EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency and Heads of Medicines Agencies propose measures to make information in application dossiers more transparent

Public consultation open until 1 September 2011

The European Medicines Agency and the Heads of Medicines Agencies (HMA) have released a guidance document on the identification of commercially confidential information and protection of personal data within the structure of the marketing-authorisation dossier for public consultation.

The draft document, which is open for comment until 1 September 2011, outlines the types of information included in marketing-authorisation applications that can be released following a request for access to documents, once a marketing authorisation has been granted.

The consultation is being conducted to gather the views of stakeholders, including pharmaceutical companies, healthcare professionals and patient organisations. The Agency and the HMA are particularly interested in receiving comments on the criteria for the release or protection of personal data, whether contractual arrangements between companies need to be maintained as confidential, and how to address the personal security of individuals involved in studies using animals. They are also inviting stakeholders to make proposals on how to make these types of request easier.

The principles outlined in the guidance document represent the outcome of extensive discussions between the Agency and Member States' medicines regulatory authorities working together in the HMA. The guidance aims to achieve a greater level of transparency and to address requests for information coming from the public more effectively and in a consistent manner.

Following the consultation period, the Agency and the HMA will work together to assess all comments received before agreeing upon a final version of the guidance document.

The final guidance will apply to applications received both by the Agency and by medicines regulatory authorities in Member States. However, these authorities will also be required to follow European or national legislation on access to documents.

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Although the ways in which the principles in this guidance document will be applied have only been considered in detail for human medicines, feedback is invited from stakeholders involved with both human and veterinary medicines.

The Agency is working with the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) on practical implementation in the veterinary field. The same principles are expected to apply for human and for veterinary medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Details of the public consultation on the draft guidance document are available on the Agency's website.
3. Information on the Agency's access to documents policy and draft transparency policy is available on the Agency's website.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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