Malta, 20 November 2007

Circular No. P17/2007

Dear Healthcare Professional,

Re: Suspension of marketing authorisations for carisoprodol-containing medicinal products

The review of carisoprodol-containing medicinal products was initiated in September 2007 following plans made for its withdrawal from the Norwegian market (scheduled to take effect as of May 2008), due to new information relating to an increased risk of abuse or addiction as well as intoxication and events related to psychomotor impairment. Following the assessment of the available information on the safety of carisoprodol-containing medicinal products, the CHMP concluded that there is evidence for carisoprodol-associated risk of abuse and addiction, intoxication and psychomotor impairment. In the light of these findings the CHMP considered that the risks of these medicines outweigh their benefits. The CHMP therefore recommended the suspension of the marketing authorisations of all carisoprodol-containing medicinal products. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the **press release** and **Questions & Answers document** issued by the EMEA, attached here for your perusal. Further to this, the European Commission will shortly publish a Decision which is legally binding in all Member States and to be implemented by all Marketing Authorisation Holders holding a license for nimesulide-containing systemic medicinal products.

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