or otherwise be made available to participants or the public⁹. Publication of data is to be considered a processing operation separate from the collection of data and EMA should thus ensure that the data quality principles¹⁰ are respected also in this regard. Although the disclosure of health data of some participants may derive from the publication of the record of the meeting, EMA should not include in the documents published in relation to public hearings any data which are irrelevant or excessive in relation to the purpose (ensure the transparency of the public hearings process). For instance, it is not relevant to publish data relating to a participant’s disability or special assistance requirements.¹¹ The applicants should be properly informed of what data will be published or otherwise made available to participants.

Consequently, EMA should provide a single, specific and comprehensive data protection notice addressing all relevant points of Article 11, including publication of data, and making in particular a clear distinction between (i) the categories of data that will be collected and the categories of data that will be published, as well as (ii) the different categories of data subjects (i.e. speakers, speakers for whom travel expenses will be reimbursed, observers, carers, unsuccessful applicants, etc.) where different rules apply (as for categories of data collected, retention period, etc.

⁹ See above under point 1) The facts.

¹⁰ Article 4 of the Regulation.

¹¹ C.f. point 4 in the notification, according to which, “*the information submitted to EMA will be made public for all participants who make an intervention at the public hearing (with the exception of personal contact details)*”

The EDPS strongly recommends that EMA:

- clarify which data on observers and speakers that will be published, having due consideration for the data quality principle;
- provide a single, specific and comprehensive data protection notice, addressing all relevant points of Article 11, including publication of data, and making a clear distinction, where necessary, between (i) the categories of data that will be collected and the categories of data that will be published, as well as (ii) the different categories of data subjects. EMA should make the data protection notice readily available to the applicants, for instance via a link in the application form and the Guidance document. The EDPS expects to receive a copy of the data protection notice.

d) Data retention

According to Article 4(1)(e) of the Regulation, data should not be kept for longer than is necessary for the purposes for which the data were collected.

The notification states that the personal data of participants (both speakers and observers) to the public hearing “*will be kept for a period of 2 years after the end of the PRAC meeting during which the public hearing was held.*” The same applies to members of the public whose requests to speak at the public hearing were declined. Furthermore, the personal data of speakers for whom EMA covers the travel expenses “*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.*”

EMA has confirmed that no differentiation will be made between different categories of data and that also health data, if any, will be stored for two and five years respectively. The retention period of two years have been set to guarantee the alignment with the time-limit for potential complaints before the European Ombudsman made by applicants whose application to participate at the public hearing has been refused. EMA considers that the documents received in the context of applications to participate in public administrative procedures should be preserved in their integrity during the period in which it is mandatory to keep them (two and five years respectively). According to EMA, any interference to the integrity of these documents kept for legal reasons would not seem to be compatible with the principle of good administration.

The EDPS can accept a retention period of two years of the personal data, including health data, for the reasons outlined above since the health data may be directly relevant to the participation (or refusal of request to participate) in the public hearing. However, as regards the personal data of speakers whose travel costs will be reimbursed by EMA, the EPDS is of the opinion that it is not necessary to keep all data, including health data, for an additional three years for auditing purposes. EMA should keep only personal data necessary for discharging the budget, such as for example an attendance form signed by the speaker during the public hearing. In this regard, the EDPS refers to Article 48 of the Rules of application of the Financial Regulation, according to which “*personal data contained in supporting documents shall be*

deleted where possible when those data are not necessary for budgetary discharge, control and audit purposes".¹²

As far as speakers are concerned, the EDPS **recommends** that EMA keep only data necessary for auditing purposes for five years and remove the other data after two years.

3) Recommendations and suggestions for improvement

In this Opinion, the EDPS has made recommendations to ensure compliance with the Regulation. Provided that the above recommendations are implemented, the EDPS sees no reason to believe that there is a breach of the Regulation.

For the following **recommendations**, the EDPS expects **implementation and documentary evidence** thereof within **three months** of the date of this Opinion:

1. Provide a specific and comprehensive data protection notice to the processing of personal data necessary for the organisation of public hearings and make it readily available to the applicants.
2. Re-evaluate the retention period of five years of personal data that are not necessary to keep for auditing purposes.

Done at Brussels, 17 January 2017

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¹² <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R1268-20160101&from=EN>