



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommends withdrawal of dextropropoxyphene-containing medicines

Finalising a review of the safety and efficacy of dextropropoxyphene-containing medicines, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that their risks, particularly the risk of potentially fatal overdose, are greater than their benefits. The Committee therefore recommended that the marketing authorisations for these medicines be withdrawn across the European Union. The withdrawal will be gradual to allow time for the safe transfer of patients to appropriate alternative therapies, in line with national recommendations.

Dextropropoxyphene is a painkiller used to treat acute and chronic pain. It has been available as a prescription-only medicine for about 40 years, either on its own or in combination primarily with paracetamol, as tablets, capsules, suppositories and solutions for injection.

There have been concerns over intentional and accidental fatal overdose with dextropropoxyphene-containing medicines for some years and a number of Member States had carried out independent safety reviews of these medicines authorised in their territories. These reviews have led to different conclusions, with some Member States withdrawing dextropropoxyphene-containing medicines from, and others maintaining them on, their markets.

In order to provide for a harmonised level of protection of public health across the European Union, the European Commission asked the European Medicines Agency, in November 2007, to carry out a full assessment of the benefits and risks of combination-medicines containing dextropropoxyphene and paracetamol. This assessment was to determine whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn. Later, the procedure was extended to medicines that contain dextropropoxyphene as the only active substance.

The available data have not provided evidence that dextropropoxyphene-containing medicines are more effective than other alternative painkillers. However, data from forensic centres and national mortality statistics from several Member States showed a significant number of deaths associated with overdose. Because no other adequate measures could be identified to minimise these risks sufficiently, the CHMP recommended that these medicines should be withdrawn from the market.

The Agency's recommendation has been forwarded to the European Commission for the adoption of a legally binding decision.

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Notes:

1. More information is available in a [question-and-answer document](#)
2. The review was initiated by the European Commission under Article 31 of Directive 2001/83/EC, as amended. This type of procedure may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information.

3. Medicines containing dextropropoxyphene on its own are authorised in 10 Member States (Belgium, Denmark, Greece, Spain, Finland, France, Italy, Luxembourg, the Netherlands and Sweden) and medicines containing dextropropoxyphene combined with paracetamol (sometimes with caffeine) are authorised in six Member States (Belgium, Cyprus, France, Luxembourg, Malta, and Portugal) and Norway.
4. 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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