25 November 2024
EMA/283094/2023 Rev. 2[1]

European Medicines Agency's Data Protection Notice

For the Experts Management Tool and the handling of competing interests

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the handling of competing interests of scientific committees' members and experts, EMA Management Board members and members of the Experts Panels on Medical Devices and in vitro diagnostic medical devices (hereinafter "EXPAMED") involved in EMA activities in accordance with Regulation (EC) No 726/2004[2], Regulation (EC) 1394/2007[3], Regulation (EU) 2022/123[4], Regulation (EU) 2017/745[5] and the Agency's Code of Conduct[6] as well as listing them with their expertise, declaration of interests (DoI) and curriculum vitae (CV) in EMA's Experts Management Tool. Further details are provided in EMA's policy 0044 on the handling of competing interests of scientific committees' members and experts[7], EMA's policy 0058 on the handling of competing interests of Management Board members[8] and 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[9].

[1] This revised version contains changes regarding the replacement of the Experts database by the Experts Management Tool, including now members of the EMA Management Board and members of the Expert Panels on Medical Devices and in vitro diagnostic medical devices and stemming from the revision of policy 0044 and policy 0058.
[2] 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
[3] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products
[4] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
[5] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
[6] EMA Code of conduct – EMA/385894/2012 Rev.1, https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf
[7] EMA Policy 0044 - EMA/136875/2022, https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en.pdf
[8] EMA Policy 0058 - EMA/MB/89374/2020 Rev 1, https://www.ema.europa.eu/en/documents/other/policy-58-european-medicines-agency-policy-handling-competing-interests-management-board-members_en.pdf
[9] Expamed document D 4.3, https://health.ec.europa.eu/system/files/2023-04/policy-mngt-conflicts_en.pdf

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. Who is responsible for processing your data?

1.1. Who is the data controller?

The Agency is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Human Medicines Division is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address: Datacontroller.HumanMedicines@ema.europa.eu

1.2. Who are the data processors?

The Agency engages third parties to process data on behalf of EMA to provide, maintain and where applicable improve the Experts Management Tool.

The contact details of the data processors are the following:

ServiceNow

Luchthaven Brussel-Nationaal 1K

Zaventem, Brussels 1930, Belgium

Deloitte

Deloitte Consulting & Advisory BV

Gateway Building, Luchthaven Brussel Nationaal 1 J, 1930 Zaventem, Belgium

2. Purpose of this data processing

The purpose of this data processing activity is the registration of **scientific committees' members and experts**, **Management Board members and EXPAMED members** in EMA's Experts Management Tool and the handling of competing interests when these members and experts are involved in EMA activities.

According to Regulation (EC) 726/2004, **scientific committees' members and experts and Management Board members** shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality.

This includes members (including, where relevant, alternates or observers) of the:

- EMA Management Board
- Committee for Medicinal Products for Human Use (CHMP)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Committee for Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Paediatric Committee (PDCO)
- Committee for Advanced Therapies (CAT)
- Pharmacovigilance Risk Assessment Committee (PRAC)

and experts involved in EMA's activities.

Involvement in EMA's activities means all activities carried out at the Agency in the context of the authorisation, supervision and maintenance of medicinal products for human and veterinary use. This includes meeting attendance, involvement in the scientific assessment and guidance development, as well as participation in inspections.

In addition, in accordance with Regulation (EC) 1394/2017, **CAT members and alternates** shall have no financial or other interests in the biotechnology sector and medical device sector that could affect their impartiality.

Scientific committees' members and experts and Management Board members should also have no interests in the medical device industry which could affect their impartiality when involved in activities regarding specific categories of medical devices and in vitro medical devices as foreseen in Regulations (EU) 2017/745 and (EU) 2017/746.

The same requirement on interests in the pharmaceutical and medical device industry applies to members and experts of the **Emergency Task Force (ETF)** and the **Executive Steering Groups on Shortages and Safety of Medicines (MSSG)** and on **Shortages of Medical Devices (MDSSG)** for activities on medical devices as foreseen in Regulation (EU) 2022/123.

Under Regulation (EU)2022/123, the Agency provides secretariat support to **expert panels on medical devices and in vitro diagnostic medical devices appointed by the European Commission.** According to Regulations (EU) 2017/745 and (EU) 2017/746, members of expert panels shall not have financial or other interests in the medical device industry which could affect their impartiality. The expert panels are designated for the assessment of the clinical evaluation and performance evaluation of medical devices and in vitro diagnostic medical devices, as well as for the provision of scientific, technical and/or clinical advice in relation to medical devices.

The Agency uses the personal information of **scientific committees' members and experts, Management Board members and EXPAMED** members to:

- Maintain and update a list of scientific committees' members and experts, Management Board members and EXPAMED members with their expertise, declaration of interests (DoI) and curriculum vitae (CV).
- Ensure that they have no interests in the pharmaceutical and/or medical device industry, and for CAT members and alternates no 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, which could affect their impartiality with regard to their involvement in relevant EMA activities.
  The DoI of scientific committees' members and experts, of Management Board member and of EXPAMED members include both direct and indirect interests in the abovementioned industry or sector. Management Board members also declare personal interests, other than interests in the pharmaceutical or the medical device industry in view of transparency.
  Prior to involvement in an activity, the DoI is evaluated to determine if a person can be involved in the activity or not, and if restrictions on the involvement apply in accordance with the relevant policy on handling of competing interests.
- Maintain the membership of groups in which persons are involved, e.g. committee, working party, scientific advisory group, management board, expert panel, ETF, MSSG, MDSSG, as well as record the outcome of the DoI evaluation for the involvement of the person in a group or in an EMA activity.

- Send communications to individuals or members of a group, e.g. individual reminders to the expert or an EMA staff member on an action in the Experts Management Tool itself or a message to all members of a group regarding an EMA activity.
- Check the correctness of the information contained in the DoI through a quality assurance system of ex ante and ex post control checks.
- For purpose of transparency, the Agency publishes the current and valid (i.e. if less than 1 year old) DoI of Management Board members, scientific committees' members and experts together with their CV on its website. The DoI and CV of the EXPAMED members are provided to the European Commission for publication on their website as per the European Commission privacy statement for processing of personal data related to expert selection procedures (link).
  All Management Board members, scientific committees' members, experts and EXPAMED members must be included in the Agency's Experts Management Tool prior to the first appointment resulting in involvement in activities at the level of the Agency (meeting attendance, scientific evaluation or assessment, inspections, guidance development, etc.).
  Current and previous DoIs and CVs of Management Board members, scientific committees' members and experts from the Experts Management Tool are accessible to the public, on request.
- Conduct a mandatory pre-screening of the declared interests prior to the acceptance of the appointment of Management Board and scientific committee members by the Nominating Authority, i.e. the Member States and the European Commission. Moreover, the possibility of pre-screening of any expert prior to involvement in the Agency's activities is offered to the Nominating Authority.

3. Personal Data concerned

In this processing operation the Agency processes data directly collected from you when you submit your contact details, areas of expertise, DoI and CV in the Experts Management Tool. Such data may include the following:

- Basic personal information, i.e., first name, family name, previous family name, title, gender, nationality, organisation/institution and professional address or private address, business, mobile or private telephone number and e-mail;
- Personal information about qualifications (CV), i.e. work experience, education and training, publications, projects, memberships, other relevant information;
- Personal information about areas of expertise, i.e.
  for scientific committees' members and experts: quality, non-clinical, clinical, pharmacovigilance, epidemiological surveillance and risk management, data science and analytics, inspections, official control of medicines, patient/consumer/animal/healthcare professional representation, regulatory affairs, shortages, medical devices, digital health technologies;
  for EXPAMED members: circulatory system, orthopaedics, traumatology, rehabilitation, rheumatology, neurology, general and plastic surgery and dentistry, obstetrics and gynaecology, gastroenterology and hepatology, respiratory and anaesthetic devices, intensive care, endocrinology and diabetes, nephrology and urology, ophthalmology, in vitro diagnostic medical devices (IVD).

  Note to patient representatives: When you register yourself as a patient representative, you are exempt from the mandatory completion of the CV. However, you may choose to indicate any experience you have with specific medicinal products, classes of medicinal products, medical devices, specific diseases, specific disease programmes or similar. It is acknowledged that as a

patient representative, you are not necessarily a patient yourself. Therefore, stating your expertise does not imply disclosure of personal health information. Please remember, as per the Experts Management Tool's instructions, not to share any data concerning your 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 your family members or your colleagues.

- Personal information about any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical and/or medical device company;
- Personal information about any consultancy activity providing advice (including training on a one-to-one basis or involvement in the repurposing of a medicinal product) to a pharmaceutical and/or medical device company regardless of contractual arrangements or any form of remuneration;
- Personal information about any strategic advisory role for a pharmaceutical and/or medical device company, i.e. participating (with a right to vote/influence the outputs) in a(n) (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of a pharmaceutical and/or a medical device company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration;
- Personal information about financial interests, i.e. any economic stake in a pharmaceutical and/or medical device company including:
  - Holding of stocks and shares, stock options, stock warrants, equities, bonds, ownership or partnership interest in the capital of such pharmaceutical and/or medical device company. The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the sector concerned) and they are independently managed (i.e. the individual has no influence on their financial management);
  - Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a pharmaceutical and/or medical device company in a personal capacity, other than payment for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation and travel costs);
  - Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product and/or a medical device owned by the individual or of which the individual is directly a beneficiary;
- Personal information about involvement of the individual or the individual's organisation in the repurposing of a medicinal product;
- Personal information about the undertaking of tasks relating to the position of principal investigator or investigator;
- Personal information about any grant or other funding received from a pharmaceutical and/or medical device company by an organisation/institution to which the individual belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the individual whether or not it is related to research work.
- Personal information about interests of first line members of the family (i.e. spouse or partner, children and parents), to the best of the knowledge of the individual, i.e. name of the pharmaceutical and/or medical device company of current employment, current consultancy, current strategic advisory role and/or current financial interests for the close family member. The

exact family relationship or the name of the family member do **not** have to specific and are not collected.

For **CAT members and alternates**, in addition, personal information about the above-mentioned activities in the biotechnology sector or medical device companies where the medical device is used or to be used in combined advanced therapy medicinal products are collected and processed.

For **Management Board members**, in addition, personal interests, other than interests in the pharmaceutical or the medical device industry are collected and processed, i.e. interests in other entities possibly providing services to the Agency and positions in a governing body of a professional organisation with an interest in the field of pharmaceuticals other than a pharmaceutical or medical device company.

The above personal data is collected directly from the individual it relates to.

Other personal data may be collected **as part of the DoI** submitted by the members of the Management Board, scientific committees and experts and expert panels.

As part of the processing operations in the Experts Management Tool, the following data may be collected when you access the tool:

- User information:
  - User name and email address as listed in the EMA Account Management
  - 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, i.e. documenting the activities performed within the Experts Management Tool

The Experts Management Tool also includes a list of Nominating Authorities (National Competent Authorities) who support the registration of new scientific committees' members and experts in the tool, with the name of the authority, the names of the contact persons at the authority and the names of the Head of Agency and their delegated authority.

4. Legal Basis for data processing

When you provide your data, EMA processes your data in accordance with this Data Protection Notice and 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.

The processing of personal data of **scientific committees' members and experts, Management Board members and EXPAMED members** to ensure their impartiality when involved in EMA activities is necessary for the performance of the Agency's tasks as provided for under:

- Articles 26(1)(a), 62 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

In this regard, please note that you have the **right to object** against the processing as explained in Section 8 below.

5. Transfer of personal data outside of EU/EEA

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, i.e. the transfer is made from a register which, according to Union law, is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down in Union law for consultation are fulfilled in the particular case.

6. How long do we keep your data?

The Agency holds the minimum amount of personal data that is necessary for the abovementioned purposes.

Information on the expertise, the **DoIs and CVs of scientific committees' members and experts and of Management Board members** are kept for 15 years after the member or expert ceases 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.

Upon completion of the retention period, the Agency will securely dispose of the personal data in accordance with the applicable legislation.

7. Who has access to your information and to whom is it disclosed?

A scientific committees' member and expert, Management Board member and EXPAMED member may designate another person to access on their behalf the Experts Management Tool to provide the relevant information. The designated person can only access the information of the designating person. Such access can be revoked at any time by the designating person.

The data collected will be processed internally by designated staff within the EMA Divisions, Task Forces and Advisory Functions responsible for the involvement of scientific committees' members and experts, Management Board members and EXPAMED members in EMA activities and the handling of competing interests.

Contact persons for the Experts Management Tool at the National Competent Authorities process the requests for registration of new scientific committees' members and experts for which they are the nominating authority for person, i.e. approving or rejecting the request in the tool. They can only

consult the data from the persons for which they are the nominating authority, i.e. contact details, areas of expertise, DoIs and CVs.

The latest DoI, i.e. if less than 1 year old, together with the latest CV, the interest level assigned to the DoI and the nominating authority of the person, of experts are published on the EMA corporate website (www.ema.europa.eu) whilst ensuring that personal data legislation is adhered to.

The name, professional address, DoI, i.e. if less than 1 year old, and CV of scientific committees' members and of Management Board members are published on dedicated webpages on the EMA corporate website (www.ema.europa.eu) whilst ensuring that personal data legislation is adhered to.

The names of chairs and members of other groups, e.g. working parties, may be published on dedicated webpages on the EMA corporate website (www.ema.europa.eu) whilst ensuring that personal data legislation is adhered to.

Minutes of Management Board and scientific committee meetings are published on the EMA corporate website for transparency (www.ema.europa.eu) and include the list of participants and information on restrictions applicable to the meeting following the assessment of the participants' DoI.

The Agency provides the DoIs and CVs of EXPAMED members to the European Commission for publication on the Commission's website (health.ec.europa.eu/medical-devices-panels_en) whilst ensuring that personal data legislation is adhered to.

The Agency may share the personal data included in the Experts Management Tool with:

- the Nominating Authority of scientific committees' members and experts, i.e. national competent authority in the Member State or the European Commission
- the Nominating Authority of EXPAMED members, i.e. the European Commission
- EMA Management Board 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.
- the public in case of a request for information, e.g. current and previous DoIs, current and previous CVs, or in case of a request for an access to documents
- the European Commission if requested in the framework of the collaboration between the European Commission and the Agency.

The Agency may also share the personal data included in the Experts Management Tool with other EU institutions and bodies, as well as with other third-parties, when the Agency is required to do so by law, including for monitoring, auditing or inspection purposes in accordance with European Union law. The Agency will not disclose personal information to third parties unless there is a lawful ground to do so.

8. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.

- **Right to rectification** – You have the right to obtain – without undue delay - the rectification or completion of your personal data if it is inaccurate or incomplete.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the EMA's information about Data protection and privacy, hosted at www.ema.europa.eu/en/about-us/data-protection-privacy.
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of EMA's information about Data protection and privacy: www.ema.europa.eu/en/about-us/data-protection-privacy.

9. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or that it is not carried out in compliance with this Data Protection Notice or EMA's information about Data protection and privacy, please contact the **Internal Controller** at Datacontroller.HumanMedicines@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en