DEPARTMENT OF HEALTH

No. 499 **8 June 2011**

NO **C 44** **2011**

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCE ACT, 1965 (ACT 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 Medicines Control Council held on **4 March 2011** 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.

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MANDISA HELA
REGISTRAR OF MEDICINES

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 UITSLUITNG	APPLICANT/ APPLIKANT
43/30.2/0290	ROTARIX LIQUID ORAL VACCINE	Vaccine	**Regulation 8 and Regulation 1:** (Definitions) in respect of the printing in 6-point Helvetica.		GSK SA (Pty) Ltd
36/30.1/0347	INFANRIX HEXA		**Regulation 8:** Labelling of medicines intended for human administration in so far as bilingualism, inclusion of the scheduling status and registration number on the immediate container label; and **Regulation 8(3):** to allow for the inclusion of additional information of the label of the medicine which will include the name of the Belgium Applicant GSK Biologicals s.a. Rixensart, Belgium and some text in French and Spanish	**Provided that** the exemption is only valid for the following batches and quantity: **Batch** / **Quantity (doses)** A21AA987A / 8140 A21CA996B / 9800 **TOTAL** / **17 940**	GSK SA (Pty) Ltd
20/28/0679	FLUORESCITE 10%		**Regulation 10:** To include a Patient Information Leaflet in the packaging of the product.		Alcon Laboratories SA (Pty) Ltd
D/8.2/0263 35/8.2/0025	FENWAL TRIPLE OPTICA containing FENWAL PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT SOLUTION; and FENWAL SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL SOLUTION		**Regulation 8:** labelling of medicines intended for human administration in so far as bilingualism, inclusion of the scheduling status and registration number on the immediate container label; and **Regulation 8(3):** to allow for the inclusion of additional information on the label of the medicine which will include the directions for use printed in the following languages: Slovakian, Croatian, Turkish, Romanian, Polish, Hungarian, Czech, Slovene.	**Provided that** the exemption is only valid for the following batches and quantity: **Batch** / **Quantity (doses)** 10E11L52 / 11001 10E18L51 / 20988 **TOTAL** / **31 989**	Adcock Ingram Critical Care
Various	SCHEDULE 0 HUMAN MEDICINES	Various	Section 22G and Section 18A relating to the supply of the medicine according to a bonus system and a transparent pricing system which includes a single exit price for a period of two years from the date of publication in the Government Gazette.		Various

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 UITSLUITNG	APPLICANT/ APPLIKANT
41/8.1/1086 41/8.1/1087 41/8.1/1088	KOGENATE FS 250 KOGENATE FS 500 KOGENATE FS 1000		**Regulation 8(1):** Labelling of medicines intended for human administration in so far as bilingualism. Regulation 891)(a) the inclusion of the scheduling status. Regulation 8(1)(c) registration number. On the immediate container label (tamper proof plastic bag) and the outer container label (carton).	**Provided that** it does not exceed 300 units per annum.	Bayer Healthcare
C24/219	INTRAMED SODIUM CHLORIDE 0.9%		**Regulation 8:** Labelling of medicines intended for human administration in so far as bilingualism, inclusion of the approved Proprietary name, scheduling status, registration number and warning "Keep out of reach of children" on the immediate container label.		Bodene (Pty) Ltd