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GOVERNMENT NOTICES

COMMONWEALTH OF AUSTRALIA

Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On 16 August 2013 a delegate of the Secretary of the Department of Health and Ageing for the purposes of sections 14 and 14A of the *Therapeutic Goods Act 1989* ("*the Act*") gave consent to the following:

(a) the supply by Novartis Vaccines and Diagnostics Pty Ltd, North Ryde NSW 1678 (the Company) of the products :

- BEXSERO – multicomponent Meningococcal B vaccine (recombinant, adsorbed) suspension for injection 0.5mL pre-filled syringe without needle (AUSTR 190718) and
- BEXSERO – multicomponent Meningococcal B vaccine (recombinant, adsorbed) suspension for injection 0.5mL pre-filled syringe with needle (AUSTR 190719)

AND

(b) for the above goods not to conform with the requirements of Therapeutic Goods Order No. 69 (General requirements for labels for medicine, TGO 69), the products being imported into and supplied in Australia notwithstanding they do not conform with the requirements of the Therapeutic Goods Order 69, in that the syringe labels do not comply with Clauses 3(2)(b) & (c).

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

1. This exemption applies only to non-compliance of the syringe labels with Clauses 3(2)(b) & (c) of Therapeutic Goods Order 69.
2. The labelling of the products must comply with all other parts of Therapeutic Goods Order 69 in all respects.

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