EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

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HMA/EMA recommendations on transparency

Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation

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

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

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

The principles of 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 are also based on the responses on a questionnaire sent to all National Competent Authorities on national practices with regard to release of information about applications for generic medicinal products.

This recommendation should be read in connection with HMA/EMA recommendations already agreed and published on HMA and EMA websites:

1. 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.
2. Recommendations on the handling of requests for access to Periodic Safety Update Reports (PSURs).

Heads of Medicines Agencies and the 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.

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- EMA and National Competent Authorities should have a common approach on what should be considered as commercially confidential, in particular whilst procedures to assess marketing authorisation applications are ongoing. In view of the lack of a legal definition and for the purpose of harmonisation 'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information.
- As common principle it can be agreed that information that is already in the public domain can not be regarded as commercially confidential.
- Active publication or disclosure upon request for access to documents can be done when an overriding public interest in disclosure can be identified.

What information can be released with regard to new applications for medicinal products BEFORE an opinion or decision?

This applies for generics/biosimilars, non-prescription medicinal products and innovative medicinal products.

1. Name of active substance	Yes, for generics only active moiety, no salts, esters or derivatives
2. Invented name	No
3. Name of the applicant	No
4. Legal basis	No
5. Therapeutic class	Yes
6. Date of submission	No
7. Member States concerned	No
8. Other information	No

What information can be released about new applications AFTER an opinion or decision?

This applies for generics/biosimilars, non-prescription medicinal products and innovative medicinal products.

1. Name of active substance	Yes, including salts, esters or derivatives
2. Invented name	Yes
3. Name of the applicant	Yes
4. Legal basis	Yes
5. Therapeutic class	Yes
6. Date of submission	Yes
7. Member States concerned	Yes, available in MRI Product Index
8. Other information	SmPC, PL, PAR, parts of the dossier after deletion of CCI and PPD. See Recommendations on dossier (in preparation)