

Clobutinol – containing cough preparations withdrawn due to adverse cardiac effects

Europe, Worldwide. The European Medicines Agency (EMA) has recommended withdrawing the marketing authorization for cough medicines containing clobutinol (1). This recommendation is based on the Agency's review of the safety of clobutinol and its conclusion that the benefits of medicines containing clobutinol no longer outweigh their risks. In 2007 the German medicines regulatory authority suspended the marketing authorization for medicines containing clobutinol based on information from the manufacturer (Boehringer Ingelheim) that clobutinol was linked to adverse cardiac effects.

Boehringer Ingelheim had shared the preliminary results of a study that was being performed in healthy volunteers; these results showed that the use of clobutinol led to QT-prolongation. The Committee on Medicinal Products for Human Use (CHMP) has now reviewed all available information on the safety of clobutinol and has concluded that:

- The use of clobutinol is linked to a clear risk of QT prolongation
- This risk increases when patients take higher doses of the medicine.

The EMA advises that:

- Patients who are currently taking clobutinol should consult their doctor or pharmacist to discuss alternative treatments;
- The risk linked to clobutinol therapy is temporary, so there is no risk in patients who have taken the medicine in the past; and
- Prescription providers should not issue any new prescriptions for clobutinol.

In September 2007 Boehringer Ingelheim laboratories announced their decision to voluntarily withdraw the products (Silomat) from the global markets (2).

References:

1. Press Release. EMA, 18 October 2007 (www.emea.europa.eu)
2. Letter to prescribers. AFSSAPS, 4 September 2007 (<http://agmed.sante.gouv.fr>).

[Source: WHO Pharmaceuticals Newsletter]