Public Health Regulation Department
Dipartiment ghar-Regolazzjoni Saħħa Pubblika
Ministry for Health, the Elderly and Community Care

19 July 2010

Med Auth file no: P05/2010
DH Circular No. 157/2010

To all: Medical Practitioners,
Dentists,
Pharmacists,

Re: European Commission Decision on marketing authorisations of medicinal products for human use which contain the active substance "dextropoxyphene"

On 14 June 2010 the European Commission adopted a decision to revoke national marketing authorisations of medicinal products for human use which contain the active substance "dextropoxyphene". The revocation was published on 14 June 2010 and shall be effected in 15 months from the date of publication of the said commission decision.[1] The withdrawal will be gradual to allow time for the safe transfer of patients to appropriate alternative therapies. The revocation thus fully comes into force on 14 September 2011.

Dextropropoxyphene is a painkiller used to treat acute and chronic pain in the EU. It has been available in Malta as a prescription-only medicine in combination with paracetamol, as tablets (Medonol ®, Distalgesic ®, Destirol ®).

This revocation is the outcome of an EU wide review of the safety and efficacy of dextropoxyphene triggered due to concerns over intentional and accidental fatal overdose with dextropropoxyphene-containing medicines for some years in a number of Member States. 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 (EMA), 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was to determine whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn. The available data did not provide 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

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could be identified to minimise these risks sufficiently, the EMA recommended that these medicines should be withdrawn from the market in all EU Member States.

In Malta, no intentional and accidental fatal overdose with dextropoxyphene containing medicinal products have been reported to the Medicines Authority. However, the European Commission decision shall apply in all Member States.

What are the recommendations for prescribers?

- Prescribers should carefully consider the best alternative treatments for patients currently taking dextropropoxyphene-containing medicines.
- Prescribers should be aware that the availability of dextropropoxyphene-containing medicines will decrease as the withdrawal takes place. Manufacturing of the products may stop before the end of the revocation period.

What are the recommendations for patients?

- Patients who are currently receiving dextropropoxyphene-containing medicines should speak to their doctor at their next appointment to review their treatment.

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

Dr Ray Busuttil
Director General (Public Health Regulation)
Licensing Authority

1. http://ec.europa.eu/health/documents/community-register/2010/20100614784 90/anx_78490_en.pdf