European Medicines Agency
Press office

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PRESS RELEASE

European Commission legalisation of EMEA certificates to end

The legalisation of EMEA certificates of medicinal products by the European Commission Representation in the United Kingdom will be stopped from 1 November 2005. This follows consultation with the stakeholders concerned.

The EMEA issues certificates of medicinal products to confirm the marketing authorisation status of products that have been authorised through the centralised procedure or of products for which a centralised marketing authorisation application has been submitted to the EMEA.

The certification scheme is part of the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce. EMEA certificates allow health authorities in countries outside the European Union to ascertain the marketing status of a particular medicinal product within the EU, which they could take into account when evaluating that product for approval within their own country.

When the Agency was created in 1995, it was requested that EMEA certificates be legalised by the European Commission because health authorities in countries outside the EU were unfamiliar with the activities of the Agency at that time. Now that the EMEA has been in operation for more than 10 years and further to consultation with interested parties, legalisation by the Commission is considered superfluous.

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NOTES

1. More information on the EMEA certification scheme can be found on the EMEA website here.
2. This press release together with other information on the work of the EMEA can be found on the EMEA website at www.emea.eu.int.

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