MEDICINES CONTROL COUNCIL

EXEMPTIONS IN TERMS OF SECTION 36 OF ACT 101

Section 36 Exclusion of any drug from operation of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). – The Minister may, on the unanimous recommendation of the members present at any meeting of the Council, by notice in the *Gazette* exclude, subject to such conditions as he/she may determine, any medicine from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice**.**

Section 18(4) Labels and advertisements - The Council may authorise a deviation from the prescribed format and contents of any label.

Regulation 8(3) Labelling - The Council may authorise the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included.

Exemptions/Withdrawal of exemptions in terms of the provisions of Section 36 of the Medicines and Related Substances Act, 1965 for the period February 2005 to June 2005

C8 - Council meeting of 11 Feb 2005					
REGISTRATION NO./ REGISTRASIENR.	**NAME OF MEDICINE/ NAAM VAN MEDISYNE**	**FORM OF PREPARATION/ BEREIDINGSVORM**	**PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT**	**CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING**	**APPLICANT/ APPLIKANT**
27/26/0181	Immukine 0,1mg	Tablets	Regulation 8 (1): Information to appear on the immediate container label: Bilingualism, (a) Scheduling status, (b) Proprietary name, (q) Registration number, (r) Name of Holder of Certificate of Registration		Ingelheim Pharmaceuticals (Pty) Ltd
S/16.4/144	Strepsils Orange-C	Tablets	Regulation 9 Bilingualism Regulation 9(1): inclusion of a package insert	Provided that the packaging of all carton packs of 2, 4, 6, 8 or 24 complies with the requirements of Regulation 10 (1) to contain a patient information leaflet.	Booths Healthcare (Pty) Ltd
S/16.4/144	Strepsils Orange-C (Aluminium packaging of 2's)	Tablets	Regulation 9 Bilingualism Regulation 9 (1): inclusion of a package insert and Regulation 10(1): inclusion of a patient information leaflet	Provided that the Aluminium packaging of 2's complies with the requirements of an abbreviated PIL Regulation 10 (1) and that the reference to "insect bites" be removed from the text under the heading "what this medicine is used for" on the Patient Information Leaflet.	Booths Healthcare (Pty) Ltd
E/16.4/46	Strepsils Soothing Honey & Lemon	Tablets	Regulation 9: Bilingualism Regulation 9 (1): inclusion of a package insert	Provided that the packaging of all carton packs of 2, 4 6, 8 or 24 complies with the requirements of Regulation 10 (1) to contain a patient information leaflet.	Booths Healthcare (Pty) Ltd

C8 - Council meeting of 11 Feb 2005					
REGISTRATION NO./ REGISTRASIENR.	**NAME OF MEDICINE/ NAAM VAN MEDISYNE**	**FORM OF PREPARATION/ BEREIDINGSVORM**	**PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT**	**CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING**	**APPLICANT/ APPLIKANT**
E/16.4/46	Strepsils Soothing Honey & Lemon (Aluminium packaging of 2's)	Tablets	Regulation 9: Bilingualism Regulation 9 (1): inclusion of a package insert and Regulation 10 (1): inclusion of a patient information leaflet	Provided that the Aluminium packaging of 2's complies with the requirements of an abbreviated PIL Regulation 10 (1) and that the storage condition of the medicine be identified as to include reference to "below 25 °C"	Booths Healthcare (Pty) Ltd
29/34/0037	Oxygen	Gases	Regulation 8 (1): Bilingualism	Provided that the name of the medicine remains "Oxygen" and that the wording "may cause fire and explosion" be added under the heading "Risk"	Afrox Care
29/34/0044	Nitrous Oxide	Gases	Regulation 8 (1): Bilingualism	Provided that the name of the medicine remains "Nitrous Oxide" and that the wording "may cause fire and explosion" be added under the heading "Risk"	Afrox Care

REGISTRATION NO./ REGISTRASIENR.	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGSVORM	PROVISIONS FROM WHICH EXCLUDED / BEPALINGS WAARVAN UITGESLUIT WITHDRAWN / HERROEP	APPLICANT/ APPLIKANT
29/34/0037	Oxygen	Gases	Medicines Control Council resolution RN 147 October 1994 of 1. Regulation 1 (proprietary name): The requirement that each medicine shall have a unique “proprietary name” as defined in regulation 1. 2. Regulation 9: The requirement that the container of every medicine which is sold shall have a label attached on which the details prescribed in regulation 9 appears. 3. Regulation 10: The requirement that each package of a medicine shall be accompanied by a package insert.	Afrox Care
29/34/0044	Nitrous Oxide	Gases	Medicines Control Council resolution RN 147 October 1994 of 1. Regulation 1 (proprietary name): The requirement that each medicine shall have a unique “proprietary name” as defined in regulation 1. 2. Regulation 9: The requirement that the container of every medicine which is sold shall have a label attached on which the details prescribed in regulation 9 appears. 3. Regulation 10: The requirement that each package of a medicine shall be accompanied by a package insert.	Afrox Care

C9 - Council meeting of 8 April 2005					
REGISTRATION NO./ REGISTRASIENR.	**NAME OF MEDICINE/ NAAM VAN MEDISYNE**	**FORM OF PREPARATION/ BEREIDINGSVORM**	**PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT**	**CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING**	**APPLICANT/ APPLIKANT**
370305	Mabcampath	Injection (immediate container label)	Regulation 8 (1) (immediate container label): Labelling of medicine intended for administration to human insofar as: Information on the label of the product to appear in English and at least one other official language (f) approved name of active ingredient (p) name of Holder of Certificate of Registration Sect 19 (1) (Prescribed requirements insofar as the re-assay and re-identification of the medicine post importation. Regulation 8 (1) (outer container label): Labelling of medicine intended for administration to human insofar as: Information on the label of the product to appear in English and at least one other official language (a) in the case of a medicine listed in any Schedule made in terms of the Act, the letter 'S' followed by the number of the relevant Schedule, in a prominent type size and face and surrounded by a square border, immediately preceding the proprietary name of such medicine (c) the registration number of the medicine allocated in terms of section 15(6) of the Act (p) name of Holder of Certificate of Registration		Schering

C9 - Council meeting of 8 April 2005					
REGISTRATION NO./ REGISTRASIENR.	**NAME OF MEDICINE/ NAAM VAN MEDISYNE**	**FORM OF PREPARATION/ BEREIDINGSVORM**	**PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT**	**CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING**	**APPLICANT/ APPLIKANT**
380180	Pegasys 135 pre-filled	Injection	Regulation 8 (1) (immediate and outer container label): Bilingualism and Regulation 10: Patient Information Leaflet (1) Bilingualism (a) Scheduling status (q) Registration number (r) Name and address of the holder of the certificate of registration and Regulation 8 (3): to allow for additional information to appear on the package insert in French/Arabic	Provided that the exemption is only applicable to the supply of medicine to 100 patients per year and that the Registration Number of the product be affixed and that the package insert indicates it is a South African Package Insert	Roche Products (Pty) Ltd
Unregistered	Sandoz Cefuroxime 125 mg/5 ml	Powder	Section 15 (1): that every application for the registration of a medicine shall be submitted to the Registrar accompanied by the sample of the relevant medicine.	Provided that the sample be submitted by December 2005	Sandoz
A380656	Faslodex	Injection	Regulation 8(1) (immediate and outer container label): Bilingualism		Astra Zeneca
Unregistered	Aquacel	Wafer	Regulation 8(1) (immediate container label): Bilingualism		BristolMyers Squibb
97/3.1/7	Ketofen 20 mg	Tablet	Regulation 48 (1) (immediate container label): One official language		Merial South Africa (Pty) Ltd

C10 - Council meeting of 3 June 2005					
REGISTRATION NO./ REGISTRASIENR.	**NAME OF MEDICINE/ NAAM VAN MEDISYNE**	**FORM OF PREPARATION/ BEREIDINGSVORM**	**PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT**	**CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING**	**APPLICANT/ APPLIKANT**
T/20.1.2/33	Sandoz Flucloxacillin	Tablets	Regulation 8(1): Bilingualism	Supplied on Tender to the State and packed in Patient Ready Packs	Sandoz (Pty) Ltd
P/8.2/177	Fenwal primary container with Citrate phosphate Glucose Adenine Anticoagulant	Solution	Regulation 10: Patient Information Leaflet		Adcock Ingram Critical Care