DIPARTIMENT TAS-SAĦĦA DEPARTMENT OF HEALTH
MALTA

L-Uffiċċju tal-Uffiċjal Mediku Ewlieni *Office of the Chief Medical Officer*

DH CIRCULAR No.353/2013
DH 3619/2013

18 November 2013

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Deletion of Ritodrine 10mg Tablets from the Government Formulary List

The European Medicines Agency's Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) has endorsed by consensus new recommendations to restrict the use of medicines called 'short-acting beta-agonists'.

These medicines should no longer be used in oral or suppository forms in obstetric indications (for the care of pregnant women), such as for suppressing premature labour or excessive labour contractions. However, injectable forms of these medicines can still be given for short-term obstetric use under specific conditions.

As the PRAC recommendations have been endorsed by consensus by the CMDh, they will now be implemented directly in all Member States, according to an agreed timetable.

In Malta, the product which will be affected by these recommendations is ritodrine hydrochloride 10mg tablets (Yutopar®).

Yutopar® tablets are only licensed in obstetric indications and hence the marketing authorisation will be revoked and any Yutopar® on the market will be removed by 25th November 2013.

Consequently, ritodrine 10mg tablets will also be deleted from the Government Formulary List.

For your attention, please

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