EMA/464248/2019

Record of data processing activity relating to public hearings (public)

1.	Last update of this record, version number:	31 December 2019, version 1
2.	Reference number:	S1
3.	Name and contact details of controller:	European Medicines Agency Internally: EMA Head of Stakeholders and Communication Division: (public-engagement@ema.europa.eu or publichearings@ema.europa.eu)
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	Not applicable
6.	Name and contact details of processor (where applicable)	Not applicable
7.	Purpose of the processing	Personal data is processed for the purpose of the conducting of public hearings convened by the Pharmacovigilance Risk Assessment Committee (hereafter, "PRAC") in the context of safety referral procedures pursuant to Article 20 of Regulation (EC) 726/2004, Article 31 or Article 107i of Directive 2001/83/EC. A public hearing gives 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 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 those wishing to attend a public hearing are required to register in advance via a dedicated application form submitted to the Agency and must include the following information: Full name of the individual; a) capacity (i.e. whether the person is a patient/consumer representative or carer, a healthcare professional; academic or pharmaceutical industry

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		representative); b) affiliation (i.e. name of the organisation/ company the individual represents), if applicable; c) contact information (postal address, e-mail address, telephone number); d) country of residence; and e) for speakers a brief outline of their planned intervention and how it addresses the questions on which the PRAC is seeking public opinion. The information included within the application form will be used by the Agency to review requests to speak / observe at the public hearing and select who is invited to speak / attend the hearing. In addition, the Agency needs to be informed of any special assistance required and if a registered carer will attend.

8.	Description of categories of persons whose data EMA processes and list of data categories	The following categories of data subjects are subject to this processing operation:
		• all members of the public, including
		  ○ patient/consumer representative or carer,
		  ○ healthcare professional,
		  ○ academic or pharmaceutical industry representative, who wish to participate in the public hearings held by the PRAC.
		
		The processing operation relates to the following data categories:
		• full name of the individual;
		• capacity (i.e. whether the person is a patient/consumer representative or carer, a healthcare professional, an academic or pharmaceutical industry representative);
		• affiliation (i.e. name of the organisation/ company the individual represents);
		• contact information (postal address, e-mail address, telephone number);
		• country of residence;
		• for speakers, a brief outline of their planned intervention and how it addresses the questions on which the PRAC is seeking public opinion;
		• personal views of speakers;
		• the justification and specific assistance requirements for the individual application for participation in a public hearing, including
		  ○ data concerning health (including disabilities)

9.	Time limit for keeping the data	All data collected from individuals within the organisation of a public hearing will be retained for a period of 2 years and then deleted. Given the nature of the public hearings (live broadcast), data is made public during public hearings and recorded in the summary and written statements of each speaker, which may also include personal views. Data is not kept in paper or other physical files unless documents are exceptionally printed (and then destroyed). Data is kept electronically and deleted manually after 2 years from the date of the public hearing. In particular, a specific meeting is held in advance to decide what documents must be disposed of. This includes e-mails, inbox, outbox, documents saved in the

		DREAM database. Therefore, no automatic deletion is provided for.
10.	Recipients of the data	Relevant EMA staff members and committee members, i.e., EMA public engagement team and, specifically for the speakers, EMA meeting management team. The information submitted to the Agency will be made public for all participants who speak at the public hearing (with the exception of personal contact details and data on any specific assistance/carer required for the participation). The proceedings of the public hearing are broadcast live and a recording of the hearing, the list of all speakers, including their affiliation and any declared interests, as well as a summary of the conclusions, is published on EMA website after the hearing.
11.	Are there any transfers of personal data to third countries or international organisations?	Not applicable. International data transfers do not take place (e.g. where personal data is shared with the EMA safety committee members, this is part of the EMA network). Moreover, all the members of the public hearings must be citizens of the EU Member States.
12.	General description of security measures, where possible.	The Agency has appropriate technical and organisational measures in place, including organisational policies, to safeguard the security of personal data and ensure the confidentiality, integrity and availability of the relevant systems, services and the personal data processed within them. In particular, the data of the participants joining a PRAC public hearing will be stored on the EMA server. They will be kept in a dedicated folder situated within DREAM web-top application, which is password protected and only available to EMA staff members, based on a business need-to-know and justified basis, i.e., business roles and responsibilities.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	Details concerning the processing of your personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement, where you may find the EMA General Privacy Statement as well as the privacy statements on specific data processing operations.