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Press Office

Press release

European Medicines Agency to publish information on ongoing medicine evaluations

Data to be made public from 1 March 2012

From Thursday 1 March 2012, the European Medicines Agency will start to publish information on applications for centralised marketing authorisation for human medicines that it has received for evaluation.

The Agency will publish the international non-proprietary names (INN) and therapeutic areas for all new innovative medicines under evaluation by the Committee for Medicinal Products for Human Use (CHMP), along with information on the type of salt, ester or derivative of the active substance. For generic and biosimilar medicines, it will publish the INN and therapeutic area. It will only publish this information for medicines whose applications have been validated.

The Agency will update this information every month following the plenary meeting of the CHMP.

This initiative forms part of the drive towards increased transparency on its activities by the Agency and other European regulatory authorities. It follows the publication of recommendations on transparency of ongoing evaluations adopted by the European Medicines Agency and the Heads of Medicines Agencies in November 2010.

The new initiative expands upon the Agency's current publication of information on designated orphan medicines that are being assessed for marketing authorisation in the monthly reports of the Committee for Orphan Medicinal Products (COMP). Currently, the Agency does not publish information on other types of medicines until it has issued an opinion at the end of the assessment procedure.

This initiative also prepares for the publication of agendas and minutes of the meetings of the Agency's committees in the second half of this year.

For veterinary medicines, the Agency will coordinate with the Heads of Medicines Agencies (Veterinary) regarding the timing of the implementation of this policy.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. INNs or generic names are the globally recognised names used to identify active ingredients in pharmaceuticals. INNs are selected by the World Health Organization (WHO). For more information, see the WHO website: http://www.who.int/medicines/services/inn/en/.
3. The document 'Heads of Medicines Agencies/European Medicines Agency recommendations on transparency: Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation' is available on the Agency's website: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500099536.pdf
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu