

**DH CIRCULAR No.145/2014****DH 1694/2014****17th April 2014**

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Deletion of Ketoconazole 200mg Tablets from the Government Formulary List

The European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) has recommended that the marketing authorizations of oral ketoconazole-containing medicines should be suspended throughout the European Union. The CHMP concluded that the risk of liver injury is greater than the benefits in treating fungal infections.

The Agency's recommendations are based on a review by the CHMP which looked at available data on the benefits of oral ketoconazole and the risk of hepatotoxicity from pre-clinical and clinical studies, post-marketing spontaneous case reports, epidemiological studies and the scientific literature. The Committee also considered the advice from a group of experts in the treatment of infections.

The suspension will be effected in Malta when a final European Commission binding decision on the opinion of the CHMP is issued (in due course).

Topical ketoconazole formulations have very low systemic absorption and may continue to be used as currently approved.

As oral ketoconazole is no longer recommended, doctors should review patients being treated with this medicine for fungal infections, with a view of stopping treatment or choosing an appropriate alternative treatment.

Pharmacists should refer patients with a prescription of oral ketoconazole for fungal infections to their treating doctor.

Consequently, ketoconazole 200mg tablets will be deleted from the Government Formulary List.

For your attention please

Dr. Neville Calleja
A/Chief Medical Officer