Review of Atarax® (hydroxyzine containing medicines) started

26.06.2014 | Circular Number P19/2014

Information on hydroxyzine containing products

- Hydroxyzine containing products are approved for various uses, including relief of anxiety disorders, premedication before surgical procedures, relief of urticaria or various other conditions associated with pruritus (itching), and treatment of sleep disorders.
- In Malta hydroxyzine is marketed as Atarax® with the following products being authorised for use locally;

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Hydroxyzine Hydrochloride 10mg	Atarax	FILM-COATED TABLET	PoM	AA200/00801	Alliance Pharmaceuticals Ltd.
Hydroxyzine Dihydrochloride 2mg/ml	Atarax syrup	SYRUP	PoM	MA030/00101	UCB Pharma SA
Hydroxyzine Dihydrochloride 25mg	Atarax	FILM-COATED TABLET	PoM	MA030/00102	UCB Pharma SA

Information from the European Medicines Agency about the safety concern

The European Medicines Agency has started a review of hydroxyzine containing medicines, which have been approved in most EU countries for a variety of uses including pruritus (itching), anxiety disorders, as premedication before surgery and for sleep disorders.

The review was requested by the Hungarian medicines agency over concerns about the side effects of these medicines on the heart. This followed an examination of the benefits and risks by a marketing authorisation holder for hydroxyzine. Data from drug safety monitoring (pharmacovigilance) and published experimental studies identified a potentially increased risk of alterations of the electrical activity of the heart leading towards arrhythmias (irregular heartbeats).

The European Medicines Agency will now review the available data on the benefits and risks of hydroxyzine-containing medicines in all authorised indications, and issue an opinion on the marketing authorisations of these medicines across the EU.

For more information please visit **www.ema.europa.eu**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on hydroxyzine containing medicines. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

the Medicines Authority ADR reporting form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

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

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt