European Medicines Agency
Press Office

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Press release

European Medicines Agency launches consultation on the future of EU pharmaceutical guidelines

The European Medicines Agency has launched a public consultation exercise on proposals aimed at putting in place a transparent process for the development, consultation, finalisation and implementation of pharmaceutical guidelines.

Pharmaceutical guidelines provide essential information to be taken into account in the research and development of new medicines. 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 proposed improvements to the current guideline procedures also form part of the Agency's response to the transparency consultation exercise carried out in 2003.

An important aspect of the proposals relates to how decisions are taken on whether new guidance is needed. A consistent and transparent approach is proposed that will include an assessment of the impact on interested parties and competent authorities.

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

Comments from all interested parties on the draft proposals are now invited. All contributions should be sent to guidelinesconsultation@emea.eu.int by 8 December 2004. It is intended to implement the final document in early 2005.

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NOTES:

1. The draft 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' is available on the EMEA web site here.
2. The proposals include harmonised terminology at the EU level, in particular with regard to the use of 'guideline' as opposed to 'note for guidance'.
3. The '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.
4. 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

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