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DEPARTMENT OF HEALTH

DEPARTEMENT VAN GESONDHEID

No. R. 377

29 May 2013 No. R. 377

29 Mei 2013

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCE ACT, 1965 (ACT 101 OF 1965)

UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKER BEPALINGS VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE MIDDELS 1965 (WET 101 VAN 1965)

I, **Mandisa Hela**, Registrar of Medicines, acting by virtue of a delegation in terms of section 34A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), hereby exclude in terms of Section 36 of Act 101 of 1965, on the unanimous recommendation of the members present at a meeting of the Medicines Control Council held on **19 April 2013** the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No R510 of 10 April 2003.

Ek, **Mandisa Hela**, **Registrateur van Medisyne**, handelend kragtens 'n delegasie ingevolge artikel 34A van die Wet op Medisyne en Verwante Middels, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op **19 April 2013**, sluit hierby uit, kragtens Artikel 36 van die Wet 101 van 1965, die medisyne in die bylae hiervan vermeld van die toepassing van die daarinvermelde bepalings van die regulasies afgekondig by Goewermentskennisgewing Nr. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.

MANDISA HELA  
REGISTRAR OF MEDICINES

MANDISA HELA  
REGISTRATEUR VAN MEDISYNE

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGSVORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING	APPLICANT/ APPLIKANT
45/8.2/0175	NPLATE 250 ug	injection	<b>Regulation 8:</b> labelling of medicines intended for human administration in so far as on the container label: Bilingualism [Regulation 8(1)]. Inclusion of the scheduling status [Regulation 8(1)(a)] Registration number [Regulation 8(1) (c)]. Name of holder of certificate of registration [Regulation 8(1) (p)]. <b>Regulation 9:</b> information to appear in the Package Insert in so far as: Bilingualism [Regulation 9(1)]. Inclusion of the scheduling status [Regulation 9(1)(a)] Pharmacological classification [Regulation 9(1)(d)]. Registration number [Regulation 9 (1)(q)]. Name of holder of certificate of registration [Regulation 9(1)(r)] Date of publication of the Package insert [Regulation 9(1)(s)].	<b>Provided that</b> the exemption is only valid for 500 units of Bach number 1038400A.	Batswadi Pharmaceuticals (Pty) Ltd
Various	Schedule 0 Medicines	Various	<b>Section 22G and Section 18A</b> relating to the supply of medicine according to a bonus system and a transparent pricing system which includes a single exit price from the date of publication of this gazette.	<b>Provided that</b> the exemption is valid for a period of three (3) years from the date of publication	Various

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