

London, 20 November 2008
EMEA/623107/2008

RECOMMENDATIONS ON TRANSPARENCY

RECOMMENDATIONS on transparency related to agendas/minutes on product related issues (implementation of Article 126b of Directive 2001/83/EC as amended and Article 80 of Regulation (EC) No 726/2004)

Heads of Medicines Agencies recognise national provisions concerning access to documents and disclosure of information.

Heads of Medicines Agencies are aware that, in the framework of the pharmaceutical legislation, there are discrepancies on the implementation of Article 126b of Directive 2001/83/EC as amended concerning transparency of agendas and minutes of the scientific committees.

Heads of Medicines Agencies have agreed with the following recommendations to facilitate a common approach across the EU.

The recommendations take into account the environment in the pharmaceutical field in particular the commercially sensitive aspect of on going procedures under evaluation.

The principles on the protection of personal data provided by the EU legislation (Regulation (EC) No. 45/2001 and Directive 95/46/EC) have also to be applied and confidentiality of personal information must be ensured.

The recommendations address only scientific committees related to applications for marketing authorisation.

The recommendations do not address implementation timeframe and resources that have to be dealt with at the level of each agency. It would probably be useful to conduct an impact assessment.

It should be noted that the European Medicines Agency (EMA) is elaborating an EMA transparency policy that could impact the recommendations.

The recommendations are published on Heads of Medicines Agencies and EMA websites.

Heads of Medicines Agencies (HMA) and European Medicines Agency (EMA) recommend that:

- A common approach should apply for active publication and for disclosure upon request for access to documents. Such approach would be useful with regard to information considered as commercially confidential during the evaluation process of applications for marketing authorisations and when the opinion/decision is taken. However, it is acknowledged that outcomes may vary since each case has to be decided according to the circumstances of that specific case;
- The provisions in the pharmaceutical legislation are not exactly the same for EMA (Article 80 of Regulation (EC) No 726/2004) and for national competent authorities (Article 126b of Directive 2001/83/EC as amended) but the same general principles should apply in both cases, in particular on what should be considered as commercially confidential for applications for marketing authorisation;
- Agendas should be published around the time of the meeting.
- EMA and national competent authorities should have a common approach on what should be considered commercially confidential, in particular whilst procedures to assess marketing-authorisation applications are ongoing, as commercial confidentiality is particularly sensitive during this phase of the decision-making process;
- For on-going procedures and in order to avoid undermining the decision-making process, only the following information should be disclosed:
 - For innovative medicinal products
 - Name of the active substance
 - Type of application: National Procedure, Mutual Recognition Procedure (MRP)/Decentralised Procedure (DCP), Centralised Procedure (CP)
 - Therapeutic class
 - For generics/similar biological medicinal products and non-prescription medicinal products
 - Name of the active substance (moiety only)
 - Type of application: national, MRP/DCP, CP
 - Therapeutic class

This would apply for agendas and minutes.

- For minutes, once the decision has been taken and the procedure can be deemed concluded, public access may be granted to the minutes in compliance with the protection of confidential information (personal data or commercially confidential information).