European Medicines Agency
Press Office

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Press release
Rise in applications for medicines in 2006, concerns over budget situation for 2007 and new transparency measures

Rise in applications for medicines in 2006

The European Medicines Agency is seeing an increase in applications in 2006. The initial application forecast for the year has been revised from 61 to 91 applications, an increase of 49%. At the Management Board's 28 September 2006 meeting, Thomas Lönngren, EMEA Executive Director, indicated that this unforeseen increase was due in part to applications for new innovative medicines and for new uses of approved medicines, and in part to some additional generic, biosimilar and multiple applications. Above all, it was stressed that the applications were unexpected and the Executive Director urged companies to enter into dialogue with the Agency earlier to discuss their filing strategy.

Concerns over the budget situation for 2007

The Management Board expressed concerns for the budget for 2007, in particular because the requested European Community contribution to the Agency's budget has been significantly reduced in the current round of 2007 EU budget discussions. The Agency had originally requested €46.32 million to support its increasing involvement in public health activities, but current indications are that the Agency could receive only a small increase over the 2006 level of €34 million.

Public health obligations for the Agency that will have a major impact in 2007 include the implementation of the new regulation on medicines for children, support for small and medium-sized enterprises and increased work for orphan medicinal products. There is also the need for continued work on European telematics projects such as EudraPharm, the Community database on medicinal products, and EudraVigilance, the Community data processing network for adverse drug reactions.

The Agency continues to follow budget discussions in the European Parliament carefully and a decision on the priorities for 2007 will be taken at the Board's next meeting on 19 December 2006.

New transparency measures

Using new powers under the revised EU pharmaceutical legislation, the Management Board agreed to publish information concerning the withdrawal by a company of its marketing authorisation application after the Agency's opinion but before the Commission's decision on marketing authorisation. The Agency will also publish information on withdrawals by applicants, and on refusals by the Agency, of applications concerning new indications for approved medicines. This complements measures introduced by legislation in November 2005. The new measures currently apply only to applications concerning medicines for human use, but similar proposals concerning veterinary medicines will be made at a later time.

The Agency will publish regular information about its activities in support of small and medium-sized enterprises (SMEs). This will include the names of companies that have been assigned SME status by the Agency. The aim is to highlight the Agency's work in supporting SMEs and to encourage other eligible companies to come forward.

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