European Medicines Agency
Press Office

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Press release
European Medicines Agency finalises new procedure for EU pharmaceutical guidelines

The European Medicines Agency has finalised a new procedure aimed at putting in place a transparent process for the development, consultation, finalisation and implementation of pharmaceutical guidelines.

An important aspect of the new procedure relates to how decisions are taken on whether new guidance is needed. The document that has now been published sets out a consistent and transparent approach to assess the need for guidance and the impact for interested parties and competent authorities.

Pharmaceutical guidelines provide essential information to be taken into account in the research and development of new medicines. Based on the most up-to-date scientific knowledge they are a key part of the Agency's work within the European Union pharmaceutical regulatory system. Many of the guidelines are the result of the European Union's harmonisation activities with Japan, US and other international partners through the international conferences on harmonisation for human and veterinary medicines (ICH and VICH).

The Agency has developed the new procedure together with its scientific committees and working parties. The document describes the different types of guidelines that form part of the European pharmaceutical legislative framework. It also explains how they fit into the annual work programmes of the EMEA and outlines a harmonised procedure for their development. A reference to non-guideline documents is also included.

The improvements to the current guideline procedures are part of the Agency's response to the transparency consultation exercise carried out in 2003. A draft version was released for consultation in September 2004, and the responses received from 15 organisations/individuals are also published on the EMEA website.

The new procedure will come into effect for all draft and final guidelines published by the EMEA after 1 September 2005.

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NOTES:

1. The 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' is available on the EMEA web site here.
2. An overview of the comments received during the consultation process can be accessed here.
3. The proposals include harmonised terminology at EU level, in particular with regard to the use of 'guideline' as opposed to 'note for guidance'.
4. The document 'New EMEA transparency policy measures' (EMEA/MB/52/03-Rev.1) was adopted by the EMEA Management Board on 3 October 2003. It is available on the EMEA web site here.
5. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int

Media enquiries only to:
Martin Harvey Allchurch
Tel. (44-20) 74 18 84 27, E-mail: press@emea.eu.int