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DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. 499 **8 June 2011** **No. 499** **8 Junie 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

NR **C44** **2011**

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)

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 **4 March 2011**, 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 van10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.

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MANDISA HELA
REGISTRATEUR VAN MEDISYNE

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<tr><td>43/30.2/0290</td><td>ROTARIX LIQUID ORAL VACCINE</td><td>Vaccine</td><td>Regulation 8 and Regulation 1: (Definitions) in respect of the printing in 6-point Helvetica.</td><td></td><td>GSK SA (Pty) Ltd</td></tr>
<tr><td>36/30.1/0347</td><td>INFANRIX HEXA</td><td></td><td>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</td><td>Provided that the exemption is only valid for the following batches and quantity:<table><tr><th>Batch</th><th>Quantity (doses)</th></tr><tr><td>A21AA987A</td><td>8140</td></tr><tr><td>A21CA996B</td><td>9800</td></tr><tr><td>TOTAL</td><td>17 940</td></tr></table></td><td>GSK SA (Pty) Ltd</td></tr>
<tr><td>20/28/0679</td><td>FLUORESCITE 10%</td><td></td><td>Regulation 10: To include a Patient Information Leaflet in the packaging of the product.</td><td></td><td>Alcon Laboratories SA (Pty) Ltd</td></tr>
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35/8.2/0025</td><td>FENWAL TRIPLE OPTICA containing FENWAL PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT SOLUTION; and

FENWAL SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL SOLUTION</td><td></td><td>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.</td><td>Provided that the exemption is only valid for the following batches and quantity:<table><tr><th>Batch</th><th>Quantity (doses)</th></tr><tr><td>10E11L52</td><td>11001</td></tr><tr><td>10E18L51</td><td>20988</td></tr><tr><td>TOTAL</td><td>31 989</td></tr></table></td><td>Adcock Ingram Critical Care</td></tr>
<tr><td>Various</td><td>SCHEDULE 0 HUMAN MEDICINES</td><td>Various</td><td>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.</td><td></td><td>Various</td></tr>
</table>

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

NO **C 46** **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 **14 and 15 April 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

NR **C46** **2011**

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)

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 **14 and 15 April 2011**, 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 van10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.

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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 UITSLUITNG	APPLICANT/ APPLIKANT
36/8.5/0156	XIGRIS 20mg	Powder for Solution for Infusion	**Regulation 8**: labelling of medicines intended for human administration in so far as on the outer 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)]. **Regulation 8(3)**: to allow for the inclusion of additional information on the label of the medicine, which will include the name of the Lilly Manufacturer i.e. Lilly Pharma Fertigung und Distribution GmbH & Co. KG, Giessen, Germany.	**Provided that** the exemption is only valid for 50 units imported for 2011 and that a South African package insert be included in the product as per the provisions of Regulation 9 of the Medicines and Related Substances Act, 1965.	Eli Lilly SA (Pty) Ltd
Unregistered	Various Veterinary Medicines	Various	**Regulation 45(3)** of the Medicines and Related Substances Act, 1965 to allow for the advertising / exhibition of unregistered veterinary medicines at the 30th World Veterinary Congress to be hosted in Cape Town 10 to 14 October 2011 at the Cape Town International Convention Centre. Council resolved that in terms of Section 36 of the Medicines and Substances Control Act (Act 101 of 1965), to recommend to Minister that at the forthcoming 30th World Veterinary Congress medicines on display be exempted from the requirements of Regulation 45 (3).	**Provided that** the exemption: • Will only be applicable for the duration of the congress (10 to 14 October 2011). • No trade names are to be used or displayed on the products. • Only relevant clinical data be made available to the veterinarians.	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
Various	Various Veterinary Medicines	Various	**Section 22G** and **Section 18A** 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.	**Provided that** In the sale of veterinary medicines, all persons licensed in terms of Section 22C of the act, must not discriminate within the same category of buyers. **Note:** For the purposes of this notice "Category of buyers" refers to Veterinarians/Wholesalers, Distributors, and Intensive Animal Producers/ Feedlots as groups of customers that buy veterinary medicines. Discrimination, in relation to the sale of veterinary medicines means the operation of a differential pricing system, whereby the same veterinary medicines are sold at different prices to the same categories of buyers.	Various