18 November 2011
EMA/CHMP/898043/2011
Press Office

Press release

European Medicines Agency confirms positive benefit-risk balance of pholcodine-containing cough medicines

No firm evidence of cross-sensitisation between pholcodine and neuromuscular blocking agents used during surgery

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) confirmed that the benefits of pholcodine-containing cough medicines outweigh their risks and that these medicines should remain available for the treatment of non-productive (dry) cough in children and adults.

Patients taking pholcodine-containing medicines can continue to do so, and should contact their doctor or pharmacist if they have any questions.

The review of pholcodine-containing medicines was initiated because of concerns that there could be cross-sensitisation between pholcodine and neuromuscular blocking agents (NMBAs). It was suspected that this in turn could lead to anaphylactic reactions in some patients receiving NMBAs during emergency surgery who had previously taken pholcodine-containing cough medicines. These concerns were raised by a study that indicated that the reduction of pholcodine consumption following its withdrawal from the market in Sweden and Norway was associated with a decrease of reports of anaphylactic reactions to NMBAs in these two countries.

Following a thorough review of all available data on the safety and efficacy of pholcodine-containing cough medicines, the Committee found no firm evidence to substantiate the hypothesis of cross-sensitisation between pholcodine and NMBAs and a subsequent increased risk of anaphylactic reactions during surgery. The Committee also noted that pholcodine-containing medicines have been available for the treatment of non-productive cough in the EU for decades and existing data confirm a positive benefit-risk balance of these medicines. The Committee was therefore of the opinion that the marketing authorisations of pholcodine should be maintained in all EU Member States where it is currently authorised and that no further regulatory action is necessary.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Pholcodine-containing medicines are marketed in the following EU Member States: Belgium, France, Ireland, Lithuania, Luxembourg, Malta, Slovenia, Spain and the United Kingdom, either subject to medical prescription or as over-the-counter medicines. They may be available as syrups, oral solutions, suppositories, tablets and capsules under various trade names and as generics.
3. The Committee considered that the companies that make these medicines should conduct a post-marketing study investigating the possibility of an association between pholcodine and anaphylactic reactions to NMBAs.
4. The Committee's opinion has now been forwarded to the European Commission for the adoption of a decision.
5. The review was carried out under Article 31 of Directive 2001/83/EC. 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.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu