

Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On January 24 2013 the delegate of the Secretary of the Department of Health and Ageing for the purposes of subsection 14 and 14A of the Therapeutic Goods Act 1989 ("the Act") gave his consent to:

(a) the supply of the product desogestrel/ethinyloestradiol (MARVELON) 28 tablet blister pack [Aust R 42894], by Merck Sharp & Dohme Australia Pty Ltd, North Ryde NSW, ("the Company");

That does not conform with paragraph 3(2)(1) of Therapeutic Goods Order (TGO) 69, in that the details of the previous sponsor (Schering-Plough) are listed on the blister foil and carton labels, instead of those of the Company.

Pursuant to subsection 15(1) of the Act, the consent given by the delegate of the Secretary as described above is subject to the following conditions:

- 1. The consent to supply applies to batches 156152 and 102240 of the tablets.
- The labels to which this consent applies are identical to those currently used, having 2. the previous sponsor details.
- 3. No other changes have been made to the product desogestrel/ethinyloestradiol (MARVELON) 28 tablet blister pack [Aust R 42894].
- 4. Arrangements are in place to ensure complaints or queries concerning this product will be dealt with promptly.

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