European Medicines Agency
Press office

London, 18 October 2007
Doc. Ref. EMEA/480863/2007

PRESS RELEASE
European Medicines Agency recommends withdrawal of marketing authorisations for cough medicines containing clobutinol

Finalising a review of the safety of clobutinol-containing cough medicines in the European Union (EU), the European Medicines Agency (EMEA) concluded that the risks of these medicines are greater than their benefits and recommended that the marketing authorisations for these medicines be withdrawn throughout the EU.

Medicines containing clobutinol are available without a prescription in a number of EU Member States for the short-term treatment of irritable, non-productive cough (where the patients do not cough up any phlegm or mucus). Most of these medicines were marketed by Boehringer Ingelheim under the tradename Silomat.

The review of clobutinol-containing medicines was started in September 2007, following the suspension of the marketing authorisations for these medicines by the German competent authority, because preliminary results of a study indicated that the use of clobutinol was linked to side-effects affecting the heart. After Germany had informed the EMEA about the suspension, the Committee for Medicinal Products for Human Use (CHMP) started reviewing the safety of these medicines to reach a conclusion on whether the regulatory actions taken by Germany should be implemented throughout the EU.

Having considered all available evidence, the CHMP concluded that the use of clobutinol is associated with a risk of prolongation of the 'QT interval': this can affect the heartbeat, and is known to be linked to fainting and disruption of the heart rhythm, especially when taken in higher doses. In the light of these findings and because clobutinol is used to treat a common complaint for which alternative treatments are available, the CHMP considered that the benefits of these medicines do not outweigh their risks. The CHMP therefore recommended the withdrawal of the marketing authorisations of all clobutinol-containing medicines in the EU.

The CHMP opinion will now be sent to the European Commission for the adoption of a decision, applicable in all EU Member States.

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Notes:
1. More information about the review is available in a separate question-and-answer-document.
2. Most clobutinol-containing medicines have already been removed from the market because Boehringer Ingelheim decided to voluntarily withdraw its clobutinol-containing medicines from all markets worldwide following their suspension in Germany.
3. Clobutinol-containing medicines are available in the EU in Austria, Belgium, the Czech Republic, Germany, Greece, Finland and France.
4. The review of clobutinol was conducted under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a nationally authorised medicine as a result of the evaluation of safety data. It provides for a

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harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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