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Policy on scientific publication and representation

For European Medicines Agency's scientific committees and their members

Introduction

In the past, several external communication activities from the CXMP[1] as a whole or by the members as individuals have been recorded (reactive publications to articles, publication of CXMP guidelines, participation in conferences etc.). The approach followed was similar in every case, and it served to prepare the first version of this policy in 2006. Since, the Agency has looked more at how to develop effective communication tools and to actively communicate with healthcare professionals' organisations, learned societies and academia. The Agency has become, as consequence, progressively more proactive in this field and has promoted the publication and dissemination of its scientific outcome. In light of this fact, the section on scientific publication has undergone an extensive revision.

Scope

The policy addresses members of the European Medicines Agency's scientific committees, as well as of its working parties and scientific advisory groups whenever they participate in any communication activity with a third party. This includes:

- scientific publication;
- participation in conferences, congresses, lectures, etc;
- membership of professional bodies or organisations;
- editors in scientific journals;
- other external activities.

In every case, any action in this field will abide by the principles set out in the Agency's Code of Conduct, with particular attention to conflicts of interest, confidentiality and discretion. Attention should also be paid to CXMP rules of procedure and correspondent CXMP working party (WP)/scientific advisory groups (SAG) rules of procedure, when applicable.

[1] CXMP refers to the CHMP (Committee for Human Medicinal Products), CVMP (Committee for Veterinary Medicinal Products), COMP (Committee for Orphan Medicines), HMPC (Herbal Medicinal Products Committee), PDCO (Paediatric Committee) and CAT (Committee for Advanced Therapies).

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Definitions

Acronym	Definition
BMJ	British Medical Journal
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
COMP	Committee for Orphan Medicinal Products
CVMP	Committee for Medicinal Products for Veterinary Use
CoI	Conflict of Interests
CXMP	Combined scientific committees: CAT, CHMP, CVMP, COMP, HMPC, PDCO
EMA	European Medicines Agency
EPAR	European Public Assessment Report
HMPC	Committee on Herbal Medicinal Products
PDCO	Paediatric Committee
RAJ	Regulatory Affairs Journal
SAG	Scientific Advisory Group
WP	Working Party

Scientific publication by members of European Medicines Agency's scientific committees, its working parties and its scientific advisory groups

The European Medicines Agency is committed to a high level of transparency, openness and communication to its stakeholders. This priority of the Agency is emphasised in the EMA Road Map [The European Medicines Agency Road Map to 2015: The Agency contribution to Science, Medicines, Health] which looks at the Agency as an authoritative source of information.

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 other scientific publications (e.g. monographs, textbooks, etc.).

The Agency therefore encourages the publication of papers related to its scientific activities in scientific journals or 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 committees (CXMP), working parties (WPs) and scientific advisory groups (SAGs) in the scientific community and contribute towards its international recognition and leadership role in the field of regulatory and medical sciences.

However, the Agency needs to ensure that all papers relating to its activities and/or appearing with its name as 'affiliation' (i.e. corporate address) will be:

- of high scientific quality;
- consistent with the Agency's role;
- consistent with other expressions of the Agency's position on the subject matter;
- legally compliant;
- compliant with the principles set out in the Agency's Code of Conduct, with particular attention to conflicts of interest;

- compliant with confidentiality rules as laid down in access to document policies;
- consistent with the requirements of the Agency's Staff Regulations, if the Agency's staff member/s is/are co-author/s of the paper.

Current legislation (Regulation (EC) No 726 2004, art 55) describes the European Medicines Agency as comprising scientific committees (CXMP), the secretariat, the Executive Director and the Management Board. Standing and temporary working parties, as well as scientific advisory groups, are also mentioned as being part of the European Medicines Agency. By implication, all members of the Agency's scientific committees, working parties or scientific advisory groups, are integral parts of the Agency and share the privilege as well as the responsibility to support the Agency's publication effort. It also implies that, in principle, all CXMP-, WP- and SAG-members, are entitled to cite their Agency's affiliation and corporate address.

1. *Scope*

The scope of this section is to describe the steps to be taken in the event that:

(a) one or more members of a CXMP, WP, SAG wish to submit as (co-)authors a scientific publication concerning EMA/CXMP-relevant issues to a peer-reviewed scientific journal (such as BMJ, Lancet, etc, but also including regulatory periodicals e.g. RAJ) or to contribute to a scientific textbook;

(b) a scientific publication is deemed useful to explain, defend, or announce some regulatory action or opinion by CXMP.

Non-scientific communications, e.g. general information on the role of the Agency addressed to the public, are outside the scope of this policy, as are scientific publications describing work not related to the Agency and not appearing with the Agency's institutional or correspondence address (e.g. related to a CXMP-, WP or SAG member's previous or current employment, such as work done at a university and appearing under the name of that university).

2. *Policy statement in relation to publication activities*

2.1. Types of publication

The Agency's scientific committees generally release information about their activities on the website: the CXMP monthly report and press release, EPARs, CXMP guidelines and other related documents (e.g. public statements, reflection papers, and questions and answers documents), etc.

However, in some cases it may be useful to release information by different means, i.e. publication in scientific journal.

Publication shall be guided by a general principle of protection and promotion of public or animal health together with the provision of accurate and validated information to healthcare professionals.

At least two situations can be foreseen where publications may be useful:

a) Proactive publication

Proactive publication by CXMP, WP, SAG members is encouraged. This can consist of original articles or of reproduction for publication in scientific journals of (annotated) CXMP public documents (e.g. guidelines). The latter is regarded as an optimal way to maximise dissemination of CXMP information.

b) Reactive publications

Reactive publications should only be considered under exceptional circumstances, to clarify or rectify factually wrong statements in an article criticising an opinion or action by CXMP. In general, the Agency and its committees should avoid being drawn into debates of its opinions or actions (e.g. direct replies to CXMP-critical statements in a scientific journal).

Situations when a reaction/reply to external publications is called for may include the following:

- The publication challenges and affects general CXMP policy (e.g. CXMP rules of procedure, implementation of new legislation).
- The publication, which is related to a CXMP activity, could raise public concern. A need for clarification is deemed a matter of public interest, and necessary to avoid misinformation to the public (e.g. publication of the article "Placebo-controlled trials and the declaration of Helsinki", in The Lancet. Prof. JA Lewis et al, 2002).
- There is a sufficient level of challenge to CXMP's views on a specific issue (e.g. letter of response by Dr. Simon Day on article published on "Applied Clinical Trials" challenging CXMP's position discouraging dynamic allocation techniques).

In general, no reply to product related issues would be considered, as the EPAR is published.

The CXMP shall ensure consistency in any decision on whether a reply should be prepared and by whom. The source of the publications will always be taken into account. It is anticipated that publications in well-known and highly reputed scientific journals would create more impact and public concern, and therefore will be considered as priorities when replying to challenging articles.

2.2. Authorship

An article may be authored by one or more individuals (a) on their own behalf, or (b) "on behalf of the CXMP".

a) Authors writing on their own behalf

If CXMP, WP, SAG members write an article on their own behalf, they must state in the article that the views expressed in the article are their own and do not represent CXMP, WP, or SAG views. The following disclaimer shall be added:

"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 working parties."

In case of doubt, the Agency's legal sector shall provide guidance on whether or not the disclaimer should be added.

Authors are reminded that all requirements listed in Section 1 (Introduction and Purpose) would still have to be met, even in the presence of the disclaimer.

All articles authored on behalf of individuals shall be submitted to the full peer review process described below. This applies when the articles are related to their work at the Agency and does not apply for publications describing work not related to the Agency such as work done at a university.

b) Authors writing "on behalf of the CXMP"

Issues of general CXMP policy and CXMP opinions which are likely to raise public interest or concern may be written and authored by the CXMP Chair or CXMP member(s) "on behalf of the CXMP". In such cases:

- The proposed topic for publication will be included in the CXMP pre-mail and the topic will be added to the meeting agenda.
- Based on the criteria laid down in this policy, the CXMP will decide whether a manuscript should be prepared and who will write the draft and author it (CXMP Chair and/or individual member and/or drafting group).
- A draft reply will be presented during the following CXMP meeting for adoption.
- If faster action (e.g. response to a critical article) is needed, a written procedure can be followed.
- A disclaimer is NOT required.
- Requirement for peer review procedure (see below): this will be limited to review by one member of the Agency's legal sector.

Not withstanding the above considerations (authorship on behalf of authors as individuals or "on behalf of the committee"), the decision on who's name should or should not appear as a co-author of the publication shall be in line with the principles laid down in the current version of the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication", published by the International Committee of Medical Journal Editors (a copy of this document is available from http://www.icmje.org/ethical_1author.html).

2.3. Submission to the Agency's Publication Review Group

Prior to submission for publication in the journal editor/book editor/publisher all manuscripts should be internally reviewed by the EMA Publication Review Group. In the case of authors writing on behalf of the scientific committee the review will be limited to one member of the Agency's legal sector. However, should the committee wish it may make use also of the Publication Review Group.

The Publication Review Group will be composed ad-hoc by at least three individuals (reviewers). It is expected that the Review Group will include:

- one member of the Agency's legal sector; **plus at least two** individuals from the following list:
- a statistician (where applicable);
- other (non-author) member(s) of the CXMP/WP/SAG;
- Agency's scientific staff;
- other expert(s) from the Agency with relevant scientific competence;
- the Agency's Press Officer;
- the Senior Medical Officer of the Agency;

An individual whose name appears as a co-author on the article cannot be nominated as reviewer.

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

- the scientific quality of the manuscript;

- potential legal or other risk to the Agency associated with publication of the manuscript;
- consistency with other expressions of the Agency's (including its committees and working parties) position on the subject matter;
- compliance with confidentiality rules in force at the Agency.

The names of the members of the ad-hoc publication review group will be made known to the Agency's leading author.

All manuscripts (final version, including tables, figures and other material intended for publication) should be sent by the leading author to the Senior Medical Officer, who will nominate the ad-hoc reviewers and distribute the manuscripts to them. Comments from the reviewers shall be returned to the leading author and to the Senior Medical Officer within 15 working days. If one or more co-authors of the article is/are staff member(s) of the Agency, the Publications Review Group's decision will cover the requirements of Article 17a on behalf of the Executive Director under the Staff Regulations and will explicitly refer to Art 17a (http://intracomm.cec.eu-admin.net/statut/_en/tit12.htm).

Each member of the Publication Review Group shall declare whether they have:

- no objections to or comments on the manuscript, or
- minor comments (it is the authors' decision if they wish to address them), or
- 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 reviewers. In the event that no agreement can be reached, and where the Publications Review Group considers that the article is liable to seriously prejudice the legitimate interests of the Agency, the Publication Review Group shall inform the Executive Director who shall take a decision on publication.

2.4. Language editing

In order to ensure appropriate linguistic presentation of the Agency's publications, and to increase the chances of acceptance for publication of the manuscript by the journal editor, scientific publications should be read and edited by a trained language editor, if available. The need for language editing shall be assessed by the author in consultation with the Publication Review Group.

2.5. Confidentiality

Care must be taken not to include confidential information in any publication. The peer reviewer from the Agency's legal sector shall be provide guidance on issues related to confidentiality.

2.6. Prior notification to Pharmaceutical Industry

In some instances, it may be appropriate to inform one or more pharmaceutical companies of the intent to publish an article, e.g. in the event that the article pertains to a particular drug product. The decision if, and when companies should be informed shall be taken by the author in consultation with the Publication Review Group.

2.7. Author affiliation, address for correspondence

The author affiliation/address for correspondence of all the Agency's (co-)authors should appear in the final publication as follows:

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United Kingdom

2.8. Transfer of European Medicines Agency copyright licensing policy

The Agency allows “public” documents to be reproduced and/or distributed, totally or in part, irrespective of the means and/or the formats used, for non-commercial and commercial purposes, provided that the Agency is always acknowledged as the source of the material. (See Annex 1 for more details on the Agency’s copyright licensing policy).

Most publishers request authors to transfer copyright to them. The Agency would normally authorise affiliated (co-)authors to transfer copyright for manuscripts that have been cleared for publication by the Publication Review Group, but in some special cases copyright might become an issue. Therefore, the Agency’s Publication Review Group will decide on a case-by-case basis to what extent the Agency’s affiliated (co-)authors will be authorised to transfer copyright for Agency manuscripts.

2.9. Record keeping

It is the leading author’s responsibility to send one electronic or paper copy for central record keeping to the EMA Library, and one electronic or paper copy to the Medical Information Sector, after the manuscript has been published.

Participation in conferences of members of European Medicines Agency’s scientific committees, its working parties and its scientific advisory groups

CXMP/WP/SAG members/experts may participate in conferences and other forums, as part of their scientific activities. Two situations are envisaged:

1. The CXMP/WP/SAG member/expert participates as an individual expert at a conference related to his/her activities within the CXMP/WP/SAG, and does not formally represent the CXMP/WP/SAG. When deemed appropriate, he/she should declare so in the meeting, and the following disclaimer can be used in any material or presentation to be displayed:

   “I attend this conference as an individual expert, and do not represent the CXMP/WP/SAG. The views expressed here are my personal views, and may not be understood or quoted as being made on behalf of the CXMP/WP/SAG or reflecting the position of the CXMP/WP/SAG”.

2. More rarely, a CXMP/WP/SAG member/expert may participate at a conference and represent the Committee. The CXMP/WP/SAG member/expert, in this case, will be mandated only to express the views of the Committee and the following disclaimer should be used in any material or presentation to be displayed:

“I attend this conference to represent the CXMP. The views expressed here are the current views of the CXMP, but in no way shall be binding for the CXMP."

In this case, the following particulars will apply:

- Information on the conference, as well as the request for participation of a CXMP representative will be circulated to the CXMP/ORGAM/WP/SAG.
- The CXMP/WP/SAG will nominate a member or an expert who will attend and represent the Committee.
- The CXMP/WP/SAG representative will ensure that the views expressed at the conference are those of the Committee.
- Copy of the presentation, as well as his/her report from the conference should be made available to the Committee members upon request.
- A conference report will be circulated to the CXMP/WP/SAG.
- Depending on the impact of a conference, the CXMP/WP/SAG may request a member/expert to attend the conference, and to report back to the following CXMP/WP/SAG meeting.
- Prior to any decision on CXMP participation, the Agency's secretariat will check the nature and the funding of the conference, and will decide whether or not it is appropriate to participate. The decision will always be made on the basis of the Agency's Code of Conduct: only conferences organised by non-profit organisations will be considered; invitations for conferences organised by individual pharmaceutical companies will not be accepted.
- In any case, and whatever the type of the participation, any CXMP/WP/SAG member/expert will abide by the principles set out in the Agency's Code of Conduct. Special attention must be paid to avoid disclosure of any information of confidential nature.

Membership of members of European Medicines Agency's scientific committees, its working parties and its scientific advisory groups of professional bodies, editors in scientific journals and other external activities

CXMP/WP/SAG members/experts may become members of professional bodies (e.g. Learned Societies), as part of their scientific activities, and in the context of their own professional development. The CXMP/WP/SAG member/expert will clearly state that this membership is extended to him/her only as an individual, and in no way he/she can act as a member on behalf of the CXMP/WP/SAG. It does not include representation in an institutional context (e.g. European Commission, European Directorate for the Quality of Medicines –EDQM).

If the CXMP/WP/SAG member/expert were to actively participate by any means in the professional body (i.e. give a presentation) the disclaimer as in the previous section would be used.

CXMP/WP/SAG members/experts may also become editors or peer reviewers for scientific journals. This activity is encouraged and is regarded as a positive contribution to the Committee in terms of scientific expertise and experience. This activity is extended to the CXMP/WP/SAG member/expert as an individual, and in no way shall be binding on the CXMP/WP/SAG.

CXMP/WP/SAG members/experts may also become members of ethics committees or of data on safety monitoring boards (DSMB). The CXMP/WP/SAG member/expert will clearly state that this membership is extended to him/her only as an individual, and in no way he/she can be a member on behalf of the CXMP/WP/SAG. This membership has to be declared to the Agency, so that any potential conflict of interest during an evaluation process can be anticipated.

ANNEX 1

European Medicines Agency's copyright licensing policy

According to current EU and International legislation[2], the European Medicines Agency has copyright and other intellectual property rights in the documents that it produces.

Documents categorised, as 'Public' are made available to the public and may be reproduced and/or distributed, totally or in part, irrespective of the means and/or the formats used, for non-commercial and commercial purposes, provided that the European Medicines Agency is always acknowledged as the source of the material. Such acknowledgement must be included in each copy of the material.

Citations may be made from such material without prior permission, provided the source is always acknowledged.

The European Medicines Agency is indemnified from and against all costs, proceedings, claims, expenses and liabilities whatsoever arising from any breach by any legal or natural person as a result of any representation or warranty providing to be a misrepresentation.

These permissions do not apply to content supplied by third parties. Therefore, for documents where copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

This policy is into force since 01 January 2008.

[2] Directive 2001/29/EC of the Parliament and of the Council of 22 May 2001 on the Harmonisation of certain aspects of copyright and related rights in the information society, Berne Convention for the Protection of Literary and Artistic Works as revised in 1971, WTO Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) signed on April 1994, WIPO Copyright Treaty of 1996.

Document History

Original policy:

Committee	Presented	Adopted
CHMP	October and November 2005	January 2006
COMP	November 2005	January 2006
CVMP	November 2005	January 2006
HMPC	November 2005	January 2006

Revised policy:

Committee	Presented	Adopted
CAT	May 2010	May 2010
CHMP	May 2010	May 2010
COMP	May 2010	May 2010
CVMP	May 2010	May 2010
HMPC	November 2010	December 2010
PDCO	May 2010	May 2010