



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 July 2021  
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## Privacy Statement regarding the Experts database and the handling of competing interests of scientific committees' members and experts

The European Medicines Agency (hereinafter "EMA" or "Agency") processes personal data in accordance with Regulation (EU) 2018/1725<sup>2</sup>. This Privacy Statement explains how the Agency collects and uses personal data of the members of the scientific committees and experts involved in EMA activities for the purpose of checking for competing interests in accordance with Regulation (EC) No 726/2004<sup>3</sup> and the Agency's Code of Conduct<sup>4</sup> and listing them with their expertise, declaration of interest (DoI) and curriculum vitae (CV) in EMA's experts database. Further details are provided in policy 0044 on the handling of competing interests of scientific committees' members and experts<sup>5</sup>.

This privacy statement does not relate to staff and experts at the level of the National Competent Authorities participating in the (evaluation) work (with respect to the authorisation, supervision and maintenance of medicinal products) at national level for services provided to the Agency.

### 1. Who is the data controller?

The Agency is ultimately responsible for complying with Regulation (EU) 2018/1725. Internally, the Head of Human Medicines Division has been appointed to act as Internal Controller.

Should you wish to get in touch with the Internal Controller, please contact [ExpertsDB@ema.europa.eu](mailto:ExpertsDB@ema.europa.eu).

### 2. Purpose of this data processing

According to Regulation (EC) No 726/2004, the members of the scientific committees and experts shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality.

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<sup>1</sup> This revised version contains changes regarding the entity appointed as Internal Controller and stemming from the revision of policy 0044.

<sup>2</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

<sup>3</sup> Regulation (EC) No 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

<sup>4</sup> EMA/385894/2012 Rev.1, [https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct\\_en.pdf](https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf)

<sup>5</sup> EMA/626261/2014, Rev. 1. [https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees\\_en.pdf](https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en.pdf)



This includes members (including, where relevant, alternates) of the following scientific committees:

- 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 activities at the level of the Agency.

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.

The Agency uses the personal information of the members of the scientific committees and experts to:

- Maintain and update the list of all scientific committees' members and experts involved in EMA activities with their expertise, declaration of interests (DoI) and curriculum vitae (CV);
- Ensure that they have no interests in the pharmaceutical industry, and for CAT members and alternates no interests in the biotechnology sector and medical device sector, which could affect their impartiality with regard to their involvement in EMA activities;
- Check the correctness of the information contained in the DoI through a quality assurance system of ex ante and ex post control checks;
- Enter in a register held by the Agency all indirect interests as per DoI (i.e. information regarding principal investigator, investigator, involvement of the expert's organisation in the repurposing of a medicinal product, grant or other funding to an organisation/institution and close family member interests) which could relate to the pharmaceutical industry and for CAT members and alternates to the biotechnology sector and medical device sector. The DoI of scientific committees' members and experts include both direct and indirect interests. For purpose of transparency, the Agency publishes the DoI of members and experts together with their CV on its website. All scientific committees' members and experts must be included in the Agency's experts database prior to the first appointment resulting in involvement in activities at the level of the Agency (meeting attendance, scientific evaluation, inspections, guidance development, etc.). Data from the experts database is accessible to the public, on request, at the Agency's offices.
- Conduct a mandatory pre-screening of the declared interests prior to any formal nomination 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. What personal data do we collect and how?**

#### ***3.1. Personal Data concerned***

The Agency collects and processes the following personal data:

- Basic personal information about the data subject, i.e., surname, first name, nationality, organisation/company and professional address, business telephone number, fax number and e-mail;
- Personal information about qualifications (CV), i.e. work experience, training and education, expertise, publications, projects, memberships;
- Personal information about expertise (nomination form), i.e. qualifications – degrees, diplomas and professional affiliations, present position and time spent in current assignment, general category of activities, specific functional expertise, language knowledge, expertise in quality, expertise in pre-clinical, expertise in clinical, expertise in target species, expertise in pharmacovigilance and risk management, expertise in control/inspections GMP/GLP/GCP, expertise in patient/consumer representation;
- Personal information about any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical company;
- Personal information about any consultancy activity where the concerned expert provides advice (including training on a one to one basis) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration;
- Personal information about any strategic advisory role for a pharmaceutical company, i.e. any activity where the expert is 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 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 company including:
  - Holding of stocks and shares, stock options, stock warrants, equities, bonds and or partnership interest in the capital of such pharmaceutical 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 pharmaceutical sector) 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 company to the expert 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 owned by the individual or of which the individual is directly a beneficiary;
- Personal information about involvement of the expert or the expert'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 company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

For CAT members and alternates, in addition, personal information about the above-mentioned activities in the biotechnology sector and medical device sector are collected and processed.

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

Personal information about the interests of the first-line members of the family of the expert (i.e. spouse or partner, children and parents) may also be collected, i.e. name of the pharmaceutical company of current employment, current consultancy, current strategic advisory role and/or current financial interests for the close family member, to the best of the knowledge of the expert.

Other personal data may be collected as part of the DoI submitted by the members of the scientific committees and experts. Please refer to the Regulation (EC) No 726/2004, the EMA's Code of Conduct and EMA's policy 0044 on handling of competing interests of scientific committees' members and experts for more information.

### **3.2. Legal Basis for data processing**

Processing the personal data of the members of the scientific committees and experts is necessary for the management and functioning of the Agency and for ensuring impartiality of the members and experts in the execution of their tasks. This processing of personal data is necessary for the performance of a task carried out in the public interest in line with the Agency's obligation for checking competing interests under Article 63 of Regulation (EC) No 726/2004.

### **3.3. Sharing of personal data**

The Agency may share the personal data included in the database with the following functions, divisions, and institutions:

- the Nominating Authority, i.e. national competent authority in the Member State or the European Commission.

The Agency may also share the personal data included in the database 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.

The Agency publishes the DoIs and CVs of all experts including the assigned interest levels on the corporate website ([www.ema.europa.eu](http://www.ema.europa.eu)) whilst ensuring that personal data legislation is adhered to.

## **4. 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 are kept for 15 years after the expert ceases their activities with the EMA, i.e. following a request from the Nominating Authority or from the expert to remove the information from the experts database; the entry is also removed if the expert has not updated his/her DoI in the last 3 years. Upon completion of the retention period, the Agency will securely dispose of the personal data in accordance with the applicable legislation.

## 5. Data Security

The Agency has put in place appropriate technical and organisational measures (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to your personal data.

The Agency takes all the necessary measures to ensure the maximum safety and security of personal data held both offline and online, in a hardcopy and digital form.

## 6. Your data protection rights

Under Regulation (EU) 2018/1725 data subjects (i.e. the individual whose personal data is processed) have the following rights:

- **Right to be informed** – This Privacy Statement explains how EMA collects and uses personal data with regard to the experts' involvement in EMA activities. If you have any questions about this data processing, please contact [ExpertsDB@ema.europa.eu](mailto:ExpertsDB@ema.europa.eu).
- **Right to access** – data subjects have the right to access their personal data, i.e. request and obtain a copy of the personal data processed by EMA.
- **Right to rectification** – data subjects have the right to obtain the rectification or completion of inaccurate or incomplete personal data.
- **Right to erasure** – data subjects have the right to request EMA to delete or stop processing their data, for example where the data is no longer necessary for the purposes of processing. In certain cases the 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 object** – data subjects have the right to object at any time to the processing of their data on grounds related to their particular situation.

These rights can be exercised in accordance with the provisions of Regulation (EC) 2018/1725. More detailed information concerning your rights is available in the EMA General Privacy Statement: [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).

## 7. 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 Privacy Statement or the EMA General Privacy Statement, please feel free to contact the **Internal Controller** or the **EMA Data Protection Officer**.

The contact details of the Internal Controller are the following: [ExpertsDB@ema.europa.eu](mailto:ExpertsDB@ema.europa.eu); for the postal address, please visit <https://www.ema.europa.eu/en/about-us/contact/how-find-us>.

The contact details of the Data Protection Officer are the following: [dataprotection@ema.europa.eu](mailto: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](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)