



European Medicines Agency
Press office

London, 22 September 2005
Doc. Ref. EMEA/311762/2005

Press release

European Medicines Agency proposes new, faster scientific advice procedure

The European Medicines Agency has launched a two-month public consultation exercise on proposed improvements to the way it provides scientific advice on the research and development of new medicines.

The provision of scientific advice to sponsors, whether pharmaceutical industry or other researchers, is one of the main priorities for the EMEA and is a key part of the Agency's response to the EU strategy for improving the competitiveness of European-based research and development of medicines. The main features of the revised procedure include the earlier and greater involvement of external experts in developing advice, and a faster delivery of the advice to sponsors.

The EMEA has provided scientific advice to sponsors since 1996. The introduction of the new EU pharmaceutical legislation gives the EMEA a greater mandate to provide scientific advice, particularly regarding the development of new therapies, with direct responsibility for the Executive Director to establish efficient structures for the provision of scientific advice.

The earlier and greater involvement of experts and assessors at all stages of the revised procedure will allow a faster response to sponsors, with the timelines expected to be reduced from 100 days to between 40 and 70 days. In addition, the EMEA scientific secretariat will have a reinforced role in ensuring the consistency of the advice given.

The Scientific Advice Working Party is a multi-disciplinary group of the Committee for Medicinal Products (CHMP) with wide scientific expertise in preclinical safety, pharmacokinetics, statistics and specialist fields, including cardiology, oncology, diabetes, neurodegenerative disorders and infectious diseases such as HIV infection.

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NOTES

1. The deadline for comments on the **revised procedure** is 22 November 2005 and should be sent to spiros.vamvakas@emea.eu.int
2. Information on the provision of scientific advice at the EMEA, including guidance on the current procedure and time schedules for submission of requests, can be found [here](#).
3. Fees for scientific advice range from € 11,600 to € 69,600 depending on the nature of the advice being sought. Further information on the fees payable is available [here](#).
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at <http://www.emea.eu.int>

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