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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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GOVERNMENT NOTICES GOEWERMENSKENNISGEWINGS

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 755

7 June 2002

REGULATIONS UNDER THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT No. 101 OF 1965): AMENDMENT

The Minister of Health has, in terms of section 35 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), on the recommendation of the Medicines Control Council, made the regulations contained in the Schedule hereto.

SCHEDULE

Definition

1. In this Schedule "the Regulations" means the regulations published by Government Notice No. R. 352 of 21 February 1975, as amended.

Substitution of regulation 35 of the Regulations

2. The following is hereby substituted for regulation 35 of the Regulations:

"FEES

35. The following fees shall be payable to the Registrar:

(1) Category A medicines:

(a) Human medicines, including Biologicals, compounded in its entirety in the RSA or not, for which an application for registration has been submitted as contemplated in section 15 of the Act:

(i) Application for registration—

- (aa) of medicine contemplated in section 15 (hereinafter referred to as an old medicine): R5 000 per application;
- (bb) of New Chemical Entities: R30 000 per application;
- (cc) of AMRP: R30 000 per application;
- (dd) of Fast Track: R30 000 per application;
- (ee) of Biological: R30 000 per application;
- (ff) of Biological EDL: R12 000 per application;
- (gg) of Generic: R12 500 per application;
- (hh) of Generic EDL: R10 000 per application;
- (ii) of Products containing similar active ingredients: R20 000 per application.

(2) Category C medicines:

(a) Veterinary medicines, including Biologicals, whether compounded in the RSA or not:

(i) Application for registration—

- (aa) of medicine in section 14 (3) (hereinafter referred to as an old medicine): R800 per application;
- (bb) of New Chemical Entities: R3 800 per application;
- (cc) of Generic: R3 800 per application;
- (dd) of Homeopathic: R3 800 per application;

(ii) In respect of the registration of a medicine, the registration of which has been approved by the Council in terms of section 15—

- (aa) of Old medicines: R600 per application;
- (bb) of New Chemical Entities: R600 per application;
- (cc) of AMRP: R600 per application;
- (dd) of Fast Track: R600 per application;
- (ee) of Biological: R600 per application;
- (ff) of Biological EDL: R600 per application;
- (gg) of Generic: R600 per application;

- (hh) of Generic EDL: R600 per application;
- (ii) of Products containing similar active ingredients: R600 per application;
- (iii) fees for registration of Veterinary medicines, including Biologicals whether compounded in the RSA or not—
 - (aa) of Old medicines: R600 per application;
 - (bb) of New Chemical Entities: R600 per application;
 - (cc) of Generic: R600 per application;
 - (dd) of Homeopathic: R600 per application;
- (iv) Annual fees in respect of the retention of the registration of the medicines, the registration of which has been approved by the Council:
 - (aa) of Old medicines: R550;
 - (bb) New Chemical Entities: R550;
 - (cc) AMRP: R550;
 - (dd) Fast Track: R550;
 - (ee) Biological: R550;
 - (ff) Biological EDL: R550;
 - (gg) Generic: R550;
 - (hh) Generic EDL: R550;
 - (ii) Products containing similar active ingredients: R550;
- (v) Annual fees in respect of the retention of the registration of the veterinary medicines, the registration of which has been approved by the Council—
 - (aa) Old medicines: R350;
 - (bb) New Chemical Entities: R350;
 - (cc) Generic: R350;
 - (dd) Homeopathic: R120;

Amendments

- (vi) Fees in respect of application for administrative amendments which include an amendment of an entry in the register, and transfer of the certificate of registration—
 - (aa) Administrative: R220;
- (vii) Fees in respect of application for technical amendments which include an amendment of entry in the register, and transfer of the certificate of registration—
 - (aa) Technical: R600;

Other fees

- (viii) Newly created fees for services rendered for which no fees were charged—
 - (aa) Screening fee: R1 050;
 - (bb) Clinical trial (C): R6 300;
 - (cc) Clinical Trial (N): R3 150;
 - (dd) Clinical Trial (A): R1 050;
 - (ee) Clinical Trial (T): R320;
 - (ff) Any other clinical trial: R1 075;
 - (gg) Package Insert amendment: R2 100;
 - (hh) Rescheduling: R1 900;
 - (ii) Resubmission Clinical data: R1 900;
- (ix) Newly created fees for which permits and certificates were issued and no fees were charged—
 - (aa) WHO Certificates: R525;
 - (bb) Free Sale Certificates: R265;
 - (cc) GMP Certificates: R525;
 - (dd) Import Permit: R315;
 - (ee) Export Permit: R315;
 - (ff) Narcotic Permit: R525;
- (x) Fees created for services for which no fees were charged—inspections—
 - (aa) Pre-approval inspections—Super site: R160 per hour;

- (bb) Pre-approval inspection—Major site: R140 per hour;
- (cc) Pre-approval inspection—Standard: R120 per hour;
- (dd) Pre-approval inspection—Minor: R110 per hour;
- (ee) Follow-up inspection—Super site: R110 per hour;
- (ff) Follow-up inspection—Major site: R90 per hour;
- (gg) Follow-up inspection—Standard: R60 per hour;
- (hh) Follow-up inspections—Minor site: R50 per hour.

The above fees are applicable with effect from the 1st July 2002.

MANTO TSHABALALA-MSIMANG
Minister of Health

DEPARTMENT OF LABOUR DEPARTEMENT VAN ARBEID

No. R. 754

7 June 2002

NOTICE OF EXEMPTION IN TERMS OF SECTION 40 (1) OF THE OCCUPATIONAL HEALTH AND SAFETY ACT, 1993

Under section 40 (3) (b) of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), I, Moses Pudikabekwa, appointed as chief inspector in terms of section 27 (1) of the said Act, and by virtue of the power delegated to me by the Minister of Labour in terms of section 42 (1) of the Act, hereby grant exemption in terms of section 40 (1) until 1 June 2003 to all test stations that are registered under the incorporated health and safety standard South African Bureau of Standard 019:1985 under regulation 10 of the Vessels under Pressure Regulations, published under *Government Gazette* Notice No. R. 1591 of 4 October 1996.

This exemption is subject to the following conditions:

1. All test stations shall obtain accreditation before approval from the government endorsed national accreditation body, the "South African National Accreditation System"; and
2. the accreditation in terms of clause 7.2.2 of the South African Bureau of Standard 019 as amended, as incorporated under regulation 10 of the Vessels under Pressure Regulations, shall be in terms of—
 - (a) ISO 17020 "General criteria for the operation of various types of bodies performing inspection"; and
 - (b) SABS 1825 "Portable gas cylinder test stations—approval and general requirements".

M. PUDIKABEKWA
Chief Inspector

DEPARTMENT OF MINERALS AND ENERGY DEPARTEMENT VAN MINERALE EN ENERGIE

No. R. 759

7 June 2002

MINES AND WORKS ACT, 1956 (ACT No. 27 OF 1956)

DECLARATION OF WORK IN THE NATIONAL INTEREST

Under section 9 (1) (f) of the Mines and Works Act, 1956 (Act No. 27 of 1956), I, Phumizile Mlambo-Ngcuka, Minister of Minerals and Energy, hereby declare that in my opinion the performance of all work necessary and incidental to the normal production of gold and the development of access ways to payable ore reserves on Sundays, at the mine known as Placer Dome Western Areas Joint Venture—South Deep in the District of Westonaria, Province of Gauteng, is necessary in the national interest for a period of one year from 1 July 2002.

P. MLAMBO-NGCUKA
Minister of Minerals and Energy

DEPARTMENT OF PUBLIC SERVICE AND ADMINISTRATION DEPARTEMENT VAN STAATSDIENS EN ADMINISTRASIE

No. R. 753

7 June 2002

AMENDMENT OF PUBLIC SERVICE REGULATIONS, 2001

The Minister for the Public Service and Administration has, under section 41 of the Public Service Act, 1994 (promulgated under Proclamation No. 103 of 1994), amended the Public Service Regulations, 2001 (promulgated under Government Notice R. 1 of 5 January 2001), as amended, as set out in the Schedule.

SCHEDULE

The following regulations are hereby substituted for regulations III J.3 and J.4 of Chapter 1:

"J.3 From 1 April 2001, the annual report shall include such information on planning, service delivery, organisation, job evaluation, remuneration, benefits, personnel expenditure, the utilisation of consultants, affirmative action, recruitment, promotions, termination of services, performance management, skills development, injury on duty, labour relations, leave and discharge due to ill-health, as the Minister determines. In this regulation 'consultant' means a natural or juristic person or a partnership who or which provides in terms of a specific contract on an ad hoc basis any of the following professional services to a department against remuneration received from any source:

- (a) The rendering of expert advice;
- (b) the drafting of proposals for the execution of specific tasks; and
- (c) the executing of a specific task which is of a technical or intellectual nature,

but excludes an employee of a department.

J.4 The Minister shall determine from time to time the format in which the information referred to in regulation III J.3 is to be included in the annual report."

**DEPARTMENT OF TRADE AND INDUSTRY
DEPARTEMENT VAN HANDEL EN NYWERHEID**

No. R. 758**7 June 2002**

**HOUSING DEVELOPMENT SCHEMES FOR RETIRED PERSONS ACT
(ACT No. 65 OF 1988)**

I, Alexander Erwin, Minister of Trade and Industry hereby declare under section 11 (h) of the Housing Development Schemes for Retired Persons Act, 1988 (Act No. 65 of 1988), Mooigelee Oord a development on Erf. 901 and 806, Faerie Glen Extension 2, a housing development scheme for the purposes of the mentioned Act.

A. ERWIN
Minister of Trade and Industry

**SOUTH AFRICAN REVENUE SERVICE
SUID-AFRIKAANSE INKOMSTEDIENS**

No. R. 774

7 June 2002

**CUSTOMS AND EXCISE ACT, 1964.-
AMENDMENT OF SCHEDULE NO. 2 (NO. 2/107)**

Under section 56 of the Customs and Excise Act, 1964, Part 1 of Schedule No. 2 to the said Act is hereby amended to the extent set out in the Schedule hereto.

**M MPAHLWA
DEPUTY MINISTER OF FINANCE**

SCHEDULE

I Item	II				III Rebate Items	IV Imported from or originating in	V Rate of anti- dumping duty	Annotations
	Tariff Heading	Code	C D	Description				
215.11		"02.06	61	By the substitution for code 02.06 to tariff heading 8201.30 of the following: Picks (excluding those certified by Divy-Jyot Agricultural Pvt Ltd and by Fivestar Agrico Pvt Ltd as being manufactured by them and subsequently exported by Indo Euro Exports of 280 Shiv Kutir, Ground Floor, Veer Savarkar Marg, Shivaji Park, Mumbai 100 028 India)		India	57,7%"	
		"05.06	65	By the substitution for code 05.06 to tariff heading 8201.30 of the following: Picks certified by Divy-Jyot Agricultural Pvt Ltd and by Fivestar Agrico Pvt Ltd as being manufactured by them and subsequently exported by Indo Euro Exports of 280 Shiv Kutir, Ground Floor, Veer Savarkar Marg, Shivaji Park, Mumbai 100 028 India		India	4,6%"	

No. R. 774

7 Junie 2002

**DOEANE- EN AKSYNSWET 1964.-
WYSIGING VAN BYLAE NO. 2 (NO. 2/107)**

Kragtens artikel 56 van die Doeane- en Aksynswet, 1964, word Deel 1 van Bylae No. 2 by genoemde Wet hiermee gewysig in die mate in die Bylae hierby aangetoon.

**M MPAHLWA
ADJUNKMINISTER VAN FINANSIES**

BYLAE

I Item	II				III Kort= ing= items	IV Ingevoer vanaf of afkomstig van	V Skaal van anti- dumping reg	Anno= tasies
	Tarief= pos	Kode	T S	Beskrywing				
215.11		"02.06	61	Deur kode 02.06 by tariefpos 8201.30 deur die volgende te vervang: Pikke (uitgesonderd dié gesertifiseer deur Divy-Jyot Agricultural Pvt Ltd en deur Fivestar Agrico Pvt Ltd as synde deur hulle vervaardig en vervolgens uitgevoer deur Indo Euro Exports van 280 Shiv Kutir, Ground Floor, Veer Savarkar Marg, Shivaji Park, Mumbai 100 028 India)		Indië	57,7%"	
		"05.06	65	Deur kode 05.06 by tariefpos 8201.30 deur die volgende te vervang: Pikke gesertifiseer deur Divy-Jyot Agricultural Pvt Ltd en deur Fivestar Agrico Pvt Ltd as synde deur hulle vervaardig en vervolgens uitgevoer deur Indo Euro Exports van 280 Shiv Kutir, Ground Floor, Veer Savarkar Marg, Shivaji Park, Mumbai 100 028 India		Indië	4,6%"	

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