17 December 2024
Executive Director
EMA/33844/2022

Policy on publications by EMA staff and EMA scientific committee members on EMA's work

POLICY/0015
Status: Public
Effective date: 1 January 2025
Review date: 31 December 2027
Supersedes: EMA/299379/2019 (Policy 0015, rev 1) and supersedes and replaces Policy on scientific publication and representation for European Medicines Agency scientific committees and their members (Policy 0025, EMA/231477/2005 rev. 1)

1. Introduction and purpose

The European Medicines Agency (hereinafter referred to as the Agency or EMA) is committed to a high level of transparency and timely communication to the public. The Agency's scientific committees generally release information about their activities on the Agency's website in the form of committee minutes and press releases, European Public Assessment Reports (EPARs), guidelines and other related documents (e.g. public statements, reflection papers and questions-and-answers documents).

However, it is also of strategic interest to release information specifically targeting the scientific community, i.e. publication in scientific journals. The Agency encourages sharing the outcome of its scientific evaluations and regulatory work, its policies and its results from publicly funded research in reputable scientific articles and is committed to enabling publication of these works in open access journals. The strategic priorities outlined in the European Medicines Agency's network strategy[1] are particularly important to guide scientific publications on topics of strategic importance. Publication planning and prioritisation is regularly reviewed within the Agency to maximise impact.

It is acknowledged that the principal mode of dissemination of information within the academic world and among learned societies is by way of publication in (usually peer-reviewed) scientific journals or in other scientific communications (e.g. congress materials, monographs, textbooks). Aside from helping the Agency to achieve its goal of transparency and communication, such publications will help raise the visibility of the Agency and of the members of its scientific committees, working parties and other bodies in the scientific community, and contribute towards its international recognition and leadership

[1] European medicines agencies network strategy

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

role in the field of regulatory and medical sciences. Participation in editorial boards by scientific committee members and EMA staff is also encouraged.[2]

The Agency recognises the right to the freedom of expression of everyone in the European Union (EU), as set in the Charter of Fundamental Rights of the EU. EMA staff members, under Article 17a (1) of the Staff Regulations (SR), annex 1, have the right to freedom of expression, with due respect for the principles of loyalty and impartiality.

This policy sets out EMA's approach and requirements to ensure that publications on EMA's work by EMA staff as well as members of EMA scientific committees, their working parties, scientific advisory groups and other bodies maintain high standards of quality, rigour and consistency.

2. Scope

For EMA staff, this policy covers scientific, regulatory, legal and non-scientific publications related to EMA activities as well as EU matters.

For members, alternates and experts of scientific committees and other bodies, this policy covers only scientific publications related to EMA activities. Non-scientific communications, and scientific publications presenting work not related to the Agency are outside the scope of this policy.

The arrangements put in place to implement this policy may depend on the nature of the publication (scientific publication versus other publications). If such is the case, it will be highlighted.

Work related to an individual's previous or current employment and submitted under the sole affiliation of that employer are outside the scope of this policy. However, guidance with respect to authorship and affiliations in such situations can be found in section 4.2.

3. Definitions

For the purpose of this policy the following definitions apply:

- "Author" means any person whose name is presented on a publication byline in recognition of their contribution;
- "Lead author" means the publication author ensuring that an article adheres to the requirements laid down in this policy. This is usually an EMA staff member;
- "Members and experts of Scientific committees and other bodies" means members, alternates and experts of an EMA scientific committee or an EMA working party, scientific advisory group or other bodies (i.e. the Emergency Task Force, the Executive Steering Group on Shortages and Safety of Medicinal Products or the Executive Steering Group on Shortages and Safety of Medical Devices);
- "EMA staff", means EMA staff members (Temporary Agent, Contract Agent), Seconded National Expert and Trainee;
- "Collaborating expert" means an expert recruited by EMA under EMA policy 0083;
- "Interim" means an individual employed by an external provider that has a contract with the Agency following a procurement procedure for the provision of temporary workers. Interims are not staff members and may contribute to the activities of the Agency only on a temporary basis;

[2] EMA staff may undertake such work as part of their duties or as an external activity. Members of scientific committees, working parties or other bodies participating in such activities are considered to be carrying out the work as an individual. The activities shall in no way be binding on the Agency, committee, working party or other body.

- "Scientific Publications team" refers to the team within the Agency who are responsible for the oversight and review of scientific publications.

4. Policy statement

EMA aims to ensure that all publications on EMA's role, activities and remit, prepared by EMA staff, as well as by members and experts of EMA Scientific committees and other bodies:

- contribute to the timely dissemination to the scientific community of the work done by the Agency and EU Regulatory Network, in order to increase their scientific knowledge of medicines and related relevant Agency activities and priorities;
- are consistent with EMA's role and remit or, if not, that EMA is made aware in advance of the view(s) expressed by the author(s);
- are consistent with, or take due account of, EMA's official position or, if not, that EMA is made aware in advance of the view(s) expressed by the author(s);
- disclose potential conflicts of interest regarding the content of the publication;
- are of high quality;
- respect the need for confidentiality, protection of personal data and the EMA Code of Conduct[3];
- are not liable to prejudice seriously the legitimate interests of EMA or the EU;
- and, specific to EMA staff members, are in accordance with Article 17a of the Staff Regulations (see annex 1).

4.1. Advance notification (for EMA staff only)

Section 4.1 of this policy applies only to EMA staff as defined in section 3.

EMA staff need to provide advance notification of their intent to write a publication.

The amount of information to be provided will depend on which of two scenarios applies:

1) Publications within the scope of EMA's agreed priorities for scientific publications to be submitted to peer-reviewed journals.
2) Publications out of the scope of EMA's agreed priorities for scientific publication. This also includes scientific publications related to EMA activities to be submitted to non-peer reviewed journals, book chapters, social media, blogs, etc., and non-scientific publications.

Scenario 1: Publications within the scope of EMA's agreed priorities for scientific publication

EMA staff wishing to write a scientific publication should inform and seek the agreement of their line manager. Upon agreement of the line manager, such publications are treated as part of EMA staff duties and should be drafted during working time.

The lead author, shall notify the Scientific Publications team of their intent to write an article, using the template on EMA's scientific publications intranet page. This will ensure adequate planning and oversight across the Agency and confirm that the article is relevant for the Agency and in scope of the agreed priorities for scientific publication. It is also important to highlight to the Scientific Publications

[3] The European Medicines Agency code of conduct

team when the publication may express divergent views to the official position held by EMA on a given issue or in the exceptional case where co-authorship with industry is considered.

Scenario 2: Publications out of the scope of EMA's agreed priorities for scientific publication

For any publication not included in the agreed priorities for scientific publications, advance notification is also needed. To provide the advance notification, EMA staff, whether they intend to publish alone or with others, on any matter related to EMA activities or to any EU matter, shall inform their line manager and explain the rationale of and the drivers for the publication.

The line manager, after consultation with other EMA entities as necessary, shall inform the person intending to draft a publication of any relevant comments to consider when developing the work. The line manager shall also inform them whether work on the publication may be treated as part of EMA duties or should be done outside of official working time. This is a key decision as it impacts the establishment of copyright upon publication (see section 4.3.8).

Irrespective of whether the work is done as part of EMA duties or not, the lead author shall notify the Scientific Publications team of the decision to start work on the publication, using the template on EMA's scientific publications intranet page. This notification ensures adequate planning and oversight across the Agency. It is also important to highlight to the Scientific Publications team when the publication may express divergent views to the official position held by EMA on a given issue or in the exceptional case where co-authorship with industry is envisioned.

4.2. Authorship and affiliations

Any individual who has contributed to the development of a scientific publication should be able to be an author on that publication, irrespective of whether they are EMA staff, members or experts of Scientific committees and other bodies, collaborating experts or interim workers. Anyone included as an author should meet the criteria laid down in the current version of the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals", published by the International Committee of Medical Journal Editors[4].

Personal or institutional competing interests of authors or collaborating institutions need to be identified (by the lead author) and evaluated by EMA peer reviewers.

The lead author shall ensure that, in the interest of transparency, all authors disclose their affiliation. All authors should list not only their main employer (e.g. public private partnership, National Competent Authority or university), but also their affiliation with an EMA Scientific Committee or other body, if applicable.

The affiliation to EMA or one of its scientific committees should not be used when:

- the work presented is not related to EMA activities or experience. If an author chooses to present the EMA affiliation in such cases, the work submitted shall comply fully with the requirements and processes laid down in this policy;
- the work presents the outcome of work done by or for a commercial/industry entity when the author was employed there. Such work must never be authored under an EMA affiliation, and any conflict of interest must be declared appropriately;
- the author is affiliated with a commercial/industry entity at the time of publication. Where former EMA staff, members or experts of Scientific committees and other bodies, collaborating experts or interims present work that includes EMA data, the publication shall state that these were obtained

[4] http://www.icmje.org/recommendations/

when the author was employed or otherwise affiliated with the Agency. In these cases, the lead shall inform the Scientific Publications team of the publication for their awareness and guidance on how to best proceed.

When EMA staff are the corresponding author and a postal address will be presented as part of the author's affiliation, the full name and acronym of the Agency and its official address should appear in the final publication.

Affiliation aspects in case of industry co-authorship

EMA publications do not usually include industry-affiliated authors, in particular when only a single company is represented on the author byline, other than for specifically agreed exceptions. Industry authorship for publications can be accepted for initiatives prepared jointly within multi-stakeholder groups that include industry stakeholders, subject to justification (e.g. for articles without a commercial purpose which are not promoting products, or articles discussing implementation of new initiatives/legislation for which the industry's perspective is relevant). Where applicable, industry authorship on behalf of a trade association will be stated. In such cases, the Scientific publication team should be informed by the lead author.

Collaborating experts and interims

Authors of an EMA publication who fall within the category of "collaborating experts or interim shall be asked to confirm in writing (following a template agreement), at the outset of the writing process, that they will comply with all aspects laid out in this policy, including the internal review process and the copyright regime.

4.3. Process for EMA peer review of scientific publications (for EMA staff and scientific committee members)

The peer-review process must be followed by EMA staff and members and experts of EMA scientific committee and other bodies within the scope set out in section 2.

The peer-review process is coordinated by the Agency's Scientific Publications team. In accordance with this policy, they have the following responsibilities and tasks for scientific and other publications:

- Maintain a tracking table of publications submitted for review;
- Co-ordinate the EMA peer-review process, including:
  - Nominating reviewers, including replacements when a reviewer notifies the Scientific Publications team they cannot review (due to, e.g. a conflict of interest or scheduling conflict). The nomination may consider reviewers with the appropriate expertise proposed by the lead author, provided the person has not contributed to the drafting of the publication;
  - Ensuring that the reviewers are aware of their tasks;
  - Arranging a review, as needed, by the Legal Department or the Institutional and Policy Department;
  - Informing the lead author of the names of the reviewers;
  - Informing EMA's Press Office of the publication submitted for review;
  - Ensuring that the timelines for review and other steps as set out in this policy are adhered to.

4.3.1. Submission of a publication for EMA peer review

Prior to submission to the journal/editor/book editor/publisher, all publications by EMA staff and by members and experts of EMA scientific committees and other bodies, which relate to work done by EMA or the EU, or present the Agency as the affiliation of at least one of the authors, should be reviewed by nominated EMA peer reviewers who will need to clear the publication for submission to the journal. The submission of the publication for review fulfils an EMA staff member's obligation under Article 17a (2) of the Staff Regulations (See Annex 1).

The lead author should send the publication to EMA's Scientific Publication team. The publication should be a clean, final version of the manuscript, without comments or track changes, and should include all tables, figures and other material that will be submitted for publication, as well as the disclaimer (see section 4.3.7). If applicable, a justification should be included for industry authorship (e.g. a publication prepared jointly with other multi-stakeholder groups including industry stakeholders (see section 4.2 above)).

The lead author may suggest peer reviewers for consideration, as long they have not been involved in the drafting of the publication.

Submission for EMA peer review should be made a minimum of 30 working days in advance of the planned submission date to the journal/editor/book editor/publisher. The EMA peer-review process may take up to 15 working days. The timelines of the review process take account of the 30 working days provided for in the Staff Regulations to enable EMA to comment on a proposed publication on any EMA or EU matter.

The lead author is notified by the Scientific Publications team, within 30 working days, of the receipt of the publication and of the review outcome (including any potential escalation to EMA's Chief Medical Officer). If no decision is notified within the specified period, the Agency is deemed to have no objections.

4.3.2. Nomination of reviewers

Within 2 working days of the receipt of a publication, the Scientific Publications team nominates at least one reviewer and may nominate up to two further reviewers in the event that specific expertise is required. An individual whose name appears as an author on the article cannot be nominated as a reviewer. Where applicable, due consideration is given to the peer reviewers suggested by the lead author.

- A reviewer shall be a member of EMA staff or an external EMA expert with relevant expertise on the subject matter.
- It is the responsibility of any reviewer who has a conflict of interest in relation to a publication to notify promptly the Scientific Publications team. The EMA independence policies apply in relation to conflicts of interest.[5] A reviewer who lacks availability or expertise should also notify the Scientific Publications team. In that event, the Scientific Publications team will identify and nominate a replacement reviewer.
- To take account of issues of a legal nature or any legal impact for EMA or in cases requiring a legal clarification, the Scientific Publications team will forward the draft publication to the Head of the Legal Department, who may appoint a member of the Legal Department for an opinion.

[5] Handling competing interests | European Medicines Agency (europa.eu)

- If the publication raises issues of a policy or institutional nature, or if the publication might impact policy for the Agency or require a policy clarification, the Scientific Publications team will forward the publication for an opinion to the Head of the Institutional and Policy Department.
- Where the article concerns any other EU matter and does not specifically relate to EMA, an ad-hoc consultation is arranged with a reviewer who has knowledge of the subject matter.

The names of the reviewers will be made known to the lead author.

4.3.3. Tasks of the peer reviewers

The peer reviewers shall consider and comment on (in the following order of priority):

- consistency with the EMA procedure, practice and/or policy;
- consistency with the EMA position;
- legitimacy of divergence from the EMA official position;
- the (scientific) quality of the publication;
- the affiliations of authors, flagging any issue that might indicate a reputational concern, conflict of interest or other matter of concern;
- potential legal or other risks to EMA associated with the publication;
- confidential information or personal data, ensuring that no such information is disclosed unintendedly;

Within 15 working days following their nomination, the peer reviewers shall send comments to the lead-author and to the Scientific Publications team. Each reviewer shall declare, in writing, whether they have:

- no objections to or comments on the publication;
- minor comments (it is the author(s)'s decision to address these comments);
- major comments or objections: these will have to be addressed by the author(s) to the satisfaction of the reviewer(s). It is expected that most major comments or objections can be resolved through communication between the author(s) and the reviewer(s);
- state the nature of escalation required where there is an absence of consistency with the EMA position/policy or if a precedent is established.

If the reviewers' written comments do not include any major comments, the article can be submitted to the journal/editor/book editor/publisher.

4.3.4. Arbitration

If a major objection or, following escalation, absence of consistency cannot be resolved, the reviewer shall inform the Scientific Publications team within a further 5 working days. If, after revision of the publication by the authors, the Scientific Publications team considers that content is still liable to prejudice seriously the legitimate interests of the Agency or the EU, the Scientific Publications team, within 2 working days, will send the publication to the Executive Director or to the Chief Medical Officer (CMO), as delegated in this section, for a final decision within a further 6 working days. This decision is notified by the Scientific Publications team to the lead-author. The lead author is asked to take account

of the decision. Where the issue could seriously undermine the interests of the Agency or the EU, the lead author shall ensure further revision of the publication.

The CMO is delegated by the Executive Director to take decisions within 6 working days of notification on cases that are escalated and shall:

- Co-ordinate discussion by reviewers and author(s);
- Facilitate resolution in the event of major comments from reviewers;
- If unresolved, escalate to relevant internal EMA fora, and, where necessary;
- Escalate to the Executive Director, setting out the issue and demonstrating that the matter is liable to prejudice seriously the legitimate interests of the Agency or the EU.

In the event that the CMO is an author of a publication, arbitration of the case is handled by the Executive Director.

The total period for review, any escalation process and a final decision is 30 working days from the submission of the publication for EMA peer review, respecting the provisions of Article 17a(2) of the Staff Regulations as regards EMA staff members.

4.3.5. Language editing

In order to ensure linguistic quality of EMA publications and increase the chances of acceptance of the publication by the editors, scientific publications should be read and edited by an EMA medical writer, if available. The need for language editing shall be assessed by the reviewers in consultation with the lead author.

4.3.6. Prior notification to EMA partners and stakeholders

The Scientific Publications team, in liaison with relevant EMA organisational entities, shall determine whether prior notification of an upcoming publication is needed to inform the European Commission (EC) and/or other stakeholders, e.g. (Co-)Rapporteurs or one or more pharmaceutical companies, in case the subject matter pertains to a particular medicinal product.

4.3.7. Disclaimer

All manuscripts that present an EMA affiliation shall be submitted with the following disclaimer:

For articles authored only by EMA staff or members and experts of Scientific committees and other bodies:

"The views expressed in this article are the personal views of the author(s) and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or other bodies."

For articles co-authored by individuals other than EMA staff or members and experts of Scientific committees and other bodies (e.g. academics, members of learned societies, members of other regulatory agencies):

"The views expressed in this article are the personal views of the authors and may not be understood or quoted as being made on behalf of or reflecting the position of the regulatory agency/agencies or organisations with which the authors are employed/affiliated."

4.3.8. Transfer of copyright

EMA staff members

Under Article 18(1) of the Staff Regulations, all rights in any writings or other work created by EMA staff in the performance of their duties shall be the property of the EMA. While the moral rights remain with the author, this provision transfers the economic rights to the Agency.

Most publishers request authors to transfer the copyright to them. However, for works created in the performance of their duties, EMA staff are not empowered to transfer the rights, and they should obtain prior EMA agreement with any transfer of rights. Where the article has been cleared for publication by EMA reviewers, copyright transfer is accepted and there is no need for further authorisation. In a case where transfer of copyright requires agreement by EMA, the lead-author shall send the request to the Scientific Publications team.

For works created by EMA staff outside the performance of their duties at the Agency, copyright remains with the author (even if the work relates to the activities of the EMA or the EU). In this case, copyright transfer is accepted and there is no need for further authorisation.

Members and experts of Scientific committees or other bodies

Most publishers request authors, the copyright owners, to transfer the copyright to them. Where the publication has been cleared by EMA reviewers, copyright transfer is accepted and there is no need for further authorisation.

Where transfer of copyright requires agreement by EMA, the lead author shall send the request to the Scientific Publication team in order to obtain prior EMA agreement of the transfer of rights.

EMA images (tables, infographic or similar) within an EMA publication

When copyright on a publication is transferred to the publisher, the copyright on any tables, infographics or similar images contained therein are also transferred by default. This means that EMA will no longer be able to use these materials, even when they have been created by the Agency, without acknowledging the publisher as the source. Consequently, tables, infographics or similar images prepared by EMA can only be included in the publication provided that the publisher confirms that EMA retains authorship for this type of content. Alternatively, other tables, infographics or similar images should be designed for the purpose of the publication only.

4.3.9. Record keeping

The Scientific Publication team keeps an overview of publications submitted for peer review and informs other internal EMA entities as needed.

Publications by EMA staff and members and experts of scientific committees or other bodies, when presenting EMA as their affiliation, are listed on the EMA website (see section 5).

4.4. Open Access

The Agency reimburses open-access publication fees in peer-reviewed journals, provided certain criteria are met. Open-access funding in principle applies to publications that are within the scope of the agreed priorities for scientific publication and where EMA author(s) significantly contributed to the article.

This support is in line with the Executive Decision on supporting scientific publications by EMA[6]. The Agency has a limited budgetary provision and has established a process to identify publications eligible for open access funding.

Eligibility for open-access fee reimbursement is assessed after completion of EMA's peer review for the publication, and evaluates the article using pre-defined criteria. As part of the review outcome, the EMA staff author will be informed as to whether or not open-access funding is granted. This information allows the EMA staff author to indicate their intent to publish the article as open access early on, for example, at the time of first submitting the publication to the chosen peer-reviewed journal. Only current EMA staff can be reimbursed.

5. Related documents

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals, http://www.icmje.org/recommendations/

EMA website for publications authored by EMA staff and members and experts of scientific committees and other bodies, https://www.ema.europa.eu/en/news-and-events/publications/scientific-publications

Policy on representing the Agency at external events (Policy 0029)

6. Changes since last revision

The policy has been amended to take the experience gained into account. It has been revised to cover within the same policy publications from members and experts of EMA scientific committee and other bodies (previously in Policy 0025) and from EMA staff, and to reflect changes in the organisational structure of the Agency.

Amsterdam,

[Signature on file]

Emer Cooke
Executive Director

[6] Executive Decision on supporting scientific publications by EMA

Annex 1

Articles 17, 17a of the Staff Regulations

Article 17

1. An official shall refrain from any unauthorised disclosure of information received in the line of duty, unless that information has already been made public or is accessible to the public.

2. An official shall continue to be bound by this obligation after leaving the service.

Article 17a

1. An official has the right to freedom of expression, with due respect to the principles of loyalty and impartiality.

2. Without prejudice to Articles 12 and 17, an official who intends to publish or cause to be published, whether alone or with others, any matter dealing with the work of the Union shall inform the Appointing Authority in advance.

Where the Appointing Authority is able to demonstrate that the matter is liable seriously to prejudice the legitimate interests of the Union, the Appointing authority shall inform the official of its decision in writing within 30 working days of receipt of the information. If no such decision is notified within the specified period, the Appointing authority shall be deemed to have had no objections