



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 December 2013  
EMA/555647/2013  
Stakeholders and Communication

## Principles for publication of agendas and minutes of EMA scientific committees

### 1. Introduction and purpose

Provisions relating to transparency and in particular to the publication of proceedings of EMA scientific committees, listed in Annex I, are set out in a number of different legal texts applicable to the EMA and the Member States – specifically the following:

- Article 26 of Regulation (EC) No 726/2004 requires that the Agency shall make public the agendas and minutes of the CHMP, the PRAC and of the Co-ordination Group (CMDh) as regards pharmacovigilance activities.
- Article 80 of Regulation (EC) No 726/2004 requires that, in order to ensure an appropriate level of transparency, rules shall be adopted to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation and supervision of medicinal products which is not of a confidential nature.
- Article 126b of Directive 2001/83/EC states that Member States shall ensure that their competent authority makes publicly available its rules of procedure, and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes.
- Regulation (EC) No 1049/2001 sets out the rules for the granting of access to documents by the European Institutions.

In addition, the Heads of Medicines Agencies and the EMA published recommendations on transparency related to agendas/minutes on product related issues in 2008. The principles described in this document have taken into account such recommendations, but will propose a greater level of transparency with respect to the published content.

Demands for information and openness on the Agency's activities continue to increase. Meeting such demands for increased transparency requires the right balance between making more information and documents available more quickly in the interest of public health, and protecting commercially confidential information, while also complying with personal-data legislation.



As an important part of opening up the operations of the EMA, the Agency has committed to a gradual and stepwise increase in the Agency's level of transparency, in the field of both product and non-product related activities. The outcome of such exercise is apparent in the large amount of information already made public on product related activities. For example, information on all applications for human medicines under review by the Agency is already made public.

In this regard, the Agency has committed to publish the agendas and minutes for all seven scientific committees by the end of 2013. Agendas and minutes of the COMP, PDCO and PRAC, as well as the pharmacovigilance sections of the CMDh agendas and minutes, have been published from mid-2012 onwards. The experience on the publication of these documents has been taken into account in the development of this document.

This document will be reviewed, as appropriate, by March 2015 taking into account the experience gained.

## 2. Scope

These principles are applicable to the prospective publication of the agendas and minutes of all the scientific committees of the European Medicines Agency.

This document sets out the high-level principles, as well as the implementation of the publication of agendas and minutes of the EMA scientific committees.

Taking into account that the agendas and minutes of the PRAC, PDCO and COMP have been published since 2012, the publication of the documents of these committees will follow the principles as outlined in this policy, with changes, as applicable, to any current practices.

## 3. Principles

The following principles apply:

1. The principles are applicable across all of the EMA scientific committees.
2. The starting point for publication of agendas (listing the agenda topics for discussion at the plenary meeting) and minutes of all EMA scientific committees is that everything is transparent, with exceptions limited to commercial confidentiality and personal data protection, or otherwise justified by the need to avoid unnecessary public alarm, particularly at a stage where the assessment by the relevant committee is not completed. Commercially confidential information and personal data will be redacted in the published documents. However, the aim should be to keep redaction to a minimum.
3. In case of procedures/products undergoing discussion in different committees, it is expected that the same level of transparency will apply to the information published in the documents of the committees involved.
4. No information will be published with respect to Scientific Advice and Protocol Assistance requests, in consideration that such information is considered commercially confidential.
5. Information will not be published on quality variations, in consideration that such information is considered commercially confidential.
6. The names of the (Co)-Rapporteurs are published for post-authorisation applications in the frame of the centralised procedure, as well as for arbitration and referral procedures.

7. The names of responsible staff members (e.g. PTLs) will not be published, regardless of whether the procedure is in the pre- or post-authorisation phase.
8. The minutes should provide a good quality reflection of the main discussions and conclusions/outcomes.
9. Personal reflections/views of committee members will not be minuted, unless the member(s) explicitly request that their name and opinion is reflected in the minutes.
10. Lists of participants, declared interests and applicable restrictions should be reflected in a fully harmonised manner.
11. The agendas of all committee meetings will be published by the end of the week preceding the meeting and, at the latest, on the first day of the committee meeting. In case of new items included after publication of the agenda, such new items will only be reflected in the published minutes of the meeting. The minutes of all EMA scientific committee meetings will be published in the week following their adoption by the committee.

## 4. Application of the principles

The application of these principles has the following consequences:

### ***Pre-opinion in the framework of marketing authorisation applications:***

Published agendas and minutes will include information on INN and indication (as provided by SIAMED as applicable) for human medicinal products<sup>1</sup>/species and therapeutic area for veterinary medicinal products, procedure numbers, as well as the indication that a specific timetable was established for ongoing pre-authorisation procedures. Such information will be published on, for example, eligibility requests, classification requests, paediatric investigation plans.

The minutes will reflect the high-level procedure outcome or milestone – e.g. adoption of list of questions.

### ***Opinion in the framework of marketing authorisation applications:***

The outcome of formal voting procedures will be published. In case no re-examination has been requested, the names of individuals expressing divergent views after voting will be published in the minutes of the meeting where the voting took place. In case re-examination has been requested, the outcome of such re-examination has to be awaited before publication of the names of individuals expressing divergent views can take place.

### ***Post-authorisation applications, as well as arbitration and referral procedures:***

The published agendas and minutes will include full information on the procedures concerned, irrespective if the procedure is finalised or not. This covers variations including extensions of indication, extensions of marketing authorisation (such as a new pharmaceutical form, a new route of administration, a new strength, a new presentation), with the exception of quality variations. This covers also all arbitration/referral procedures.

---

<sup>1</sup> In case the marketing authorisation application relates to an orphan medicine, the (invented) name and the name of the applicant will be published since such information is already in the public domain.

The outcome of formal voting procedures will be published. For those procedures where re-examination is possible the following applies: In case no re-examination has been requested, the names of individuals expressing divergent views after voting will be published in the minutes of the meeting where the voting took place. In case re-examination has been requested, the outcome of such re-examination has to be awaited before publication of the names of individuals expressing divergent views can take place.

For those procedures where re-examination is not possible the names of individuals expressing divergent views after voting will be published in the minutes of the meeting where the voting took place.

## **Annex I: List of EMA scientific committees**

- [Committee for Medicinal Products for Human Use \(CHMP\)](#)
- [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#)
- [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 \(CAT\)](#)