Malta 2nd August , 2010
Circular No. P09/2010

Dear Healthcare Professional

Re; European Medicines Agency recommends restricting the use of modafinil for the treatment of narcolepsy only; all other indications to be removed from product information

The European Medicines Agency has recommended restricting the use of modafinil-containing medicines. The medicine should only be used to treat sleepiness associated with narcolepsy. Doctors and patients should no longer use the medicine for the treatment of idiopathic hypersomnia, excessive sleepiness associated with obstructive sleep apnoea and chronic shift work sleep disorder.

Modafinil is a wakefulness promoting agent, currently licensed in 21 countries in Europe, including Malta, under the tradename Provigil® 30mg.

The review by the Agency's Committee for Medicinal Products for Human Use (CHMP) was initiated because of a number of safety concerns, relating to psychiatric disorders, skin and subcutaneous tissue reactions as well as significant off-label use and potential for abuse.

On the basis of the available data the Committee concluded that the benefits of these medicines only outweighed their risks in the therapeutic indication narcolepsy, a chronic sleep disorder characterised by excessive daytime sleepiness. For all other indications the Committee found that the risk for development of skin or hypersensitivity reactions and neuropsychiatric disorders outweighed the evidence for clinically important efficacy. Therefore, the Committee concluded that all other indications should be withdrawn from the marketing authorisations of these medicines.

The risk of development of serious skin and hypersensitivity adverse reactions appears to be higher in children than in adults. The Committee concluded that the product information should carry a recommendation saying that modafinil should not be prescribed to children.

The CHMP also identified particular cardiovascular risks with modafinil and recommended that the use of the medicine be contraindicated in patients with uncontrolled moderate to severe hypertension and in patients with cardiac arrhythmias.

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The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal. More information on this review is available in a separate **questions-and-answers** document

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

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