18th December 2011

Circular No. P18 /2011

Dear Healthcare Professional,

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

The European Medicines Agency has completed a review of the safety and effectiveness of pholcodine, following concerns that its use may put people at risk of developing anaphylactic reactions to neuromuscular blocking agents used during surgery. The European Medicines Agency's Committee for Medicinal Products 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 cough in children and adults.

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 cross-sensitisation was the cause of analphylactic reactions in some patients receiving NMBAs during emergency surgery and who had previously taken pholcodine-containing cough medicines. These concerns were raised by a study[1] 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 and that no further regulatory action is necessary.

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Pholcodine containing products are available in Malta as the non-prescription medicines Cofsed adult and paediatric linctus, Daynurse capsules and oral solution and in Tixylix dry-cough syrup.

A European Commission decision on this opinion will be issued in due course. The full **press release** and **question and answer** document issued by the EMA are attached here for your perusal.

Healthcare professionals are encouraged to maintain vigilance on pholcodine containing medicines. Suspected adverse drug reactions may be reported using the Medicines Authority yellow card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorization holder or their local representatives.

Healthcare professionals are encouraged to check the Medicines Authority website regularly for product safety updates as these are issued on an ongoing basis.

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