



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2009
EMA/CHMP/815033/2009
Press Office

Press release

European Medicines Agency recommends withdrawal of benfluorex from the market in European Union

The European Medicines Agency has recommended the withdrawal of all medicines containing benfluorex in the European Union, because their risks, particularly the risk of heart valve disease, are greater than their benefits.

Doctors should stop prescribing benfluorex-containing medicines and consider alternative treatments. Patients currently taking the medicines should make an appointment with their doctor at a convenient time. Because heart valve disease can develop some years after treatment, patients who have taken benfluorex in the past should tell their doctor so that they can be checked for the signs and symptoms of heart valve disease.

Benfluorex is approved for use in overweight patients with diabetes, combined with an appropriate diet.

The Agency's Committee for Medicinal Products for Human Use (CHMP) reviewed available data on the safety and efficacy of these medicines because the French and Portuguese authorities had recalled them from their markets over safety concerns. The Committee concluded that the data indicate a risk of heart valve diseases associated with the use of benfluorex. The Committee also noted that the efficacy of benfluorex in the treatment of diabetes is limited. The Committee therefore was of the opinion that the benefits of these medicines no longer outweigh their risks and recommended the revocation of their marketing authorisations from all markets in the European Union.

The Committee's opinion has been forwarded to the European Commission for the adoption of a decision.

Notes

1. More information is available in a [question-and-answer document](#).
 2. The review was initiated 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 decentralised authorised medicine as a result of the evaluation of safety data. It provides for a 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.

3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu