European Medicines Agency
Press Office

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Press release
European Medicines Agency finalises set of guidelines on similar biological medicines and publishes two more new concept papers

The European Medicines Agency today published a set of five final guidelines on similar biological medicinal products. They are intended to give guidance to industry in the development of this new type of applications for marketing authorisation.

A general regulatory guideline on similar biological medicinal products was finalised in September 2005. The guidelines published today give guidance on quality, non-clinical and clinical issues. The product class specific annexes to the guideline on non-clinical and clinical issues give guidance for certain classes of medicines: those containing insulin, containing somatropin and those containing recombinant granulocyte-colony stimulating factor. The guidelines come into effect from 1 June 2006. In addition, a further class specific annex for medicines containing epoetin will also be available shortly.

The finalisation of the guidelines follows an extensive public consultation exercise, including a workshop held in Paris in December 2005, which generated feedback from regulators, industry, academia, healthcare professionals and patient groups. In accordance with the Agency's commitment to transparency, an overview of comments received will be published shortly.

In parallel, the Agency has also published two new concept papers. The first is a concept paper on comparability of biotechnology-derived medicinal products after a change in the manufacturing process (non-clinical and clinical issues). The second is a concept paper on immunogenicity assessment of therapeutic proteins. The public consultation period on these two concept papers is open until 1 June 2006.

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NOTES

1. The adopted EMEA guidelines are available here and other draft guidelines are available here.
2. The newly published concept papers can be found here.
3. The Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions for two similar biological medicinal products in January and February 2006. The summary of opinion for Omnitrope can be found here and the summary of opinion for Valtropin can be found here.
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the EMEA website: http://www.emea.eu.int

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