DEPARTMENT OF HEALTH

No 951 **29 September 2006**

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO 101 OF 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 Medicine Control Council held on **11 August *2006*** the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No. R.510 of 10 April 2003.

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MANDISA HELA
REGISTRAR OF MEDICINES

DEPARTEMENT VAN GESONDHEID

No 951 **29 September 2006**

UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKERE BEPALING VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET NR. 101 VAN 1965)

Ek, ***Mandisa Hela, Registrateur van Medisyne***, handelend kragtens 'n delegasie ingevolge artikel 34A van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op **11 *August 2006***, sluit hierby uit, kragtens Artikel 36 van Wet 101 van 1965, die medisyne in die Bylae hiervan vermeld van die toepassing van die daarinvermelde bepalings van die regulasies afgekondig by Goewermentskennisgewing No. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in the Bylae vermeld.

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MANDISA HELA
REGISTRATEUR VAN MEDISYNE

REGISTRATION NO/ REGISTRASIE NO	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARA-TION/ BEREIDINGS-VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAAR-DES VIR UITSLUITING	APPLICANT/ APPLIKANT
A400052	Platosin 10MG/10 ML Platosin 50MG/50 ML		*Regulation 8(1) Labelling of medicines intended for administration to humans (immediate container label): Bilingualism*		Pharmachemie
[illegible]	[illegible]		*Regulation 10 (1) each package of a medicine shall have a patient information leaflet*	Provided that: the exemption is only applicable to the supply of medicines to 10 patients per year	Boehringer Ingelheim
35/34/0065	Rouvax		*Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)* *(1) Bilingualism* *(a) Scheduling status* *(c) Registration number* *(e) Quantity of each Active ingredient* *(p) The name of the Holder of Certificate of Registration* And *Regulation 8 (3) The Council may authorise the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included* Aventis Pasteur	Provided that it is only applicable to: a) The Department of Health scheduled measles campaign 2007. b) Aventis to import 700 000units of Rouvax vaccine for the campaign. c) A once off exemption for the Department of Health measles campaign during 2007.	Aventis Pharma

NX/34/156	Parvolex Injection		*Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)* *(1) Bilingualism* *(c) Registration number* *(p) The name of the Holder of Certificate of Registration* And *Regulation 8 (3) The Council may authorise the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included:* • *DBL*	Provided that: a) Only a small consignment of 596 packs of 10 units every three to four months imported from the manufacturer in Australia	GlaxoSmithKline
A38/3.2/0562	Bondronat 50		*Regulation 8 Labelling of medicines intended for administration to humans – Blister foil* (b) Proprietary name And *Regulation 8 (3) The Council may authorize the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included:* Authorisation to allow for the Proprietary name to appear as "Bondronat 50mg" And for the name of the API to appear in besides English, French or Spanish text.	Provided that: a) the exemption is only applicable for 100 patients per year.	Roche
39/26/0028	Alimta 500mg		*Regulation 8 Labelling of medicines intended for administration to humans*	Provided that: a) It is for state	Eli Lilly

			(1) Bilingualism *(a) Scheduling* *(b) Proprietary name* *(c) Registration number* *(p) Name of the Holder of the Certificate of Registration* And *Regulation 8 (3)* *The Council may authorize the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included:* Authorisation to allow for information to appear on the "Fix--Form" label in, besides English, French, Dutch, Italian, German or Spanish text and to use the clinical trial label for the donation of the product to the State.		
H1088 (Act 101/1965) Unregistered Unregistered	Spongostan Sponge Spongostan Sponge Surgiflo Haemostatic Matrix		Excluded from Section 14(2): Prohibition of sale of medicines that are subject to registration and are not registered.	Further, the applicant to be reminded that these products could be in future called up for registration.	Johnson & Johnson