

No. 588

30 May 2008 No. 588

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

UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKERE BEPALINGS VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 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 5 **October 2007** 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.

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 5 **Oktober 2007**, 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 Nr. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in the Bylae vermeld.

  
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**MANDISA HELA**  
**REGISTRAR OF MEDICINES**

  
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**MANDISA HELA**  
**REGISTRATEUR VAN MEDISYNE**

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGS-VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING	APPLICANT/ APPLIKANT
R/20.2.3/153	Sandoz Pyrazinamide 500	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)</i> (1) <i>Bilingualism</i>		Sandoz (Pty) Ltd
Q/20.2.3/176	Sandoz Ethambutol HCl 400	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)</i> (1) <i>Bilingualism</i>		Sandoz (Pty) Ltd
35/20.2.3/0018	Rimstar	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)</i> (1) <i>Bilingualism</i>		Sandoz (Pty) Ltd
32/20.2.3/0549	Rimcure Paed 3-FDC	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)</i> (1) <i>Bilingualism</i>		Sandoz (Pty) Ltd
35/20.2.3/0280	Rimactazid 150/75	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)</i> (1) <i>Bilingualism</i>		Sandoz (Pty) Ltd
H/20/2/3/0036	Rimactazid 300/150	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label)</i> (1) <i>Bilingualism</i>		Sandoz (Pty) Ltd

37/20/2/3/0026	Rimactazid Paed 60/30	Tablet	<i>Regulation 8 Labelling of medicines intended for administration to humans (immediate container label) (1) Bilingualism</i>		Sandoz (Pty) Ltd
A410145	Gardasil vial and syringe	Vial and Syringe	<i>Regulation 8(1) Labeling of medicines intended for administration to humans (immediate container label): Bilingualism</i>		MSD
Unregistered	Colgate Disclotabs	Tablets	<i>Be exempted from Section 14(2): Prohibition of sale of medicines that are subject to registration and are not registered</i>		Colgate-Palmolive (Pty) Ltd
36/30.1/0123	Diftavax	Vaccine	<i>Regulation 8(1): Bilingualism</i>	<b>Provided that the exemption is valid for six months from the date of publication</b>	Aventis Pharma (Pty) Ltd
T/30.1/0668	Rouvax	Vaccine	<i>Regulation 8(1): Bilingualism</i>	<b>Provided that the exemption is valid for six months from the date of publication</b>	Aventis Pharma (Pty) Ltd
	Schedule 0 medicines		<i>Be exempted from the provisions of Section 18A and from Section 22G in so far as the matter relates to a single exit price</i>	<b>Provided that the exemption is valid for a period of 3 years from the date of publication.</b>	