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Dextropropoxyphene-containing medicines to be withdrawn from the European market

In June 2009 the European Medicines Agency (EMA) announced the recommendation to withdraw dextropropoxyphene-containing medicines from the European market (1). The Agency based its decision on the advice of its Committee for Medicinal Products for Human Use (CHMP) that the risks from these products, particularly the risk of potentially fatal overdose, exceed their benefits.

Dextropropoxyphene is a painkiller used to treat acute and chronic pain. It has been in use for over forty years, either on its own or in combination with other medicines such as paracetamol, in the form of tablets, suppositories and solutions for injection.

There have been some concerns about intentional and accidental fatal overdose with dextropropoxyphene-containing substances. Safety reviews of these products carried out in the past have led to different conclusions, with some European Member States withdrawing these products from their markets (2). The CHMP carried out a full review of the safety and efficacy of these medicines in order to assist the European Commission in providing a more harmonized level of protection across the European Union from the risks of these medicines.

The CHMP carried out a full assessment of the benefits and risks of medicines containing dextropropoxyphene alone and of medicines containing dextropropoxyphene in combination with paracetamol, to determine whether the marketing authorizations for these medicines should be maintained, varied, suspended or withdrawn. The Committee concluded that the available data do not provide evidence that these medicines are more effective than other alternative painkillers; that forensic data and national mortality statistics show a significant number of deaths associated with overdose of dextropropoxyphene-containing medicines. Because no adequate measures could be identified to minimize these risks sufficiently, the CHMP recommended that these medicines should be withdrawn from the European market.

This Alert is being issued for wider dissemination of the EMA recommendation to withdraw dextropropoxyphene-containing medicines from the European market.

References:

1. European Medicines Agency recommends withdrawal of dextropropoxyphene-containing medicines. EMA Press Office, 25 June 2009 (www.emea.europa.eu).
2. WHO Pharmaceuticals Newsletter No. 1, 2005 (<http://www.who.int/medicines/publications/newsletter/en/index.html>).