European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency introduces new, faster scientific advice procedure

The European Medicines Agency has finalised its 'New Framework for Scientific Advice & Protocol Assistance', which introduces significant changes to the way the Agency provides scientific advice on the research and development of new medicines.

The main aspects of the new framework include:

- earlier and greater systematic involvement of internal and external experts from the pre-submission phase to the final adoption of scientific advice;
- faster delivery of the advice to sponsors to allow finalisation within 40 to a maximum of 70 days;
- broader scope for requesting scientific advice and for follow-up requests;
- enlarged Scientific Advice Working Party, with 26[1] instead of 22 members;
- reinforced role for the EMEA secretariat in ensuring the consistency of the advice given;
- increased transparency and communication with stakeholders.

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. It helps sponsors to develop new medicines in a faster and more effective manner, which, ultimately, helps to speed up access of patients to innovative new medicines. In addition, to facilitate access of smaller companies, sponsors that are micro, small or medium-sized enterprises (SMEs) may now benefit from a 90% fee reduction for scientific advice[2].

The 'New Framework for Scientific Advice & Protocol Assistance' was released for public consultation with stakeholders and interested parties in September 2005; an overview of responses received from 12 organisations is published on the EMEA website. It will come into effect as of 1 July 2006. Updated EMEA scientific advice and protocol assistance guidance will be published on the EMEA website.

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NOTES

1. The 'New Framework for Scientific Advice & Protocol Assistance' is available here.
2. Procedural timelines and deadlines for new requests for scientific advice and protocol assistance submitted can be found here.
3. An overview of the comments received during the consultation process and the EMEA responses to these comments can be found here.
4. The Scientific Advice Working Party is a multidisciplinary group of the Committee for Medicinal Products for Human Use (CHMP) with wide scientific expertise in preclinical safety, pharmacokinetics, statistics and specialist fields, including cardiology, oncology, diabetes, neurodegenerative disorders and infectious diseases. The revised 'Mandate, objectives and rules of

[1] Rev. 2: The Mandate, Objectives and Rules of Procedure of the Scientific Advice Working Party (SAWP) (EMEA/CHMP/SAWP/69686/04 rev 4) adopted by the CHMP on 25 April 2006 has been amended by the CHMP in May 2006 (Rev. 5) by adding an additional member to the three already proposed to the composition of the SAWP

[2] Rev. 1: Addition to reference to special support for small or medium-sized enterprises

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procedure' of the Scientific Advice Working Party (SAWP) was adopted by the CHMP on 31 May 2006. It is available on the EMEA website here.

5. Scientific advice provided by the Agency to sponsors developing designated orphan medicinal products is referred to as protocol assistance and is offered free of charge.
6. Information on incentives available for SMEs is available on the EMEA website: http://www.emea.eu.int/SME/SMEoverview.htm
7. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.eu.int

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