

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

| 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 | <p>Regulation 8: labelling of medicines intended for human administration in so far as on the outer container label:</p> <p>Bilingualism [Regulation 8(1)].</p> <p>Inclusion of the scheduling status [Regulation 8(1)(a)]</p> <p>Registration number [Regulation 8(1) (c)].</p> <p>Name of holder of certificate of registration [Regulation 8(1) (p)].</p> <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.</p> | <p>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.</p> | Eli Lilly SA (Pty) Ltd |
| Unregistered | Various Veterinary Medicines | Various | <p>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.</p> <p>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).</p> | <p>Provided that the exemption:</p> <ul style="list-style-type: none"> 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 |

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|------------------------------------|--|---|--|--|-------------------------|
| 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. | <p>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.</p> <p>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.</p> <p>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.</p> | Various |

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