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European Medicines Agency
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European Medicines Agency's Data Protection Notice

For committees, Working Parties (WPs), Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)

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 committees, as well as Working Parties (WPs), Scientific Advisory Groups (SAGs) and Ad-hoc Expert Groups (AHEGs) established by these committees. This includes:

- The Management Board consultation of nominations to the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Veterinary Medicinal Products (CVMP);
- Processing of contact points for committees, WPs, SAGs and AHEGs for internal use;
- Personal data processed during the meetings of the scientific committees, WPs, SAGs and AHEGs.

For the purpose of this Data Protection Notice, committees shall include those specified under Article 56 of Regulation (EC) No 726/2004[1], namely:

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

In addition, this Data Protection Notice also includes:

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0726-20220128

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- the Coordination Group for Mutual Recognition and Decentralised Procedures - human (CMDh), as established in Article 27 of Directive 2001/83/EC[2]
- the Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products (CMDv), as established in Article 142 of Regulation (EU) 2019/6[3]

WPs, SAGs and AHEGs shall mean those groups established by the committees to advise them on issues relating to their fields of expertise, as provided for in Article 56(2) of Regulation (EC) No 726/2004.[4]

1. Who is responsible for processing your data?

1.1. Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of the Agency, the Head of Human Medicines Division and the Head of Veterinary Medicines Division are appointed as "internal controller" for their respective area and jointly for the groups that pertain to both.

You may contact the relevant internal controller via the following email addresses:

datacontroller.HumanMedicines@ema.europa.eu
datacontroller.veterinary@ema.europa.eu
For the Management Board consultation of nominations to the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Veterinary Medicinal Products (CVMP), the Head of Institutional and Policy is appointed as "internal controller".
You may contact the internal controller via the following email address:
MBSecretariat@ema.europa.eu

1.2. Who is the data processor?

The Agency may engage third parties to process data on behalf of the Agency and, in particular, to:

Processor	Purpose
Microsoft Ireland Operations Limited[5] One Microsoft Place, South County Business Park, Leopardstown, Dublin 18 D18 P521, Ireland	To provide an online teleconference platform to conduct the meetings (MS Teams). To exchange information and store contact lists to

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20250101
[3] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0006-20220128
[4] More information on Working Parties can be found here: https://www.ema.europa.eu/en/committees/working-parties-other-groups
[5] For more information on how EMA processes your personal data when using Microsoft 365, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-use-microsoft-applications-onedrive-outlook-365-teams-sharepoint_en.pdf

Processor	Purpose
Telephone: +353 (1) 706-3117	facilitate communication.
OpenText: 15 Zuidtoren, Hoofddorp, 2132LS, Netherlands Data protection officer: DPO@opentext.com	Document repository and storage of contact lists to facilitate communication.
Cisco Systems, Inc[6] Haarlerbergweg 13-19, 1101 CH Amsterdam, Netherlands privacy@cisco.com	To provide an online teleconferencing platform to conduct the meetings (Cisco Webex).
ServiceNow[7] Luchthaven Nationaal 1K Zaventem Brussels 1930 **Axianseu Digital Solutions S.A.** Edificio Atlantis, Av.Dom João II, 44C, Piso 5, 1990-095 Lisbon **Deloitte Consulting & Advisory BV** Gateway Building, Luchthaven Brussel Nationaal 1 J, 1930 Zaventem, Belgium	To provide a platform and manage service or incident requests (Help Desk).

2. Purpose of this data processing

The purpose of this data processing activity is the provision of the technical and organisational support for the conduct of committee, WP, SAG and AHEG tasks and meetings, which are core to the Agency's scientific work and play a vital role in the authorisation of medicines in the European Union. This includes:

- For CHMP and CVMP, the consultation of the Management Board on the proposed appointment of a member or an alternate.
- The provision of a list of contact points of members/alternates and additional experts of EMA committees, coordination groups, WPs, SAGs and AHEGs for internal use by the same committee, coordination group, WP, SAG or AHEG for the performance of the Agency's tasks, including secretariat tasks, as well as facilitating communication between

[6] For more information on how EMA processes personal data when using Cisco Webex, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-cisco-webex-meetings-webex-events-participants_en.pdf

[7] For more information on how EMA processes your personal data in the context of the Help Desk, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-ema-help-desk_en.pdf

committee/coordination group/WP/SAGs/AHEGs members/alternates/regular experts. This includes making the data available in the Managing Meeting Documents (MMD) system or Sharepoint, as applicable for the use by committee/coordination group/WP/SAG/AHEG members.

- For the conduct of meetings[8]:
    - handling invitations and participation; reporting on the meetings and meeting follow-ups, such as sharing presentations among participants and additional information.
    - to allow for online audio-video connection to the meeting.
    - when asking questions or making comments, participants can either use video and/or audio or send their questions using the chat/Q&A function.
    - Using voting system and handling voting records, proxy forms, proxy-related correspondence, divergent positions

2.1. Personal data concerned

In this processing operation the Agency may process your personal data, such as:

- For the consultation of the Management Board for CHMP and CVMP appointment of members and alternates:
    - Curriculum Vitae (CV) (Europass or Expert Management Tool format) which may include: first name, family name, previous family name, title, gender, nationality, organisation/institution and professional address or private address, contact details; information about qualifications and areas of expertise, i.e., work experience, education and training, publications, projects, memberships and other relevant information.[9]
    - Nomination letter from the nominating authority, which contains:
        - Name and last name of the individual nominated
        - Name and last name, job title, place of employment of the letter's signatory (normally the Head of NCA)
        - Name and last name, job title, place of employment of other individuals concerned in the nomination (e.g. minister of health of the concerned Member State)
    - Declaration of Interest (DoI) which includes name and last name, place of employment, country, any interests declared with relation to pharmaceutical

[8] For more information on how EMA processes your personal data in meetings and events, please see European Medicines Agency privacy statement for the organisation of meetings and events. Available here: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-organisation-meetings-events_en.pdf

[9] For more information on how EMA processes your personal data in the context of the Experts Management Tool and the handling of competing interests, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-regarding-experts-database-handling-competing-interests-scientific-committees-members-experts_en.pdf

companies, medical device companies, research organisations, and any other information declared.

- DoI evaluation form, which includes name and last name, group (e.g. CHMP) and role (e.g. member, alternate), interest level, country that the expert will represent, number of DoI evaluation, name and last name of DoI creator and approver, and DoI evaluation outcome.
- Areas of expertise which includes name and last name, group (e.g. CHMP), specific areas of expertise.

- For the purpose of maintaining a contact list of committee, coordination group, WP, SAG and AHEG members and regular experts:
  - First and last name;
  - Professional contact details:[10] address, telephone number and email address;
  - Area(s) of expertise;
  - Emergency 24 Hour Fax Number, if provided;
  - Emergency 24 Hour Telephone Number, if provided;
  - Mobile Number, if provided;
  - Personal Title, if provided;
  - Position Title, if provided.
- For the conduct of committee, coordination group, SAG, AHEG and WP meetings:
  - Host registration information, e.g. name, business email address.
  - User generated information, e.g. comments posted on the meeting chat, questions/answers submitted on a (i.e. Teams) Q&A
  - Information regarding participation in the meetings
  - Analytics data, e.g. IP address, user agent identifier, hardware type, operation system type and version, meeting session information, call attendee information (including email address, username, phone number), etc.
  - Comments reflecting a member's views on a topic if the participant expresses their wish for it to be reflected on the minutes.
  - Voting system and voting-related information:
    - Name and last name, business email address
    - Position taken in the voting (e.g., in favour/positive or against/negative)

[10] In limited cases (e.g. for patients), this might be a private address.

- Proxy form: name and last name, committee, affiliation, name and last name to whom the vote is given by proxy to.
- Divergent positions: name and last name included in the meeting minutes and/or the opinion of the committee, reasons on why their opinion diverges from the majority (as per Article 61(7) of Regulation (EC) No 726/2004, and 141(3) of Regulation (EU) 2019/6).

2.2. Legal basis of the processing

The processing of personal data is necessary for the performance of the Agency tasks carried out in the public interest as required by European Union legislation, as set out in Article 5(1)(a) of the EUDPR. In particular, the processing of data is necessary for the performance of tasks carried out in the public interest as provided for under:

- Article 55 of Regulation (EC) 726/2004[11] establishes the Agency as the body responsible for the coordination and implementation of the centralised procedure for the authorisation and supervision of medicinal products for human and veterinary use. To do this, Article 56 establishes that the Agency shall comprise the committees and a secretariat to provide technical, scientific and administrative support for the Committees, and ensure appropriate coordination between them.
- According to Article 27(1) of Directive 2001/83/EC[12], the Agency provides the secretariat of the CMDh.
- According to Article 139(7) of Regulation (EU) 2019/6[13] the Agency provides the secretariat of the Committee for Veterinary Medicinal Products (CVMP) for technical, scientific and administrative support and appropriate coordination between the CVMP and other committees of the Agency.
- According to Article 142(2) of Regulation (EU) 2019/6 the Agency provides the secretariat of the CMDv.
- Article 56(2) of Regulation (EC) 726/2004 and Article 139(3) of Regulation (EU) 2019/6 allow for the scientific committees to establish standing and temporary working parties and scientific advisory groups.
- Article 61 of Regulation (EC) 726/2004 and Article 140(1) of Regulation (EU) 2019/6 establishes that each Member State shall, after consultation of the Management Board, appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human/Veterinary Use

[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0726-20220128
[12] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20250101
[13] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0006-20220128

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

2.3. Transfer of personal data outside of EU

Experts from regulatory authorities and international organisations of third countries may participate in meetings for the purpose of international cooperation in the area of public and animal health and safety, efficacy, and quality of medicines. In this context, personal data may be transferred on the basis of a derogation, namely Article 50(1)(d), i.e., the transfer is necessary for important reasons of public interest.

3. How long do we keep your data?

- The personal data in the consultation package of information sent to the EMA Management Board is retained for a period of 15 years following the end of the mandate of the nominee. In the event that the person put forward is not nominated, the consultation package is retained for 6 months following the end of the consultation.
- For the contact lists, your data will remain active in the list as long as you are a member/alternate/expert of the scientific committees, coordination groups and/or a member/expert of the WPs, SAGs, AHEGs.
- For meetings, as applicable:
    - For the personal data processed by the teleconferencing platforms when participating in the meetings, please consult the dedicated DPN for Microsoft Teams and Cisco Webex.
    - Meeting minutes and the personal data contained therein are kept in accordance with EMA's retention policy.
    - For the personal data processed by the voting system used during the meetings, please consult the dedicated DPN for Microsoft Teams or for surveys conducted via EUSurvey.[14]

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

The data collected will be processed internally by staff within the EMA Division responsible for the committees, coordination groups, SAGs, AHEGs and WPs, as well as:

- For nominations of CHMP and CVMP, the Management Board Secretariat and all members and alternates of the Management Board. The name of the nominee is included in the published

[14] https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-conducting-surveys-eusurvey_en.pdf

minutes of the Management Board meeting subsequent to the conclusion of the Management Board written consultation procedure.

- Since members/alternates/experts will have to be included in the Agency's Experts Management Tool as part of the nomination process, both their CV and declaration of interest will already be publicly available through that tool. Once appointed as member/alternate, the name of the member/alternate concerned will be published as part of the full membership composition on the EMA website, except for AHEGs as it is an ad hoc meeting.
- The contact list will be visible to EMA Staff and appointed members/alternates and subject-matter experts as applicable who have been granted access to MMD/Sharepoint on a need-to-know basis.
- For meetings, information technology staff responsible for facilitating the online teleconferencing platform.

Under certain conditions outlined in law, personal data may be disclosed to third parties, (such as the European Anti-Fraud Office, the Court of Auditors, the European Ombudsman, the Court of Justice of the EU, the European Data Protection Supervisor) if necessary and proportionate for lawful, specific purposes in accordance with European Union law.

5. 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 your 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 incorrect 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.
- **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.

6. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful, or it is not in compliance with this Data Protection Notice or the general EMA Privacy Statement, please contact:

Internal Controller at datacontroller.HumanMedicines@ema.europa.eu and/or datacontroller.veterinary@ema.europa.eu and/or MBSecretariat@ema.europa.eu

EMA Data Protection Officer at dataprotection@ema.europa.eu.

Address	Postal Address	EMA Switch Board
European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands	European Medicines Agency PO Box 71010 1008 BA Amsterdam The Netherlands	+31 (0)88 781 6000

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