



European Medicines Agency
Press office

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PRESS RELEASE

EMEA and FDA publish implementation plan for confidentiality arrangement

The EMEA and FDA have published the implementation plan for the confidentiality arrangement that was signed by the European Commission, EMEA and FDA on 12 September 2003.

The implementation plan details the information and documents the two agencies will exchange and the process for monitoring the implementation of the plan itself. The plan applies to all products that fall within the remit of the EMEA and FDA. Medicines authorised at Member State level are not included, except where they are referred to the EMEA in an arbitration or other referral procedure. The plan includes both regular and ad hoc exchange of information, including information on pre-authorisation and post-authorisation applications, inspections and guidance documents. An exchange programme for staff of both agencies is also foreseen.

A key part of the plan is a pilot programme for companies to obtain parallel scientific advice from the two agencies. The programme includes a mechanism for the EMEA, FDA and companies to exchange views on scientific issues during the development phase of new medicinal products. The parallel advice programme will in particular focus on important breakthrough drugs. A general principles document for this programme has also been published.

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NOTES:

1. 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>
2. The implementation plan and the general principles document on parallel scientific advice can be found [here](#)
3. The public statement together with the text of the Exchange of Letters between the European Commission, EMEA and FDA can be found [here](http://www.emea.eu.int/htms/general/direct/pr.htm) (www.emea.eu.int/htms/general/direct/pr.htm).

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