22.02.2005
Circular No. P02/2005

Medicines Authority Statement Re: Compound Preparations containing Dextropropoxyphene and Paracetamol (Co-proxamol) and its indication for mild to moderate pain

After discussion of the above-mentioned issue at the Pharmacovigilance Working Party (PhVWP) of the European Medicines Agency (EMEA), the Medicines Authority is disseminating the following:

Prescribers and dispensers are informed that in Malta co-proxamol contains dextropropoxyphene and is therefore to be dispensed through a medicinal prescription only (confer to Legal Notice 200 of 2004). Furthermore, following discussions at the PhVWP, the product information for co-proxamol is amended as follows:

Indications:
- For the treatment of mild to moderate pain in adults where first line analgesics have proved ineffective or are inappropriate. Co-proxamol should not be used for *any* chronic pain indication.
- Co-proxamol should not be used in patients aged <18 years.

Contra-Indications:
- Patients who are alcohol-dependent or who are likely to consume alcohol whilst taking co-proxamol.
- Patients who are suicidal or addiction-prone.

Special warnings:
- *Never* exceed the recommended dose.
- *Never* consume alcohol while taking a course of co-proxamol.

In addition the following prescribing and dispensing advice is recommended:

(1) the quantities of co-proxamol dispensed at any one time should be controlled and any dispensing on repeat prescription should be documented on the prescription;
(2) prescribers and pharmacists should advise patients to avoid the consumption of alcohol while using co-proxamol. Any repeat prescriptions should not exceed three months and the dosage should be included on the prescription. The dosage should not to exceed the recommended dose; and patients should be advised to avoid the consumption of alcohol while using co-proxamol.