# Restrictions on use of short-acting beta-agonists in obstetric indications – CMDh endorses PRAC recommendations

31.10.2013 | Circular Number P24/2013

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.

These recommendations follow a review by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC), which looked into the known risk of cardiovascular side effects with high doses of short-acting beta-agonists when used as tocolytics (medicines that suppress labour contractions). See Medicines Authority Circular **P20/2013.**

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.

Products affected in Malta

Yutopar tablets 10mg (Ritodrine hydrochloride).

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

**Dr John J Borg PhD (Bristol)**
**Post-licensing Director**



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