

Malta, 20 March 2006

Circular No. P04/2006

Dear Healthcare Professional,

Re: Isotretinoin-containing medicinal products

On 17th October 2003, a Commission Decision was published concerning the placing on the market of the medicinal products for human use which contain the substance “Isotretinoin”. This Commission Decision outlines the measures that need to be taken in order to avoid pregnancy in female patients taking isotretinoin. Pregnancy is an absolute contraindication to treatment with isotretinoin since there is a great risk of very severe and serious malformation of the foetus. These measures include the revision of the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of isotretinoin-containing medicinal products and the implementation of a Pregnancy Prevention Programme (PPP) by the Marketing Authorisation Holders (MAHs) of such products.

There are currently two isotretinoin-containing medicinal products on the market in Malta. These are Roaccutane® (marketed by Roche) and Decutan® (marketed by Actavis). The PPP will need to be implemented for all isotretinoin-containing medicinal products with a Marketing Authorisation.

The Medicines Authority will closely follow the local implementation of the PPP and inform all concerned about their obligations with regards to the PPP in due course.