EMA/283093/2023

Record of data processing activity for the Experts Management Tool and the handling of competing interests (public)

1.	Last update of this record, version number:	25 November 2024, version 3
2.	Reference number:	H4
3.	Name and contact details of controller:	Controller: European Medicines Agency (EMA) Internally: Head of Human Medicines Division, EMA Contact: Datacontroller.HumanMedicines@ema.europa.eu
4.	Name and contact details of Data Protection Officer (DPO):	Contact: dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processor (where applicable)	**ServiceNow** Luchthaven Brussel-Nationaal 1K Zaventem, Brussels 1930, Belgium **Deloitte** Deloitte Consulting & Advisory BV Gateway Building, Luchthaven Brussel Nationaal 1 J, 1930 Zaventem, Belgium
7.	Purpose of the processing	To maintain and update a list of scientific committees' members and experts, Management Board members and EXPAMED members involved in EMA activities with their

		expertise, declaration of interests (DoI) and curriculum vitae (CV). To ensure the integrity of decision-making processes at the EMA, in particular by fulfilling the legal obligation to ensure that EMA is a transparent and open EU institution and that scientific committee members and experts, Management Board members and EXPAMED members involved in EMA activities have no financial or other interests in the pharmaceutical and/or medical device industry that could affect their impartiality. Both in line with Article 15(1) TFEU, Articles 26(1)(a), 62 (2) and 63 of Regulation (EC) 726/2004, Article 22 of Regulation (EC) 1394/2007, Article 32(3) of Regulation (EU) 2022/123, Article 107 of Regulation (EU) 2017/745, EMA's policy 0044 on handling of competing interests of scientific committees' members and experts, EMA's policy 0058 on the handling of competing interest of Management Board members, the European Commission's policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices and the EMA's Code of Conduct. Experts are nominated for involvement in EMA activities and included in the EMA Experts Management Tool. Management Board members and scientific committees' members and experts are listed with their DoI and CV on the EMA website for transparency. Those of the EXPAMED members are published by the European Commission (EC) on the EC website. DoIs are evaluated to determine if members and experts can participate in an EMA activity or not and if restrictions are applicable to their involvement. EMA processes the data in accordance with Article 5(1)(a) of Regulation (EU) 2018/1725, i.e. processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body.
8.	Description of categories of persons whose data EMA processes and list of data categories	In the Experts Management Tool, the EMA processes the following data on every scientific committee member and expert, Management Board member and EXPAMED member involved in an activity of the Agency in the context of: • EMA Management Board meetings and activities • the authorisation, supervision and maintenance of medicinal products for human and veterinary use, including meeting attendance, scientific assessment and

		guidance development, as well as participation in inspections • the consultation for specific categories of medical devices/in vitro medical devices by Notified Bodies • the assessment of the clinical evaluation and performance evaluation of medical devices and in vitro diagnostic medical devices **Contact details** [kept centrally, accessible to EMA staff and NCA contact points] • Name • Title • Gender • Nationality • Organisation/institution and professional address or private address • Business, mobile or private telephone number and email **Areas of Expertise** [kept centrally, accessible to EMA staff and NCA contact points] For scientific committees' members and experts: • Expertise in quality • Expertise in non-clinical • Expertise in clinical • Expertise in pharmacovigilance, epidemiological surveillance and risk management • Expertise in data science and analytics • Expertise in inspections • Expertise in official control of medicines • Expertise in patient/consumer/animal/healthcare professional representation • Expertise in regulatory affairs • Expertise in shortages • Expertise in medical devices • Expertise in digital health technologies For EXPAMED members: • Expertise in medical devices and in vitro medical devices

		Declaration of interest [kept centrally, accessible to EMA staff and NCA contact points and published on the EMA or EC website] <u>Direct interests</u> • employment in pharmaceutical and/or medical device companies • consultancy to pharmaceutical and/or medical device companies • strategic advisory role for pharmaceutical and/or medical device companies • financial interest in pharmaceutical and/or medical device companies • involvement of the expert in the repurposing of a medicinal product <u>Indirect interests</u> • principal investigator in pharmaceutical and/or medical device company instigated/sponsored clinical trials, clinical investigations or performance studies • investigator in pharmaceutical and/or medical device company instigated/sponsored clinical trials, clinical investigations or performance studies • involvement of the expert's organisation in the repurposing of a medicinal product • grants or funding from pharmaceutical and/or medical device companies to the organisation or institution to which the expert belongs • close family member (i.e. spouse or partner, children and parents) direct interests in pharmaceutical and/or medical device companies <u>For members and alternates of the Committee for Advanced Therapies</u> • direct and indirect interests in the biotechnology sector or medical device companies where the medical device is used or to be used in combined advanced therapy medicinal products <u>For Management Board members</u> • personal interests, other than interests in the pharmaceutical or the medical device industry <u>Other interests or facts</u> (optional)

		Interest level Calculated based on interests declared and time frame of the interests, value 'direct interests declared', 'indirect interests declared' or 'no interests declared' Date of DoI To calculate status: green (DoI less than 1 year old) or amber (DoI older than 1 year) [status only kept centrally, no amber status for EXPAMED members] *Note: Interests are defined in EMA's policy 0044 on handling of competing interests of scientific committees' members and experts, EMA's policy 0058 on handling of competing interests of Management Board members and EC's policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices.* **Curriculum vitae** [kept centrally, accessible to EMA staff and NCA contact points and published on the EMA or EC website] • Work experience • Training and education • Publications (optional) • Projects (optional) • Memberships (optional) • Additional information (optional) Note on patient representatives: Patient representatives are exempt from the mandatory completion of the CV. However, a patient representative may choose to indicate any experience he/she has with specific medicinal products, classes of medicinal products, medical devices, specific diseases, specific disease programmes or similar. This takes into account that a patient representative, is not necessarily a patient in the specified area of expertise. Therefore, stating his/her area of expertise does not imply the patient representative's disclosure of personal health information. Furthermore, as per the Experts Management Tool's instructions, patient representatives are reminded not to share any data concerning their health or other types of personal data not strictly needed in the CV, such as date of birth, telephone number, email address, or personal data of family members or colleagues. If they chose to do so anyways, they make their data manifestly public in accordance with Article 10(2)(e) of Regulation (EU) 2018/1725.

		Declaration of interest evaluation [kept centrally, accessible to EMA staff] • Activity in which the expert is involved • Outcome of the evaluation • Restrictions on individual medicinal products/medical devices and/or all medicinal products/medical devices from a pharmaceutical or medical device company **Membership management** [kept centrally, accessible to EMA staff] • Group to which the person is added • Role of the person in the group • Outcome of the DoI evaluation for the membership • Start and end date of the mandate in the group **Data collected when accessing the tool** [kept centrally]: • User information: – User name and email address as listed in the EMA Account Mangement – Unique User ID (UUID) – Browser information • Host and usage information: – IP address – User agent identifier – IP addresses along the network path – MAC address of your client (as applicable) – Geographic region – Audit log
9.	Time limit for keeping the data	Contact details, areas of expertise , DoIs and CVs of scientific committees' members and experts and Management Board members are kept for 15 years after the members or experts cease their activities with the EMA, i.e. following a request from the nominating authority or from the member or expert to de-register from the Experts Management Tool. The de-registration is also performed automatically if the member or expert has not updated their DoI in the last 3 years. Information on EXPAMED members is kept for 15 years following the end of their involvement in the panel or following

		a request from the member to de-register from the Experts Management Tool. The retention period is included in the EMA's business classification scheme. Only the current DoI, if less than 1 year old, and the current CV of scientific committees' members and experts and Management Board members are published on the EMA website. Scientific committees' members and experts with a DoI older than 1 year are removed from the website. Only the current DoI and CV of expert panel members is provided to the EC for publication on their website.
10.	Recipients of the data	EMA staff members involving scientific committees' members and experts, Management Board members and EXPAMED members have access to the Experts Management Tool upon request. They can read all contact details, areas of expertise, DoIs and CVs of all persons included in the tool. They can create and approve DoI evaluations and membership management. Data from the Experts Management Tool is accessible to the public on request. EMA Experts Management Tool administrators in H-Division, S-Division and the Management Board secretariat have write access to the Experts Management Tool to approve requests for new experts and for the de-registration of experts, to edit the list of NCA contact points and to create groups for membership. They can act on behalf of a member or expert to submit information on their behalf. EMA IT staff members have administrator rights to the Experts Management Tool. NCA contact points in the member states have write access to the Experts Management Tool for experts nominated by their authority to approve requests for a new expert. EMA Management Board members receive the DoI, CV and areas of expertise of new CHMP and CVMP members in the framework of the Management Board consultation on CHMP members as foreseen in Article 61 (1) of Regulation (EC) No 726/2004 and on CVMP members as foreseen in Article 140(1) of Regulation (EU) No 2019/6. DoIs, CVs and interest levels of scientific committees' members and experts and Management Board members are published on the EMA website for members and experts with a DoI less than 1 year old. The public may submit a request for information or an access to documents on information stored in the Experts Management Tool.

		DoIs and CVs of EXPAMED members are provided to the European Commission for publication on their website. In the framework of the collaboration between the European Commission and EMA, information on experts from the Experts Management Tool may be exchanged.
11.	Are there any transfers of personal data to third countries or international organisations?	Where for transparency purposes personal data contained in the EMA's Experts Management Tool is made public and is accessed from outside the EU/EEA, this is based on Article 50(1)(g) of Regulation (EU) 2018/1725.
12.	General description of security measures, where possible.	The Experts Management Tool is an electronic system with restricted access and secured by standard EMA security practices in line with EMA's Security policy 0076. The Experts Management Tool is not accessible to the public. Scientific committees' members and experts, Management Board members and EXPAMED members can only access the Experts Management Tool by using their personal and unique username and password (EMA account). They can only view/modify their own contact details, areas of expertise, DoI and CV. They can designate another person holding a personal and unique username and password (EMA account) to act on their behalf in the Tool for their own information. DoIs, CVs and interest levels of scientific committees' members and experts and Management Board members published on the EMA website are an extract from the Experts Management Tool including only members and experts with a DoI less than 1 year old. DoIs and CVs of EXPAMED members are provided to the European Commission for publication on their website.
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 personal data are available on the Agency's website at:www.ema.europa.eu/en/about-us/data-protection-privacy, where experts may find the relevant data protection notice for this processing activity.