Malta, January 25, 2006
Circular No. P01/2006

Re: Phenylpropanolamine (PPA) in medicinal products

It has been brought to the attention of the Medicines Authority that a chain email warning readers regarding the safety of PPA is currently in circulation. In response to the claims outlined in this email, the Medicines Authority is issuing this statement in order to provide accurate information to both patients and healthcare providers with regard to the situation in Malta.

Phenylpropanolamine (PPA) is found internationally in several over-the-counter (OTC) cough and cold preparations as a decongestant. PPA is also available internationally in OTC weight loss products. In several countries e.g. Germany, such weight loss products are available only on prescription. There are no marketing authorisations for PPA-containing medicinal products in Malta.

A study conducted at Yale University, US[1] showed that PPA increases the risk of haemorrhagic stroke (bleeding into the brain or into tissue surrounding the brain), particularly in women. Following the publication of this study, the Nonprescription Drugs Advisory Committee (NDAC) of the Food and Drug Administration (FDA), US, requested the removal of PPA from all drug products, as well as the discontinuation of products containing PPA on 06.11.2000. Until then, both PPA-containing OTC cough and cold preparations were available locally and in the UK, and weight loss products were available in the UK. Furthermore, in response to this study, on 08.11.2000[2] the Committee on Safety of Medicines (CSM) of the Medicines and Healthcare products Regulatory Agency (MHRA), UK, concluded that US data on PPA does not apply to UK products since the compound used in Europe is different to that used in the US, as well as it is available in lower doses. Thus, back then, it was not considered necessary to withdraw PPA-containing products in Europe, as well as locally.

However, over the years, patients world-wide became increasingly alarmed by repeated warnings by the FDA about the safe use of PPA, and the use of such products dropped dramatically so much so that most pharmaceutical companies decided to discontinue them voluntarily for financial reasons. On 22.12.2005[3] the FDA issued yet another warning in which it reclassified PPA which is does not consider to be safe and effective. In the same warning the FDA states that it is taking steps to remove phenylpropanolamine (PPA) from all drug products and has requested that all drug companies discontinue marketing products containing PPA.

Through the process of registration of medicinal products the Medicines Authority will continue to ensure that no medicinal products containing PPA are registered in Malta.

[1] Kernan, W. N., Viscoli, C. M., Brass, L.M., Broderick, J.P., Brott, T., Feldmann E., Morgenstern, L.B., Wilterdink, J.L., Horwitz, R.I. (2000). Phenylpropanolamine and the Risk of Hemorrhagic Stroke. *NEJM* 343:1826-1832
[2] http://www.mhra.gov.uk/home/groups/pl-p/documents/drugsafetymessage/con019555.pdf
[3] http://www.fda.gov/cder/drug/infopage/ppa/default.htm

Medicines Authority
198, Rue D'Argens, Gzira, GZR 03 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt