

No. 533 9 June 2006 No. 523 9 June 2006

<p>NO C12</p> <p>EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965</p> <p>NOT NO 101 OF 1965)</p> <p>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 23 September 2005 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.</p> <p>.....</p> <p>MANDISA HELA REGISTRAR OF MEDICINES</p>	<p>NO C12</p> <p>UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKERE BEPALING VAN DIE WET DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET NR. 101 VAN 1965)</p> <p>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 23 September 2005, 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 Goewermentskenniging No. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in the Bylae vermeld.</p> <p>.....</p> <p>MANDISA HELA REGISTRATEUR VAN MEDISYNE</p>
<p>2005</p>	<p>2005</p>

REGISTRATION NO/ REGISTRASIE NO	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARD ES VIR UITSLUITING	APPLICANT/ APPLIKANT
J/7.1.3/54	Trandate injection	Injection	Regulation 8 (1): Bilingualism Regulation 8(2)(a) scheduling status Regulation 8(2)(c) Registration number Regulation 8(2)(i) Volume Regulation 8(2)(q) Storage condition		GlaxoSmithKline
97/3.1/5 97/3.1/5	Ketofen 5mg Ketofen 10 mg	Tablet	Regulation 48(1): One official language And In terms of the provisions of Regulation 48(3) (Labels): Council authorize the inclusion on the label of a medicine of any special information that is not required by the regulation to be so included: Information on the immediate container label: 'AD US. VET - USAGE VETERINAIRE' and "Comprimidos Tabletten".		Merial South Africa Pty Ltd
V/35/128	Ceretec		Section 19(1) No person shall sell any medicine unless it complies with the prescribed requirements insofar as the requirements for the re-assay and re-identification of the medicine post importation.		Weil Organisation
Unregistered	Cefu-HEXAL 125mg/5ml		Section 15(1): that every application for the registration of a medicine shall be submitted to the registrar accompanied		Sandoz

				by the sample of the relevant medication provided that the sample be submitted by December 2005.		
37026	R-Loc Injection	Injection		Regulation 8 (1)(e): Bilingualism of the approved name of each active ingredient	Zydus Healthcare S A Pty Ltd	
37/20.1.2/0619 37/20.1.2/0620	Ampiject 0,5g Ampiject 1g	Injection Injection		Regulation 8 (1)(e): Bilingualism of the approved name of each active ingredient	Generix International SA Pty Ltd	
Q/21/1/290 Q/21.1/2910	Sandoz Metformin 500 Sandoz Metformin 850			Regulation 8 (1): Bilingualism When packed in Patient Ready Packs when supplied on State Tender.	Sandoz	
P/20.2.1/260	Sandoz Co- trimoxazole 480			Regulation 8 (1): Bilingualism When packed in Patient Ready Packs when supplied on State Tender.	Sandoz	
W/20.2.1/88	Sandoz Co- trimoxazole 960			Regulation 8 (1): Bilingualism When packed in Patient Ready Packs when supplied on State Tender.	Sandoz	
30/30.1/0517	Imovax Pneumo 23			Regulation 8 (1): Bilingualism (p)Name of Holder of certificate of Registration And In terms of the provisions of regulation 8(3) Labels Council authorize the inclusion on the label of a medicine of any special information that is not required by the regulation to be so included. All information to appear in English and French And on the outer container label the working "Temporarily International Pack"	Aventis	