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GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 1146 **12 July 1996**

THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

REGULATIONS RELATING TO THE REGISTRATION OF ADDITIONAL QUALIFICATIONS: AMENDMENT

The Minister of Health has, in terms of section 61 (1) (o), read with section 61 (4) of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act No. 56 of 1974), on the recommendation of the South African Medical and Dental Council, made the regulations in the Schedule.

SCHEDULE

1. In these regulations "the Regulations" means the regulations published by Government Notice No. R. 2275 of 3 December 1976, as amended by Government Notices Nos. R. 1829 of 16 September 1977, R. 443 of 10 March 1978, R. 1034 of 26 May 1978, R. 811 of 20 April 1979, R. 2720 of 11 December 1981, R. 1097 of 30 May 1984, R. 2731 of 13 December 1985, R. 681 of 3 April 1987, R. 205 of 19 February 1988, R. 598 of 31 March 1989, R. 997 of 3 April 1992 and R. 2411 of 17 December 1993.

2. The Regulations are hereby amended by the addition of the following qualifications under the headings as indicated:

(a) MEDICAL PRACTITIONERS

Examining authority	*Qualification*	*Abbreviation for registration*
"College of Anaesthetists of South Africa"	"Fellowship"	FCA (SA)
	"Diploma in Anaesthesiology"	DA (SA)
"College of Community Health of South Africa"	"Fellowship"	FCCH (SA)
"College of Dermatologists of South Africa"	"Fellowship"	FC Derm (SA)
"College of Family Practitioners of South Africa"	"Membership"	MCFP (SA)
	"Diploma in Primary Emergency Care"	Dip Pec (SA)
"College of Forensic Pathologists of South Africa"	"Fellowship"	FC for Path (SA)
	"Diploma in Forensic Medicine"	Dip for Med (SA)
"College of Obstetricians and Gynaecologists of South Africa"	"Diploma in Obstetrics"	Dip Obst (SA)
"College of Paediatricians of South Africa"	"Fellowship"	FC Paed (SA)
	"Diploma in Child Health"	DCH (SA)
"College of Pathologists of South Africa"	"Fellowship (Anatomical Pathology)"	FC Path (SA) ANAT
	"Fellowship (Chemical Pathology)"	FC Path (SA) CHEM
	"Fellowship (Clinical Pathology)"	FC Path (SA) CLIN
	"Fellowship (Clinical Virology)"	FC Path (SA) VIRO
	"Fellowship (Haematology)"	FC Path (SA) HAEM
	"Fellowship (Medical Microbiology)"	FC Path (SA) MICRO
"College of Psychiatrists of South Africa	"Fellowship"	FC Psych (SA)
	"Diploma in Mental Health"	DMH (SA)
"College of Radiologists of South Africa	"Fellowship (Diagnostic Radiology)"	FC Rad (SA) DIAG
	"Fellowship (Radiation Oncology)"	FC Rad (SA) ONC
College of Surgeons of South Africa	"Diploma in Ophthalmology"	Dip Ophth (SA) FFANZCA
"Faculty of the Australian and New Zealand College of Anaesthetists"	"Fellowship"	
"Royal Australian and New Zealand College of Psychiatrists"	"Fellowship"	FRANZC (Psych)
"Royal College of Anaesthetists of England"	"Fellowship"	FRCA Eng
Royal College of Physicians and Surgeons of Canada	"Fellowship (Ophthalmology)"	FRCS (Ophth) Canada
University of Aberdeen	"Master of Science in Clinical Pharmacology"	MSc (Clin Pharm) Aberdeen
"University of Bialstok"	"Doctor of Philosophy"	PhD Bialstok
University of Edinburgh	"Diploma in Social Medicine"	Dip Soc Med Edin
"University of Gdynia"	"Doctor of Philosophy"	PhD Gdynia
University of Geneva	"Doctor of Philosophy"	PhD Geneva
"University of Jerusalem"	"Diploma in Family Medicine"	DFM Jerusalem
University of London	"Master of Science in Clinical Dermatology"	MSc (Clin Derm) London
	"Master of Science in Clinical Microbiology"	MSc (Clin Micro) London
"London School of Health and Tropical Tropical Medicine"	"Master of Science in Community Health in Developing Countries"	MSc (Com H in Dev Countries) LSHTM
University of Natal	"Master of Medicine (Anaesthesiology)"	MMed (Anaes) Natal
	"Master of Medicine (Anatomical Pathology)"	MMed (Anat Path) Natal

Examining authority	*Qualification*	*Abbreviation for registration*
	"Master of Medicine (Cardiothoracic Surgery)"	MMed (Cardio-Thorac) Natal
	"Master of Medicine (Chemical Pathology)"	MMed (Chem Path) Natal
	"Master of Medicine (Community Health)"	MMed (Comm Health) Natal
	"Master of Medicine (Forensic Pathology)"	MMed (For Path) Natal
	"Master of Medicine (Surgery)"	MMed (Surg) Natal
	"Master of Medicine (Haematology)"	MMed (Haem) Natal
	"Master of Medicine (Clinical Pathology)"	MMed (Clin Path) Natal
	"Master of Medicine (Medical Microbiology)"	MMed (Micro) Natal
	"Master of Medicine (Medicine)"	MMed Natal
	"Master of Medicine (Neurosurgery)"	MMed (Neurosurg) Natal
	"Master of Medicine (Ophthalmology)"	MMed (Ophth) Natal
	"Master of Medicine (Orthopaedic Surgery)"	MMed (Orth) Natal
	"Master of Medicine (Otorhinolaryngology)"	MMed (Otol) Natal
	"Master of Medicine (Obstetrics and Gynaecology)"	MMed (O & G) Natal
	"Master of Medicine (Paediatrics and Child Health)"	MMed (Paed) Natal
	"Master of Medicine (Plastic and Reconstructive Surgery)"	MMed (Plast and Recon Surg) Natal
	"Master of Medicine (Psychiatry)	MMed (Psych) Natal
	"Master of Medicine (Radiology)"	MMed (Rad D) Natal
	"Master of Medicine (Radiotherapy and Oncology)"	MMed (Rad and Onc) Natal
	"Master of Medicine (Urology)"	MMed (Urol) Natal
	"Master of Medicine (Virology)"	MMed (Virol) Natal
	"Master of Family Medicine"	M Fam Med Natal
University of Osmania	"Diploma in Forensic Medicine"	Dip For Med Osmania
"Potchefstroom University for Christian Higher Education"	"Bachelor of Science (Honours) in Pharmacology"	BSc (Hons) Pharm Potch
University of Pretoria	"Bachelor of Science (Honours) in Physiology"	BSc (Hons) Physio Pret
Medical University of Southern Africa	"Master of Family Medicine"	M Fam Med Medunsa
"University of South Gujarat"	"Diploma in Gynaecology and Obstetrics"	DGO South Gujarat
"University of Zabrze"	"Doctor of Philosophy"	PhD Zabrze
	(b) DENTISTS	
"College of Dentistry of South Africa	"Fellowship (Maxillofacial and Oral Surgery)"	FCD (SA) MFOS
	"Fellowship (Oral Medicine and Periodontics)"	FCD (SA) OMP
	"Fellowship (Orthodontics)"	FCD (SA) ORTHOD
	"Fellowship (Prostodontics)"	FCD (SA) PROS
	"Diploma in Dentistry"	Dip Dent (SA)
Medical University of Southern Africa	"Master of Dental Surgery"	MDS MEDUNSA

No. R. 1146 **12 Julie 1996**

DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

REGULASIES BETREFFENDE DIE REGISTRASIE VAN ADDISIONELE KWALIFIKASIES: WYSIGING

Die Minister van Gesondheid het kragtens artikel 61 (1) (o), gelees met artikel 61 (4) van die Wet op Geneeshere, Tandartse en Aanvullende Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), op aanbeveling van die Suid-Afrikaanse Geneeskundige en Tandheelkundige Raad, die regulasies in die Bylae uitgevaardig.

BYLAE

1. In hierdie regulasies beteken "die Regulasies" die regulasies afgekondig by Goewermentskennisgewing No. R. 2275 van 3 Desember 1976, soos gewysig by Goewermentskennisgewings Nos. R. 1829 van 16 September 1977, R. 443 van 10 Maart 1978, R. 1034 van 26 Mei 1978, R. 811 van 20 April 1979, R. 2720 van 11 Desember 1981, R. 1097 van 30 Mei 1984, R. 2731 van 13 Desember 1985, R. 681 van 3 April 1987, R. 205 van 19 Februarie 1988, R. 598 van 31 Maart 1989, R. 997 van 3 April 1992 en R. 2411 van 17 Desember 1993.

2. Die Regulasies word hierby gewysig deur die byvoeging van die volgende kwalifikasies onder die opskrifte soos aangedui.

(a) GENEESHERE

Eksaminerende liggaam	*Kwalifikasie*	*Afkorting vir registrasie*
"Kollege van Narkotiseurs van Suid-Afrika"	"Genootskap"	GKN (SA)
	"Diploma in Anestesiologie"	DA (SA)
"Kollege van Gemeenskapsgesondheid van Suid-Afrika"	"Genootskap"	GKG (SA)
"Kollege van Dermatoloë van Suid-Afrika"	"Genootskap"	GK Derm (SA)
"Kollege van Huisartse van Suid-Afrika"	"Lidskap"	LKH (SA)
	"Diploma in Primêre Noodsorg"	Dip Pns (SA)
"Kollege van Geregtelike Patoloë van Suid-Afrika"	"Genootskap"	GK Gereg Pat (SA)
	"Diploma in Geregtelike Geneeskunde"	Dip Gereg Gen (SA)
"Kollege van Obstetrici en Ginekoloë van Suid-Afrika"	"Diploma in Obstetrie"	Dip Obst (SA)
"Kollege van Pediaters van Suid-Afrika"	"Genootskap"	GK Ped (SA)
	"Diploma in Kindergesondheid"	DKG (SA)
"Kollege van Patoloë van Suid-Afrika"	"Genootskap (Anatomiese Patologie)"	GK Pat (SA) ANAT
	"Genootskap (Chemiese Patologie)"	GK Pat (SA) CHEM
	"Genootskap (Hematologie)"	GK Pat (SA) HEMA
	"Genootskap (Kliniese Patologie)"	GK Pat (SA) KLIN
	"Genootskap (Kliniese Virologie)"	GK Pat (SA) VIRO
	"Genootskap (Mediese Mikrobiologie)"	GK Pat (SA) MICRO
"Kollege van Psigiaters van Suid-Afrika"	"Genootskap"	KG Psig (SA)
	"Diploma in Geestesgesondheid"	DGG (SA)
"Kollege van Radioloë van Suid-Afrika"	"Genootskap (Diagnostiese Radiologie)"	GK Rad (SA) DIAG
	"Genootskap (Radiologiese Onkologie)"	GK Rad (SA) ONK
Kollege van Chirurge van Suid-Afrika	"Diploma in Oftalmologie"	Dip Oft (SA)
"Faculty of the Australian and New Zealand College of Anaesthetists"	"Fellowship"	FFANZCA
"Royal Australian and New Zealand College of Psychiatrists"	"Fellowship"	FRANZC (Psych)
"Royal College of Anaesthetists of England"	"Fellowship"	FRCA Eng
Royal College of Physicians and Surgeons of Canada	"Fellowship (Ophthalmology)"	FRCS (Ophth) Canada
Universiteit van Aberdeen	"Master of Science in Clinical Pharmacology"	MSc (Clin Pharm) Aberdeen

Eksaminerende liggaam	*Kwalifikasie*	*Afkorting vir registrasie*
"Universiteit van Bialstok"	"Dokter in Wysbegeerte"	PhD Bialstok
Universiteit van Edinburgh	"Diploma in Social Medicine"	Dip Soc Med Edin
"Universiteit van Gdynia"	"Dokter in Wysbegeerte"	PhD Gdynia
Universiteit van Genéve	"Dokter in Wysbegeerte"	PhD Genéve
"Universiteit van Jerusalem"	"Diploma in Family Medicine"	DFM Jerusalem
Universiteit van Londen	"Master of Science in Clinical Dermatology"	MSc (Clin Derm) London
	"Master of Science in Clinical Microbiology"	MSc (Clin Micro) London
"London School of Health and Tropical Medicine"	"Master of Science in Community Health in Developing Countries"	MSc (Com H in Dev Countries) LSHTM
Universiteit van Natal	"Magister in Geneeskunde (Anestesiologie)"	MMed (Anes) Natal
	"Magister in Geneeskunde (Anatomiese Patologie)"	MMed (Anat Pat) Natal
	"Magister in Geneeskunde (Kardiotorakale Chirurgie)"	MMed (Kardio-Torak) Natal
	"Magister in Geneeskunde (Chemiese Patologie)"	MMed (Chem Pat) Natal
	"Magister in Geneeskunde (Gemeenskapsgesondheid)"	MMed (Gemeenskapsgesondheid) Natal
	"Magister in Geneeskunde (Forensiese Patologie)"	MMed (For Pat) Natal
	"Magister in Geneeskunde (Chirurgie)"	MMed (Shir) Natal
	"Magister in Geneeskunde (Hematologie)"	MMed (Hem) Natal
	"Magister in Geneeskundige (Kliniese Patologie)"	MMed (Klin Pat) Natal
	"Magister in Geneeskunde (Geneeskundige Mikro-biologie)"	MMed (Mikro) Natal
	"Magister in Geneeskunde (Interne Geneeskunde)"	MMed Natal
	"Magister in Geneeskunde (Neurochirurgie)"	MMed (Neurochir) Natal
	"Magister in Geneeskunde (Oftalmologie)"	MMed (Oft) Natal
	"Magister in Geneeskunde (Ortopediese Chirurgie)"	MMed (Ort) Natal
	"Magister in Geneeskunde (Otorinolaringologie)"	MMed (Otol) Natal
	"Magister in Geneeskunde (Obstetrie en Ginekologie)"	MMed (O en G) Natal
	"Magister in Geneeskunde (Pediatrie en Kindergesondheid)"	MMed (Ped) Natal
	"Magister in Geneeskunde (Plastiese en Rekonstruktiewe Chirurgie)"	MMed (Plast en Rekon Chir) Natal
	"Magister in Geneeskunde (Psigiatrie)"	MMed (Psig) Natal
	"Magister in Geneeskunde (Radiologie)"	MMed (Rad D) Natal
	"Magister in Geneeskunde (Radioterapie en Onkologie)"	MMed (Rad en Onk) Natal
	"Magister in Geneeskunde (Urologie)"	MMed (Urol) Natal
	"Magister in Geneeskunde (Virologie)"	MMed (Virol) Natal
	"Magister in Huisartskunde"	M Fam Med Natal

Eksaminerende liggaam	*Kwalifikasie*	*Afkorting vir registrasie*
Universiteit van Osmania	"Diploma in Geregtelike Geneeskunde"	Dip For Med Osmania
"Potchefstroom Universiteit vir Christelike Hoër Onderwys"	"Baccalaureus in Natuurwetenskap (Honorus) in Farmakologie"	BSc (Hons) Farm Potch
Universiteit van Pretoria	"Baccalaureus Scientae (Honorus) in Fisiologie"	BSc (Hons) Fis Pret
Mediese Universiteit van Suider-Afrika	"Magister in Huisartskunde"	M Fam Med Medunsa
"Universiteit van Suid-Gujarat"	"Diploma in Ginekologie en Obstetrie"	DGO South-Gujarat
"Universiteit van Zabrze"	"Doktor in Wysbegeerte"	PhD Zabrze
	(b) TANDARTSE	
"Kollege van Tandheelkunde van Suid-Afrika"	"Genootskap (Kaak-, Gesig- en Mondchirurgie)"	GKT (SA) KGM
	"Genootskap (Mondgeneeskunde en Periodonsie)"	GKT (SA) MGP
	"Genootskap (Ortodonsie)"	GKT (SA) ORTO
	"Genootskap (Prostodonsie)"	GKT (SA) PROS
	"Diploma in Tandheelkunde"	Dip Tand (SA)
Mediese Universiteit van Suider-Afrika	"Magister in Tandheelkundige Chirurgie"	MDS MEDUNSA

No. R. 1150 **12 July 1996**

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT No. 101 OF 1965)

GENERAL REGULATIONS

The Minister of Health in terms of section 35 of the Act, on the recommendation of the Medicines Control Council, intends to make the regulations in the Schedule hereto three months after the date of this notice. Interested parties are invited to comment hereon within fourty-five (45) days of the date of this notice. Comment should be sent to the Registrar of Medicines, Private Bag X828, Pretoria, 0001.

Additions and omissions to existing enactments are underlined and bracketted respectively.

SCHEDULE

1. Regulation 1 is amended by the inclusion of the following clauses:

Definitions

"Central Mark Control System" means a computer system, managed, secured and maintained by the Registrar of Medicines, which is used to issue to applicants, coded binary information unique to each package of a medicine or affixing thereon in the form of a multidimensional digital mark, and which is also used to record information required by regulation to be submitted to the Director-General by certain suppliers of medicines concerning the medicine's manufacturing and distribution processes.

"Multidimensional digital mark" means a computer generated, machine readable, multidimensional digital mark of at least nine square millimetres. The mark contains the prescribed information carried in a binary fashion which is unique to each package of the medicine to which it is affixed and which is authorised and supplied by the Registrar of Medicines according to a Central Mark Control System.

"Patient Information Leaflet (PIL)" means the information regarding a medicine as contemplated in regulation 10 (1).

"Scientific Package Insert" means the information regarding a medicine as contemplated in regulation 10 (4).

2. Amendment and additions to regulation 9

The following subregulation is added to regulation 9. In commenting, use the paragraph number as indicated. Note that in the General Regulations to be promulgated shortly, regulations 9 and 40 have been combined in a new regulation 12. Comments should take the labelling of veterinary medicines into consideration.

12. (5) The immediate container label and the outer label (carton) of all medicines registered in terms of the Act shall have a permanently affixed multidimensional digital mark as defined bearing at least the prescribed information applicable to the said product in the top right corner of the immediate container label or main panel of the outer label, and where a label has no logical right corner, immediately before the first letter of the proprietary name—

(i) in black;

(ii) in bright green when the medicine is sold to the State or when pre-packaged into patient ready packs by the State;

(iii) in blue when the medicine is sold for export.

Amendment to regulation 9 (1) (d). This also applies to veterinary medicines as indicated above.

(d) the approved international non-proprietary name (INN) of each active ingredient of the medicine and the quantity thereof contained in a dosage unit, or per suitable mass or volume or unit, in lettering which shall have a minimum legibility as defined in regulation 1: Provided that, for medicines containing a single active ingredient, such lettering shall not be less than **[one half]** the size of the largest lettering used for the said proprietary name and immediately following that name;

3. Regulation 10 is replaced by the following regulation:

PATIENT INFORMATION LEAFLETS (PIL's) AND SCIENTIFIC PACKAGE INSERTS:

Patient Information Leaflet (PIL)

10. (1) Save as provided in the proviso to subregulation (2) and subregulation (3), each package of a medicine shall be accompanied by a patient information leaflet, written in language that will be understandable to the layman, printed in at least the English language and in lettering having a minimum legibility as defined in regulation 1, under the headings and in the format specified in this regulation, containing only the following particulars relating to such medicine: Provided that if the package (shipper) includes more than one immediate container a patient information leaflet for every immediate container shall be included with the package (shipper). Notwithstanding the above, any other official or other language as approved by council may be used in addition:

(a) The scheduling status, that is the scheduling status of the medicine as determined from time to time by regulation;

(b) the proprietary name and dosage form of the medicine;

(c) what this medicine contains—the composition of the medicine i.e. the approved international non-proprietary name (INN) of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume of the medicine. All inactive ingredients must be listed qualitatively;

(d) what this medicine is used for—the registered indications for use of the medicine as accepted by Council in the approved scientific package insert;

(e) before taking this medicine—information regarding contra-indications, precautions, warnings, interactions, special warnings e.g. warnings concerning sedative properties of the medicine, warnings concerning the risks involved with sudden withdrawal of the medicine, etc. must be included here. The following general statements must be included in this section: "If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice." "If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice;"

(f) how to take this medicine—the recommended dosages must be included here. Any special information which the patient may require for the proper and safe use of the medicine should be provided;

(g) side effects—this section should contain in terms that the consumer will understand—

(i) the side-effects associated with the use of the particular medicine;

(ii) those side-effects which can be easily recognised by the patient;

(iii) the more serious side-effects;

(iv) information on what to do in specific circumstances, for example in the case of a missed dose, an unexpected reaction or in the case of an overdose;

(v) the following general statement: "Not all side-effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.".

(h) storage and disposal information—should contain information on how to store the medicine properly and how to dispose of unused medicine;

(i) presentation;

(j) identification of the medicine, i.e. a complete description of its physical appearance;

(k) the registration number, that is—

(i) the number allocated to the medicine by the Registrar in terms of section 15 (6) of the Act; or

(ii) in the case of a medicine in respect of which an application for registration was submitted in terms of section 14, subject to the provisions of subsection (2) (a), the reference number allocated to such application by the Registrar, followed by the expression "(Act No. 101 of 1965)";

(l) the name and business address of the applicant;

(m) the date of publishing of the patient information leaflet;

(n) the following general statements must be included:

(i) "Do not share medicines prescribed for you with others".

(ii) "Store all medicines out of reach of children".

(o) Provided that—

(i) if the Council determines that there is no applicable information to be furnished under a particular heading, such heading may be omitted with the approval of the Council;

(ii) the Council may, on application to it by an applicant, authorise the deviation from the format and content of a patient information leaflet prescribed as a condition of registration of a medicine; and

(iii) the Council may, on application being made to it by an applicant, authorise the inclusion on a patient information leaflet of any specified information not required by this regulation to be so included;

(iv) the Council may, on application being made to it by an applicant, authorise the attachment on the immediate container of a medicine, excluding a biological medicine, of the combined details prescribed in regulation 9 and this subregulation.

(2) The requirements of subregulation (1) shall apply to—

(a) any medicine sold by a medical practitioner, dentist, veterinarian, practitioner, nurse, pharmacist or authorised person in terms of section 22A (12) in the course of his/her professional activities for the treatment of a particular patient, except when the prescriber has endorsed the prescription with the words "Do not furnish details of the medicine";

(b) any medicine sold by a pharmacist, and in the case of a clinic or a hospital to outpatients, in accordance with a prescription issued by a medical practitioner, dentist, veterinarian, practitioner or nurse or authorised person in terms of section 22A (12) for the treatment of a particular patient, except when the prescriber has endorsed the prescription with the words "Do not furnish details of the medicine".

(3) The patient information leaflet does not replace the scientific package insert approved by council.

(4) Scientific Package Insert:

(a) Each medicine shall have available a scientific package insert printed in at least the English language and in lettering having a minimum legibility as defined in regulation 1, under the headings and in the format specified in this regulation. Notwithstanding the above, any other official or other language as approved by council may be used in addition.

(b) The Scientific Package Insert is to be used as an information sheet for health professionals and it will be the applicant's responsibility to provide every member of the health professions with the complete information in the scientific package insert at least—

(i) with every launch of a new product;

(ii) on request from health professionals;

(iii) with audio/visual promotional material;

(iv) by medical representatives when calling on health professionals;

(v) when a major amendment has been made to the package insert.

(c) Notwithstanding the above, this information may also be made available by means of electronic data transfer systems or any other methods as approved by Council.

(d) The following particulars relating to the medicine shall be contained in the scientific package insert:

(i) Scheduling status, as determined from time to time by regulation;

(ii) proprietary name of the medicine;

(iii) the dosage form of the medicine;

(iv) composition, that is—

(aa) the approved international non-proprietary name (INN) of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;

(bb) the approved name and percentage of any bactericidal or bacteriostatic agent included in the medicine as a preservative;

(cc) the approved name of any anti-oxidant contained in the medicine;

(dd) the quantity of ethyl alcohol included in a preparation for oral;

(ee) the warning in block letters "CONTAINS TARTRAZINE" should the medicine contain tartrazine;

(v) pharmacological classification, that is the category, the number and the description of the classification as required by regulations 4 and 5;

(vi) pharmacological action, that is a description of the pharmacological action of the medicine;

(vii) indications;

(viii) contra-indications;

(ix) warnings;

(x) dosage and directions for use;

(xi) side effects and special precautions;

(xii) known symptoms of overdosage and particulars of its treatment;

(xiii) identification of the medicine, i.e. a complete description of its physical appearance;

(xiv) presentation;

(xv) storage instructions—

(aa) which shall be practically formulated and which shall quote storage temperatures;

(bb) which shall include the words "Keep out of reach of children";

(xvi) registration number, that is—

(aa) the number allocated to the medicine in terms of section 15 (6) of the Act; or

(bb) in the case of a medicine in respect of which an application the registration was subsection in terms of section 14, subject to the provisions of subregulation (2) (a), the reference number allocated to such application, followed by the expression "(Act No. 101/1965)";

(xvii) the name and business address of the applicant;

(xviii) date of notification of approval of this package insert;

(e) Provided that—

(i) if the Council determines that there is no applicable information to be furnished under a particular heading, such heading may be omitted with the approval of the Council;

(ii) the Council, may on application being made to it by an applicant, authorise the deviation from the prescribed format and contents of a package insert;

(iii) the Council may, on application being made to it by an applicant, authorise the inclusion on a package insert of any specified information not required by this regulation to be so included.

(5) Medicines sold to the state:

(a) Each package of a medicine sold to the public sector shall contain both a patient information leaflet and a scientific package insert, where the provisions of sub-regulations 5 (b) and 5 (c) cannot be complied with.

(b) In the case of original packages of medicines sold in shippers, the patient information leaflet and the scientific package insert shall be provided in a ratio of 10 patient information leaflets to one scientific package insert.

(c) In the case of medicines sold in bulk packaging the patient information leaflet and the scientific package insert shall be provided in a ratio of 10 patient information leaflets to one scientific package insert, based on the number of packages representing a course of treatment that can reasonably be expected to be dispensed from the bulk.

4. Amendment to regulation 19

19. (1) Every prescription shall be written in legible bold print or longhand and signed by the authorised prescriber in person and shall state—

(d) the **[name]** approved international non-proprietary name (INN) and quantity of the Scheduled substance or medicine to be supplied thereunder: Provided that in the case of a Schedule 6 substance or medicine the quantity to be supplied shall be expressed in figures and well as in words: Provided further that where the prescriber has failed to express the quantity in figures and in words, the person dispensing the prescription may, after obaining confirmation from the prescriber, insert the words or figures that have been omitted.

5. Addition of a new regulation

Please note that the regulation numbers used here, and in the text, are intended to be used in the General Regulations that will be promulgated shortly. They should not be confused with the existing Regulations 23 and 37. Regulation 37 contains the forms to be used in future.

General prohibitions on the supply of medicines

LICENCES TO SELL MEDICINES

23. (3) No manufacturer of a medicine or medical device, a wholesaler or distributor thereof, shall cause any medicine or medical device to be manufactured and distributed unless such person is in possession of a licence issued by the Director-General on the recommendation of the Medicines Control Council subject to such conditions relating to the application of acceptable quality assurance principles, good manufacturing and distribution practises as the Medicines Control Council may determine.

Notwithstanding the above, the Director-General may, on the recommendation of the Medicines Control Council, withdraw such licence if the licence-holder ceases to comply with the conditions under which the licence was issued.

Further notwithstanding the above the licence shall be renewable annually and the licence-holder shall apply for renewal thereof at least 60 days before the expirty date thereof, failing which the licence shall be cancelled.

23. (4) (a) No medical pracitioner, dentist, practitioner, veterinarian or authorised nurse in terms of regulation 23 (18), shall sell any Scheduled substance or medicine unless the Registrar of Medicines, Private Bag X828, Pretoria, has been informed in the format of Form 10 prescribed in regulation 37, of the physical address of the location where such supply takes place and of the postal address, the telephone number and the initials and surname of the person as registered with the relevant statutory council, and has received confirmation that a licence has been issued by the Registrar subject to compliance by the applicant with the prescribed conditions.

(b) The licence shall be renewable annually and the licence-holder shall apply for renewal thereof at least 60 days before the expiry date thereof. Notwithstanding the above, a licence may be withdrawn if the licence-holder ceases to comply with the conditions under which the licence was issued.

PREMISES AND SECURITY

23. (10) No person shall sell any medicine on prescription unless the place from where such sale is done—

(a) has a suitably sized surface made from an impervious, washable material in good state of repair which provides sufficient space to enable the preparation of medicine for supply to the patient;

(b) is not subject to temperatures and conditions which are beyond those indicated on the label of any medicine kept in that place;

(c) as an area where equipment and other utensils can be washed which has a source of hot and cold tap water, a suitable, clean washbasin made of impervious material and a closed drainage system;

(d) has an adequate functioning ablution area, for human use, supplied with soap, towels and toilet paper and which does not open up on, or is able to contaminate the place where medicines are kept and prepared in any way;

(e) is supplied with a properly assized massmeter, mortar and pestle, spatulas and graduated measuring containers where medicinal powders, creams and ointments and liquids are required to be measured, divided or weighed for incorporation into a pharmaceutical formulation as the case may be;

(f) is supplied with adequate lighting and ventilation;

(g) has sufficient shelving from an impervious, washable material for the keeping of medicines above floor level;

(h) has restricted access to the public;

(i) is neat, clean and tidy;

(j) has sufficient floor space to ensure an efficient flow of work, effective communication and supervision;

(k) has suitable equipment to minimise cross-contamination during the counting of tablets and capsules;

(l) is equipped with a refrigerator, regularly calibrated, for the keeping of thermolabile medicines in accordance with the storage instructions on the medicine label.

23. (11) (b) No person shall sell any medicine on prescription to a patient who has young children at home, unless the medicine is packaged in child-resistant containers.

23. (20) No medical practitioner and dentist shall dispense or sell a medicine or scheduled substance on prescription to any patient under care except when, on application, has been authorised thereto by the Director-General and provided he or she has successfully completed a supplementary course in dispensing practises prescribed for this purpose by the South African Medical and Dental Council in consultation with the South African Pharmacy Council who shall determine the standards of dispensing, and is certified competent to dispense medicines. Notwithstanding the above, he or she may use such medicines, on a non-recurring basis, that are necessary only for the emergency treatment of patients.

Note: It is the intention to amend or repeal section 52A of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act No. 56 of 1974).

23. (21) A manufacturer shall not sell any medicine unless at least the following information is represented in the multidimensional digital mark as required in regulation 12 (5):

(a) The unique number of each package of medicine;

(b) the registration number of the medicine;

(c) the proprietary name of the medicine;

(d) the batch number;

(e) the expiry date of the medicine,

and this information is supplied to the Registrar of Medicines for inclusion into the Central Mark Control System.

23. (22) A pharmacist practising as a wholesaler or a distributor shall not sell any medicine unless at least the following information is linked electronically to the multidimensional digital mark as required in regulation 12 (5):

(a) The name of the person or organisation to whom the medicine is being supplied;

(b) the date of sale;

(c) the invoice number,

and this information is supplied to the Registrar of Medicines for inclusion into the Central Mark Control System.

23. (23) A authorised seller of medicine may not repackage any medicine, except when this is necessitated in filling a prescription as contemplated in regulation 19, unless at least the following information is linked electronically to the multidimensional digital mark required in regulation 12 (5):

(a) The name of person or organisation to whom the medicine is being supplied;

(b) the date of sale;

(c) the invoice number,

and this information is supplied to the Registrar of Medicines for inclusion into the Central Mark Control System.

23. (25) (a) Any person, other than those authorised by the State who has in his/her possession medicines which bear a bright green multidimensional digital mark, shall be guilty of an offence.

(b) Any person, other than an applicant for that medicine, who has in his possession a medicine which bears a blue mark, shall be guilty of an offence.

No. R. 1150 **12 Julie 1996**

WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET No. 101 VAN 1965)

ALGEMENE REGULASIES

Die Minister van Gesondheid is voornemens om kragtens artikel 35 van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), op aanbeveling van die Medisynebeheerraad, die regulasies in die Bylae hiervan vervat, drie maande na die datum van hierdie kennisgewing, uit te vaardig. Belanghebbende persone word versoek om binne vyf-en-veertig (45) dae na die datum van publikasie van hierdie kennisgewing kommentaar in verband met die voorgestelde regulasies in te dien by die Registrateur van Medisyne, Privaatsak X828, Pretoria, 0001.

Invoegings in en skrappings uit bestaande verordeninge word respektiewelik met 'n volstreep daaronder of tussen hakies aangedui.

BYLAE

1. Regulasie 1 word gewysig deur invoeging van die volgende klousules

Definisies

"Multidimensionele digitale merk" beteken 'n rekenaar-ontwerpte, masjienleesbare multidimensionele digitale merk van ten minste nege vierkante millimeter. Die merk bevat die voorgeskrewe inligting, opgeneem in 'n binêre styl, wat uniek is vir elke medisyneverpakking waarop dit aangebring is en wat deur die Registrateur van Medisyne gemagtig en in ooreenstemming met 'n Sentrale Merkbeheerstelsel verskaf is.

"Pasiënt-inligtingsblaadjie" beteken die inligting met betrekking tot 'n medisyne soos bedoel in regulasie 10 (1).

"Sentrale Merkbeheerstelsel" beteken 'n rekenaarstelsel wat deur die Registrateur van Medisyne beheer, beveilig en in stand gehou word en gebruik word om aan applikante gekodeerde, binêre inligting, uniek aan elke medisyneverpakking uit te reik, om in die vorm van 'n multidimensionele digitale merk daarop aangebring te word en wat ook gebruik word om inligting te verkry, wat kragtens regulasie deur sekere verskaffers van medisyne ten opsigte van die vervaardigings- en verspreidingsprosesse van die medisyne, aan die Direkteur-generaal verstrek moet word.

"Wetenskaplike voubiljet" beteken die inligting met betrekking tot 'n medisyne soos bedoel in regulasie 10 (4).

2. Wysigings aan en invoegings in regulasie 9

Die volgende subregulasie word in regulasie 9 ingevoeg. Wanneer kommentaar gelewer word, gebruik asseblief die paragraafnommer hierin aangedui. Let asseblief daarop dat in die Algemene Regulasies wat binnekort gepromulgeer word, regulasies 9 en 40 saamgevoeg is in 'n nuwe regulasie 12. Kommentaar moet die etikettering van veterinêre medisyne ook in aanmerking neem.

12. (5) Die onmiddellike houer-etiket en buite-etiket (karton) van alle medisyne kragtens die Wet geregistreer, moet voorsien wees van 'n multidimensionele digitale merk soos gedefinieer, wat ten minste die voorgeskrewe inligting van toepassing op die genoemde produk bevat en permanent in die boonste regterhoek van die onmiddellike houer-etiket en hoofpaneel van die buite-etiket aangebring is, en waar 'n etiket nie 'n logiese regterhoek het nie, onmiddellik voor die eerste letter van die handelsnaam—

(i) in swart;

(ii) in heldergroen wanneer die medisyne aan die staat verkoop word of wanneer dit vooraf deur die staat in pasiënt-gereedverpakkings verpak is;

(iii) in blou wanneer die medisyne vir uitvoerdoeleindes verkoop word.

Wysiging aan regulasie 9 (1) (d). Dit is ook van toepassing op veterinêre medisyne, soos hierbo vermeld.

(d) die goedgekeurde (naam) internasionale nie-handelsnaam (INN) van elke aktiewe bestanddeel van die medisyne en die hoeveelheid daarvan in 'n dosiseenheid of per geskikte massa of volume of eenheid, in letters met 'n minimum leesbaarheid soos omskryf by regulasie 1: Met dien verstande dat, in die geval van 'n medisyne wat slegs een aktiewe bestanddeel bevat, sodanige letters (minstens die helfte van die) dieselfde grootte (van) as die grootste letter moet wees wat vir die genoemde eiendomsnaam gebruik is en direk moet volg op die eiendomsnaam.

3. Regulasie 10 word deur die volgende regulasie vervang:

PASIËNT-INLIGTINGSBLAADJIE (PIB) EN WETENSKAPLIKE VOUBILJET

Pasiënt-inligtingsblaadjie (PIB)

10. (1) Behoudens die bepalings van die voorwaarde in subregulasies (2) en (3), moet elke medisyneverpakking vergesel wees van 'n pasiënt-inligtingsblaadjie, geskryf in leketaal, in ten minste Engels, waarop slegs onderstaande besonderhede met betrekking tot sodanige medisyne gedruk is in letters met 'n minimum leesbaarheid soos omskryf by regulasie 1, onder die opskrifte en in die formaat in hierdie regulasie gespesifiseer: Met dien verstande dat indien die verpakking (versendhouer) meer as een onmiddellike houer bevat, 'n pasiënt-inligtingsblaadjie vir elke onmiddellike houer in die verpakking (versendhouer) ingesluit moet wees. Nieteenstaande bovermelde kan enige ander amptelike taal of ander taal deur die Raad goedgekeur, bykomend gebruik word:

(a) Skeduleringstatus, dit is die skeduleringstatus van die medisyne soos van tyd tot tyd deur regulasie bepaal;

(b) eiendomsnaam en doseervorm van die medisyne;

(c) wat die medisyne bevat—die medisyne se samestelling, dit is die goedgekeurde internasionale nie-handelsnaam (INN) van elke aktiewe bestanddeel en die hoeveelheid daarvan in 'n dosiseenheid of per geskikte massa of volume of eenheid van die medisyne. Alle onaktiewe bestanddele moet kwalitatief gelys word;

(d) waarvoor die medisyne gebruik word—die geregistreerde indikasies vir gebruik van die medisyne soos deur die Raad aanvaar in die goedgekeurde wetenskaplike voubiljet;

(e) voordat hierdie medisyne gebruik word—inligting ten opsigte van kontra-indikasies, voorsorgmaatreëls, waarskuwings, wisselwerkings, spesiale waarskuwings, bv. waarskuwings aangaande sederende eienskappe van die medisyne, risikos verbonde aan die skielike onttrekking van die medisyne, ens. moet hier ingesluit word. Die volgende algemene stellings moet in hierdie afdeling ingesluit word: "Indien u medisyne op 'n gereelde basis gebruik kan die gelyktydige gebruik van hierdie medisyne ongewensde wisselwerkings veroorsaak. Raadpleeg asseblief u geneesheer, apteker of 'n ander lid van 'n gesondheidsorgberoep." "Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne neem, raadpleeg asseblief u geneesheer, apteker of ander lid van 'n gesondheidsorgberoep vir advies;"

(f) hoe om hierdie medisyne te neem—die aanbevole doserings moet hier vermeld word. Enige spesiale inligting wat die pasiënt vir die behoorlike en veilige gebruik van die medisyne nodig mag hê, moet voorsien word;

(g) newe-effekte—die volgende inligting moet op 'n wyse wat die verbruiker sal verstaan, in hierdie afdeling verstrek word—

(i) die newe-effekte wat met die gebruik van dié betrokke medisyne verband hou;

(ii) daardie newe-effekte wat die pasiënt maklik kan herken;

(iii) die meer ernstige newe-effekte;

(iv) inligting wat om te doen in spesifieke omstandighede, bv. in die geval waar 'n dosis oorgeslaan is, 'n onverwagse reaksie wat ontstaan of in geval van 'n oordosis;

(v) die volgende algemene stelling: "Nie alle newe-effekte wat met hierdie medisyne vermeld is, is in die pasiënt-inligtingsblaadjie ingesluit nie. Indien u algemene gesondheidstoestand verswak terwyl u hierdie medisyne neem, raadpleeg asseblief u geneesheer, apteker of 'n ander lid van 'n gesondheidsorgberoep vir advies;"

(h) bergingsaanwysings en inligting in verband met die weggooi van die medisyne—inligting in verband met die korrekte wyse van berging en hoe om van ongebruikte medisyne ontslae te raak, moet hier verstrek word;

(i) aanbieding;

(j) identifikasie van die medisyne—dit is 'n volledige beskrywing van die medisyne se fisiese voorkoms;

(k) registrasienommer, dit is—

(i) die nommer deur die Registrateur toegewys aan die medisyne ingevolge artikel 15 (6) van die Wet; of

(ii) in die geval van 'n medisyne ten opsigte waarvan om die registrasie aansoek gedoen is ingevolge artikel 14, onderworpe aan die bepalings van subartikel 2 (a), die verwysingsnommer deur die Registrateur aan sodanige aansoek toegewys, gevolg deur die uitdrukking "(Wet No. 101/1965)";

(l) die naam en besigheidadres van die applikant;

(m) datum van publikasie van die pasiënt-inligtingsblaadjie;

(n) die volgende algemene stellings:

(i) "Moenie medisyne wat vir u voorgeskryf is met ander deel nie".

(ii) "Bêre alle medisyne buite die bereik van kinders".

(o) Met dien verstande dat—

(i) indien die Raad bepaal dat daar geen toepaslike inligting onder 'n bepaalde opskrif verstrek moet word nie, sodanige opskrif met die goedkeuring van die Raad weggelaat kan word;

(ii) die Raad, wanneer 'n applikant by hom daarom aansoek doen, die afwyking van die formaat en inhoud van 'n pasiënt-inligtingsblaadjie voorgeskryf as 'n voorwaarde vir registrasie van 'n medisyne kan magtig; en

(iii) die Raad, wanneer 'n applikant by hom daarom aansoek doen, die insluiting op 'n pasiënt-inligtingsblaadjie van enige gespesifiseerde inligting waarvan sodanige insluiting nie by hierdie regulasie vereis word nie, kan magtig;

(iv) die Raad, wanneer 'n applikant by hom daarom aansoek doen, goedkeuring kan verleen dat die saamgevoegde besonderhede, voorgeskryf in regulasie 9 en hierdie subregulasie, op die onmiddellike houer van 'n medisyne, uitgesonderd 'n biologiese medisyne, aangebring kan word.

(2) Die vereistes van subregulasie (1) is van toepassing op—

(a) enige medisyne wat deur 'n geneesheer, tandarts, veearts, praktisyn, verpleegster, apteker of gemagtigde persoon kragtens artikel 22A (12), in die uitvoering van sy/haar professionele bedrywighede vir die behandeling van 'n bepaalde pasiënt verkoop word, uitgesonderd wanneer die voorskrywer die voorskrif met die volgende woorde gemerk het: "Moenie inligting in verband met die medisyne verstrek nie;"

(b) enige medisyne wat deur 'n apteker, deur 'n kliniek of 'n hospitaal aan buitepasiënte, ooreenkomstig 'n voorskrif wat deur 'n geneesheer, tandarts, veearts, praktisyn of verpleegster of gemagtigde persoon kragtens artikel 22A (12), vir die behandeling van 'n bepaalde pasiënt uitgereik is, verkoop word, uitgesonderd wanneer die voorskrywer die voorskrif met die volgende woorde gemerk het: "Moenie inligting in verband met die medisyne verstrek nie".

(3) Die pasiënt-inligtings blaadjie vervang nie die wetenskaplike voubiljet wat deur die Raad goedgekeur is nie.

(4) Wetenskaplike Voubiljet:

(a) Vir elke medisyne moet daar 'n wetenskaplike voubiljet beskikbaar wees, in ten minste Engels, gedruk in letters met 'n minimum leesbaarheid soos omskryf by regulasie 1, onder die opskrifte en in die formaat in hierdie regulasie gespesifiseer. Nieteenstaande bovermelde kan enige ander amptelike taal of ander taal deur die Raad goedgekeur, bykomend gebruik word.

(b) Die wetenskaplike voubiljet moet as inligtingstuk vir lede van die gesondheidsberoepe gebruik word en dit sal die applikant se verantwoordelikheid wees om elke sodanige lid met die volledige inligting in die wetenskaplike voubiljet te voorsien, ten minste in elk van die volgende gevalle—

(i) Met elke bekendstelling van 'n nuwe produk;

(ii) op versoek van 'n lid van 'n gesondheidsberoep;

(iii) saam met audio/visuele bemarkingsmateriaal;

(iv) deur mediese verteenwoordigers wanneer lede van gesondheidsberoepe besoek word;

(v) nadat 'n belangrike verandering aan die voubiljet aangebring is.

(c) Bykomend tot bogenoemde kan die inligting ook by wyse van elektroniese dataversendingstelsels of enige ander stelsel deur die Raad goedgekeur, beskikbaar gemaak word.

(d) Die wetenskaplike voubiljet moet die volgende inligting met betrekking tot die medisyne bevat:

(i) Skeduleringstatus, soos van tyd tot tyd deur regulasie bepaal;

(ii) eiendomsnaam van die medisyne;

(iii) doseervorm van die medisyne;

(iv) samestelling, dit is—

(aa) die goedgekeurde internasionale nie-handelsnaam (INN) van elke aktiewe bestanddeel en die hoeveelheid daarvan in 'n dosiseenheid of per geskikte massa of volume of eenheid van die medisyne;

(bb) die goedgekeurde naam en persentasie van enige bakteriedodende of bakteriostatiese agens wat in die medisyne aanwesig is as preserveermiddel

(cc) die goedgekeurde naam van enige anti-oksidant wat in die medisyne aanwesig is;

(dd) die hoeveelheid etielalkohol aanwesig in die preparaat vir mond- of parenterale toediening;

(ee) die waarskuwing in hoofletters "BEVAT TARTRASIEN" indien die medisyne so 'n bestanddeel bevat;

(v) farmakologiese klassifikasie, dit is die kategorie, die nommer en die beskrywing van die klassifikasie soos vermeld in regulasie 4 en 5;

(vi) farmakologiese werking, dit is 'n beskrywing van die farmakologiese werking van die medisyne;

(vii) indikasies;

(viii) kontra-indikasies;

(ix) waarskuwings;

(x) dosis en gebruiksaanwysing;

(xi) newe-effekte en spesiale voorsorgmaatreëls;

(xii) bekende simptome van oordosering en besonderhede die behandeling daarvan;

(xiii) identifikasie;

(xiv) aanbieding;

(xv) bergingsaanwysings—

(aa) wat prakties geformuleer moet wees en wat bergingstemperatuur moet vermeld;

(bb) wat die woorde "Hou buite bereik van kinders" moet insluit;

(xvi) registrasienommer, dit is—

(aa) die nommer toegewys aan die medisyne ingevolge artikel 15 (6) van die Wet; of

(bb) in die geval van 'n medisyne ten opsigte waarvan om die registrasie aansoek gedoen is ingevolge artikel 14, onderworpe aan die bepalings van subartikel 2 (a) die verwysingsnommer aan sodanige aansoek toegewys, gevolg deur die uitdrukking "(Wet No. 101/1965)";

(xvii) naam en besigheidsadres van die applikant;

(xviii) datum van kennisgewing van goedkeuring van hierdie voubiljet;

(e) Met dien verstande dat—

(i) indien die Raad dat daar geen toepaslike inligting onder 'n bepaalde opskrif verstrek moet word nie, sodanige opskrif met die goedkeuring van die Raad weggelaat kan word;

(ii) die Raad, wanneer 'n applikant by hom daarom aansoek doen, die afwyking van die formaat en inhoud van 'n voubiljet voorgeskryf as 'n voorwaarde vir registrasie van 'n medisyne kan magtig; en

(iii) die Raad, wanneer 'n applikant by hom daarom aansoek doen, die insluiting op 'n voubiljet van enige gespesifiseerde inligting waarvan sodanige insluiting nie by hierdie regulasie vereis word nie, kan magtig.

(5) Medisyne aan die staat verkoop:

(a) Elke medisyneverpakking wat aan die staatsektor verkoop word, moet in gevalle waar daar nie aan die vereistes van subregulasie 6 (b) en 6 (c) voldoen kan word nie, beide 'n pasiënt-inligtingsblaadjie en 'n wetenskaplike voubiljet bevat.

(b) In die geval waar oorspronklike medisyneverpakkings in versendhouers verkoop word, moet die pasiënt-inligtingsblaadjie en die wetenskaplike voubiljet in 'n verhouding van 10 pasiënt-inligtingsblaadjies tot een wetenskaplike voubiljet, verskaf word.

(c) In die geval waar medisyne in grootmaatverpakkings verkoop word, moet die pasiënt-inligtingsblaadjie en die wetenskaplike voubiljet in 'n verhouding van 10 pasiënt-inligtingsblaadjies tot een wetenskaplike voubiljet verskaf word, gebaseer op die aantal verpakkings wat na verwagting, redelikerwys as behandelingskursusse uit die grootmaat geresepteer kan word.

4. Wysiging van regulasie 19

19. (1) Elke voorskrif moet in leesbare drukskrif of gewone skrif geskryf en persoonlik onderteken word deur die gemagtigde voorskrywer en moet die volgende vermeld:

(d) die goedgekeurde naam (internasionale nie-handelsnaam—INN) en hoeveelheid van die medisyne of gelyste stof wat daarvolgens gelewer moet word: Met dien verstande dat in die geval van 'n Skedule 6 stof of medisyne die hoeveelheid wat verkoop kan word in syfers sowel as in woorde aangedui moet word: Met dien verstande voorts dat waar die persoon wat die voorskrif uitreik in gebreke gebly het om die hoeveelheid in syfers sowel as woorde aan te dui, die persoon wat die voorskrif toeberei, na die verkryging van bevesting van die persoon wat die voorskrif uitgereik het, die syfers of woorde wat uitgelaat is, kan invoeg.

5. Invoeging van 'n nuwe regulasie

Let daarop dat die regulasienommers wat hiér gebruik word en in die teks hierna, bedoel is om in die Algemene Regulasies, wat binnekort gepromulgeer word, gebruik te word. Die nommers moet nie verwar word met die bestaande regulasies 23 en 37 nie. Die voorgestelde regulasie 37 bevat die vorms wat in die toekoms gebruik moet word.

Algemene verbodsbepalings betreffende die verskaffing van medisyne

LISENSIE VIR DIE VERKOOP VAN MEDISYNE

23. (3) 'n Vervaardiger van 'n medisyne of mediese toestel, 'n groothandelaar of verspreider daarvan, mag nie toelaat dat enige medisyne of mediese toestel vervaardig en versprei word nie, tensy so 'n persoon in besit van 'n lisensie uitgereik deur die Direkteur-generaal op aanbeveling van die Medisynebeheerraad, onderworpe aan sodanige voorwaardes wat betrekking het op die handhawing van aanvaarbare gehalteversekeringsbeginsels, goeie vervaardigings- en verspreidingspraktyke, as wat die Raad mag bepaal.

Ondanks bogenoemde bepalings, mag die Direkteur-generaal op aanbeveling van die Medisynebeheerraad so 'n lisensie intrek, indien die lisensiehouer versuim om aan die voorwaardes waarvolgens die lisensie uitgereik is, te voldoen.

Verder, ondanks bogenoemde bepalings, is die lisensie jaarliks hernubaar en die lisensiehouer moet ten minste 60 dae voor die verstrykdatum, aansoek doen vir hernuwing van die lisensie. By versuim daarvan, sal die lisensie gekanselleer word.

23. (4) (a) Geen geneesheer, tandarts, praktisyn, veearts of verpleegkundige, gemagtig kragtens regulasie 23 (18) mag enige gelyste stof of medisyne verkoop nie, tensy die Registrateur van Medisyne, Privaat Sak X828, Pretoria, by wyse van Vorm 10 voorgeskryf by regulasie 37 in kennis gestel is van die straatadres van die perseel waar sodanige verkoop plaasvind en van die posadres, die telefoonnommer en die voorletters en van van die persoon soos geregistreer by die toepaslike statutêre raad, en hy of sy bevestiging ontvang het dat 'n lisensie uitgereik is deur die Registrateur, onderworpe daaraan dat die applikant voldoen aan die voorgeskrewe voorwaardes.

(b) Die lisensie is jaarliks hernubaar en die lisensiehouer moet ten minste 60 dae voor die verstrykdatum, aansoek doen vir hernuwing van die lisensie. Ondanks bogenoemde bepalings mag 'n lisensie ingetrek word indien die lisensiehouer versuim om aan die voorwaardes waarvolgens die lisensie uitgereik is, te voldoen.

PERSELE EN SEKURITEIT

23. (10) Geen persoon mag medisyne op 'n voorskrif verskaf nie tensy die perseel waarvandaan dit geskied:

(a) voorsien is van 'n oppervlak van aanvaarbaar grootte, vervaardig van ondeurdringbare, wasbare materiaal en in goeie toestand is, wat voldoene ruimte bied vir die voorbereiding van medisyne wat aan 'n pasiënt verskaf word;

(b) vry is van omgewingstoestande en temperature wat teenstrydig is met dit wat op die etikette van enige medisyne wat in sodanige plek aangehou word, verskyn;

(c) voorsien is van 'n plek waar apparaat en ander toerusting gewas kan word, wat voorsien is van warm en koue kraanwater, van 'n wasbak wat vervaardig is van ondeurdringbare materiaal en van 'n geslote dreineringstelsel:

(d) voorsien is van aanvaarbare werkende ablusiegeriewe vir gebruik deur mense en wat voorsien is van seep, handdoeke en toiletpapier, wat nie direkte toegang verleen tot, of die plek kan besmet waar medisyne gehou of voorberei word nie;

(e) voorsien is van geykte massameters, stamper en vysel, spatels en gegradueerde maatglase in die geval waar medisinale poeiers, rome, salwe en vloeistowwe afgemeet, verdeel of geweeg moet word vir byvoeging by 'n farmaseutiese mengsel, soos die geval mag wees;

(f) voorsien is van voldoende beligting en ventilasie;

(g) voorsien is van voldoende rakke, bokant vloervlak, wat gemaak is van 'n ondeurdringbare, wasbare materiaal waarop medisyne geberg kan word;

(h) beperkte toegang bied vir die publiek;

(i) skoon, sindelik en netjies is;

(j) voldoende vloerruimte het om doeltreffende kommunikasie, toesighouding en 'n effektiewe vloei van werk te verseker;

(k) voorsien is van geskikte toerusting om kruisbesmetting tydens die aftel van tablette en kapsules tot 'n minimum te beperk;

(l) voorsien is van 'n yskas wat gereeld gekalibreer word vir die aanhou van hitte-sensitiewe medisyne, in ooreenstemming met die bewaringsinstruksies op die etiket daarvan.

23. (11) (b) Geen persoon mag medisyne op 'n voorskrif verskaf aan 'n pasiënt wat klein kinders tuis het nie, tensy die medisyne in houers verpak is wat kinderbestand is.

23. (20) Geen mediese praktisyn en tandarts mag 'n medisyne of gelyste stof op voorskrif resepteer of verkoop aan enige pasiënt onder sy of haar sorg nie, tensy nadat aansoek daarvoor gedoen is, hy of sy deur die Direkteur-generaal daartoe gemagtig is en op voorwaarde dat hy of sy 'n aanvullende kursus in resepteerpraktyke, voorgeskryf deur die Suid-Afrikaanse Geneeskundige en Tandheelkundige Raad in konsultasie met die Suid-Afrikaanse Aptekersraad wat die resepteringstandaarde sal bepaal, met welslae voltooi het en as bevoeg gesertifiseer is om medisyne te resepteer. Ondanks bogenoemde bepalings mag hy of sy sodanige medisyne wat vir die noodbehandeling van pasiënte nodig is, op 'n nie-herhalende basis gebruik.

Let Wel: Daar word beoog om artikel 52A van die Wet op Geneeshere, Tandartse en Aanvullende Gesondheidsdiensberoepe, 1974 (Wet No. 56 van 1974), te wysig of te herroep.

23. (21) Geen vervaardiger mag enige medisyne verkoop tensy ten minste die volgende inligting in die multidimensionele digitale merk, soos vereis in regulasie 12 (5), vervat is:

(a) 'n Unieke nommer vir elke medisyneverpakking;

(b) die registrasienommer van die medisyne;

(c) die handelsnaam van die medisyne;

(d) die lotnommer;

(e) die medisyne se vervaldatum,

en bogenoemde inligting vir insluiting in die Sentrale Merkbeheerstelsel, aan die Registrateur van Medisyne verstrek is.

23. (22) Geen apteker wat handeldryf as groothandelaar in of verspreider van medisyne mag enige medisyne verkoop nie tensy ten minste onderstaande inligting elektronies aan die multidimensionele digitale merk, soos vereis in regulasie 12 (5), gekoppel is:

(a) Die naam van die persoon of organisasie aan wie die medisyne verskaf word;

(b) die datum van verskaffing;

(c) die faktuurnommer,

en bogenoemde inligting vir insluiting in die Sentrale Merkbeheerstelsel, aan die Registrateur van Medisyne verstrek is.

23. (23) 'n Gemagtigde verskaffer van medisyne mag geen medisyne herverpark nie, uitgesonderd wanneer dit vereis word om 'n voorskrif op te maak soos bedoel in regulasie 19, tensy ten minste onderstaande inligting elektronies aan die multidimensionele digitale merk, soos vereis in regulasie 12 (5), gekoppel is:

(a) Die naam van die persoon of organisasie aan wie die medisyne verskaf word;

(b) die datum van verskaffing;

(c) die faktuurnommer,

en bogenoemde inligting vir insluiting in die Sentrale Merkbeheerstelsel, aan die Registrateur van Medisyne verstrek is.

23. (25) (a) Enige persoon, buiten dié wat deur die Staat gemagtig is, wat medisyne wat met 'n heldergroen multidimensionele digitale merk gemerk is in sy/haar besit het, sal skuldig wees aan 'n oortreding.

(b) Enige persoon, buit die applikant van daardie medisyne, wat medisyne wat met 'n blou multidimensionele digitale merk gemerk is in sy/haar besit het, sal skuldig wees aan 'n oortreding.

DEPARTMENT OF LABOUR
DEPARTEMENT VAN ARBEID

No. R. 1134 **12 July 1996**

LABOUR RELATIONS ACT, 1956

CANCELLATION OF GOVERNMENT NOTICES

IRON, STEEL, ENGINEERING AND METALLURGICAL INDUSTRY: TECHNOLOGICAL FUND AGREEMENT

I, Tito Titus Mboweni, Minister of Labour, hereby, in terms of section 48 (5) of the Labour Relations Act, 1956, cancel Government Notices Nos. R. 450 of 24 March 1995 and R. 925 of 30 June 1995, with effect from the second Monday after the date of publication of this notice.

T. T. MBOWENI

Minister of Labour

No. R. 1134 **12 Julie 1996**

WET OP ARBEIDSVERHOUDINGE, 1956

INTREKKING VAN GOEWERMENTSKENNISGEWINGS

YSTER-, STAAL-, INGENIEURS- EN METALLURGIESE NYWERHEID: TEGNOLOGIESE FONDSOOREENKOMS

Ek, Tito Titus Mboweni, Minister van Arbeid, trek hierby, kragtens artikel 48 (5) van die Wet op Arbeidsverhoudinge, 1956, Goewermentskennisgewings Nos. R. 450 van 24 Maart 1995 en R. 925 van 30 Junie 1995 in, met ingang van die tweede Maandag na die datum van publikasie van hierdie kennisgewing.

T. T. MBOWENI

Minister van Arbeid

No. R. 1135 **12 July 1996**

LABOUR RELATIONS ACT, 1956

IRON, STEEL, ENGINEERING AND METALLURGICAL INDUSTRY: RE-ENACTMENT OF TECHNOLOGICAL FUND AGREEMENT

I, Tito Titus Mboweni, Minister of Labour, hereby, in terms of section 48 (1) (a) of the Labour Relations Act, 1956, declare that the provisions of the Agreement which appears in the Schedule hereto and which relates to the Undertaking, Industry, Trade or Occupation referred to in the heading to this notice, shall be binding, with effect from the second Monday after the date of publication of this notice and for the period ending 30 June 2000, upon the employers' organisations and the trade unions which entered into the said Agreement and upon the employers and employees who are members of the said organisations or unions.

T. T. MBOWENI

Minister of Labour

SCHEDULE

NATIONAL INDUSTRIAL COUNCIL FOR THE IRON, STEEL, ENGINEERING AND METALLURGICAL INDUSTRY

TECHNOLOGICAL FUND AGREEMENT

in accordance with the provisions of the Labour Relations Act, 1956, made and entered into by and between the

Association of Electric Cable Manufacturers of South Africa
Border Engineering Industries Association
Bright Bar Association
Cape Engineers' and Founders Association
Constructional Engineering Association (South Africa)
Covered Conductor Manufacturers' Association
Electrical Engineering and Allied Industries Association
Electronics and Telecommunications Industries Association
Ferro Alloy Producers' Association
Gate and Fence Association
Hand Tool Manufacturers' Association
Iron and Steel Producers' Association of South Africa
Lift Engineering Association of South Africa
Light Engineering Industries Association of South Africa
Materials Handling Association
Natal Engineering Industries Association
Non-Ferrous Metal Industries Association of South Africa
Plastics Manufacturers' Association of South Africa
Plumbers and Engineers Brassware Manufacturers' Association
Port Elizabeth Engineers' Association
Pressure Vessel Manufacturers' Association of South Africa
Radio, Appliance and Television Association of South Africa
Refrigeration and Air-Conditioning Manufacturers' and Suppliers' Association
Sheetmetal Industries Association of South Africa
S.A. Association of Shipbuilders and Repairers
S.A. Electro-Plating Industries Association
S.A. Engineers' and Founders' Association
S.A. Fasteners Manufacturers' Association
S.A. Industrial Refrigeration and Air-Conditioning Contractors' Association
S.A. Pump Manufacturers' Association
S.A. Reinforced Concrete Engineers' Association
S.A. Tube Makers' Association
S.A. Valve and Auctuator Manufacturers' Association
S.A. Wire and Wire Rope Manufacturers' Association

(hereinafter referred to as the "employers" or the "employers' organisations"), of the one part, and the

Metal and Electrical Workers' Union of South Africa
National Employees' Trading Union
Radio, Television, Electronics and Allied Workers' Union
S.A. Electrical Workers' Association
S.A. Yster-, Staal- en Verwante Nywerhede-Unie

(hereinafter referred to as the "employees" or the "trade unions"), of the other part,

being the parties to the National Industrial Council for the Iron, Steel, Engineering and Metallurgical Industry.

1. SCOPE OF APPLICATION OF AGREEMENT

Any reference in this Agreement to the Republic of South Africa and/or the Provinces of the Cape of Good Hope, the Transvaal, Natal and the Orange Free State shall be deemed to be a reference to the Magisterial Districts of those areas and/or provinces as they existed immediately prior to the coming into operation of the Constitution of the Republic of South Africa, 1993 (Act No. 200 of 1993), and the terms of this Agreement shall apply to and be observed throughout the Republic of South Africa by all employers and employees in the Iron, Steel, Engineering and Metallurgical Industries who are members of the employers' organisations and the trade unions, respectively.

2. PERIOD OF OPERATION

This Agreement shall come into operation on such date as may be fixed by the Minister of Labour in terms of section 48 of the Labour Relations Act, 1956, and shall remain in force until 30 June 2000 or for such period as the Minister may determine.

3. GENERAL PROVISIONS

The provisions of clauses 3, 4 and 5 of the Agreement published under Government Notice No. R. 1334 of 27 June 1980, as re-enacted and amended by Government Notices Nos. R. 1377 of 1 July 1983, R. 227 of 8 February 1985, R. 2055 of 13 September 1985, R. 1001 of 23 May 1986, R. 1797 of 21 August 1987, R. 1500 of 29 June 1990, R. 1800 of 2 August 1991, R. 894 of 28 May 1993, R. 778 of 22 April 1994 and R. 450 of 24 March 1995 (hereinafter referred to as the "Former Agreement") as further extended, renewed, amended and re-enacted from time to time, shall apply to employers and employees.

4. CLAUSE 4: SEIFSA TECHNOLOGICAL FUND

Substitute the following for subclause (2):

"(2) As from the date of coming into operation of this Agreement, employers shall pay monthly to the Fund, in respect of all their employees as referred to in clause 3 of this Agreement, a contribution of 68 cents per employee.".

Signed at Johannesburg, for and on behalf of the parties, this 17th day of May 1996.

B. NICHOLSON
Member

B. ANGUS
Member

D. G. LEVY
General Secretary

No. R. 1135 **12 Julie 1996**

WET OP ARBEIDSVERHOUDINGE, 1956

YSTER-, STAAL-, INGENIEURS- EN METALLURGIESE NYWERHEID: HERBEKRAGTIGING VAN TEGNOLOGIESE FONDSOOREENKOMS

Ek, Tito Titus Mboweni, Minister van Arbeid, verklaar hierby, kragtens artikel 48 (1) (a) van die Wet op Arbeidsverhoudinge, 1956, dat die bepalings van die Ooreenkoms wat in die Bylae hiervan verskyn en betrekking het op die Onderneming, Nywerheid, Bedryf of Beroep in die opskrif by hierdie kennisgewing vermeld, met ingang van die tweede Maandag na die datum van publikasie van hierdie kennisgewing en vir die tydperk wat op 30 Junie 2000 eindig, bindend is vir die werkgewers-organisasies en die vakverenigings wat genoemde Ooreenkoms aangegaan het en vir die werkgewers en werknemers wat lede van genoemde organisasies of verenigings is.

T. T. MBOWENI
Minister van Arbeid

BYLAE

NASIONALE NYWERHEIDSRAAD VIR DIE YSTER-, STAAL-, INGENIEURS- EN METALLURGIESE NYWERHEID

TEGNOLOGIESE FONDSOOREENKOMS

ooreenkomstig die Wet op Arbeidsverhoudinge, 1956, gesluit deur en aangegaan tussen die

Association of Electric Cable Manufacturers of South Africa
Border Engineering Industries Association
Bright Bar Association
Cape Engineers' and Founders Association
Constructional Engineering Association (South Africa)
Covered Conductor Manufacturers' Association
Electrical Engineering and Allied Industries Association
Electronics and Telecommunications Industries Association
Ferro Alloy Producers' Association
Gate and Fence Association
Hand Tool Manufacturers' Association
Iron and Steel Producers' Association of South Africa
Lift Engineering Association of South Africa
Light Engineering Industries Association of South Africa
Materials Handling Association

Natal Engineering Industries Association
Non-Ferrous Metal Industries Association of South Africa
Plastics Manufacturers' Association of South Africa
Plumbers and Engineers Brassware Manufacturers' Association
Port Elizabeth Engineers' Association
Pressure Vessel Manufacturers' Association of South Africa
Radio, Appliance and Television Association of South Africa
Refrigeration and Air-Conditioning Manufacturers' and Suppliers' Association
Sheetmetal Industries Association of South Africa
S.A. Association of Shipbuilders and Repairers
S.A. Electro-Plating Industries Association
S.A. Engineers' and Founders' Association
S.A. Fasteners Manufacturers' Association
S.A. Industrial Refrigeration and Air-Conditioning Contractors' Association
S.A. Pump Manufacturers' Association
S.A. Reinforced Concrete Engineers' Association
S.A. Tube Makers' Association
S.A. Valve and Auctuator Manufacturers' Association
S.A. Wire and Wire Rope Manufacturers' Association

(hierna die "werkgewers" of die "werkgewersorganisasies" genoem), aan die een kant, en die

Metal and Electrical Workers' Union of South Africa
National Employees' Trade Union
Radio, Television, Electronics and Allied Workers' Union
S.A. Electrical Workers' Association
S.A. Yster-, Staal- en Verwante Nywerhede-Unie

(hierna die "werknemers" of die "vakverenigings" genoem), aan die ander kant,

wat die partye is by die Nasionale Nywerheidsraad vir die Yster-, Staal-, Ingenieurs- en Metallurgiese Nywerheid.

1. TOEPASSINGSBESTEK VAN OOREENKOMS

Enige verwysing in hierdie Ooreenkoms na die Republiek van Suid-Afrika en/of die provinsies die Kaap die Goeie Hoop, Transvaal, Natal en die Oranje-Vrystaat word geag 'n verwysing te wees na die landdrosdistrikte van daardie gebiede en/of provinsies soos hulle bestaan het onmiddellik voor die inwerkingtreding van die Grondwet van die Republiek van Suid-Afrika, 1993 (Wet No. 200 van 1993), en hierdie Ooreenkoms is van toepassing op en dit moet oral in die Republiek van Suid-Afrika nagekom word deur alle werkgewers en werknemers in die Yster-, Staal-, Ingenieurs- en Metallurgiese Nywerheid wat lede van onderskeidelik die werkgewersorganisasies en die vakverenigings is.

2. GELDIGHEIDSDUUR

Hierdie Ooreenkoms tree in werking op die datum wat deur die Minister van Arbeid kragtens artikel 48 van die Wet op Arbeidsverhoudinge, 1956, vasgestel word en bly van krag tot 30 Junie 2000 of vir die tydperk wat die Minister bepaal.

3. ALGEMENE BEPALINGS

Die bepalings van klousules 3, 4 en 5 van die Ooreenkoms gepubliseer by Goewermentskennisgewing No. R. 1334 van 27 Junie 1980, soos herbekragtig en gewysig by Goewermentskennisgewings Nos. R. 1377 van 1 Julie 1983, R. 227 van 8 Februarie 1985, R. 2055 van 13 September 1985, R. 1001 van 23 Mei 1986, R. 1797 van 21 Augustus 1987, R. 1500 van 29 Junie 1990, R. 1800 van 2 Augustus 1991, R. 894 van 28 Mei 1993, R. 778 van 22 April 1994 en R. 450 van 24 Maart 1995 (hierna die "Vorige Ooreenkoms" genoem), soos van tyd tot tyd verder verleng, hernieu, gewysig en herbekragtig, is van toepassing op werkgewers en werknemers.

4. KLOUSULE 4: TEGNOLOGIESE FONDS SEIFSA

Vervang subklousule (2) deur die volgende:

"(2) Vanaf die datum van inwerkingtreding van hierdie Ooreenkoms moet werkgewers maandeliks, ten opsigte van al hulle werknemers, soos bedoel in klousule 3 van hierdie Ooreenkoms, 'n bydrae van 68 sent per werknemer in die Fonds stort.".

Namens die partye op hede die 17de dag van Mei 1996 te Johannesburg onderteken.

B. NICHOLSON
Lid

B. ANGUS
Lid

D. G. LEVY
Hoofsekretaris

No. R. 1136 **12 July 1996**

LABOUR RELATIONS ACT, 1956

ELECTRICAL INDUSTRY (KWAZULU-NATAL): AMENDMENT OF MEDICAL AID FUND AGREEMENT

I, Tito Titus Mboweni, Minister of Labour, hereby, in terms of section 48 (1) (a) of the Labour Relations Act, 1956, declare that the provisions of the Agreement (hereinafter referred to as the Amending Agreement) which appears in the Schedule hereto and which relates to the Undertaking, Industry, Trade or Occupation referred to in the heading to this notice, shall be binding, with effect from the second Monday after the date of publication of this notice and for the period ending 30 June 1997, upon the employers' organisation and the trade unions which entered into the Amending Agreement and upon the employers and employees who are members of the said organisation or unions.

T. T. MBOWENI

Minister of Labour

SCHEDULE

INDUSTRIAL COUNCIL FOR THE ELECTRICAL INDUSTRY (KWAZULU-NATAL)

MEDICAL AID FUND AGREEMENT

in accordance with the provisions of the Labour Relations Act, 1956, made and entered into by and between the

Electrical Contractors' Association (South Africa)

(hereinafter referred to as the "employers" or the "employers' organisation"), of the one part, and the

South African Electrical Workers' Association

and the

Metal and Electrical Workers' Union of South Africa

(hereinafter referred to as the "employees" or the "trade unions"), of the other part,

being the parties to the Industrial Council for the Electrical Industry (Natal),

to amend the Agreement published under Government Notice No. R. 1659 of 19 August 1988 (hereinafter referred to as the Re-enacting Agreement), as amended and extended by Government Notices Nos. R. 1214 of 9 June 1989, R. 396 of 23 February 1990, R. 1493 of 29 June 1990, R. 1872 of 10 August 1990, R. 1232 of 30 May 1991, R. 2048 of 23 August 1991, R. 2444 of 28 August 1992, R. 309 of 26 February 1993, R. 892 of 28 May 1993, R. 1139 of 2 July 1993, R. 202 of 4 February 1994, R. 2042 of 25 November 1994, R. 1006 of 7 July 1995 and R. 1232 of 18 August 1995.

1. SCOPE OF APPLICATION OF AGREEMENT

(1) Except as otherwise provided in this clause, the terms of this Agreement shall apply to and be observed in the Electrical Industry (Natal) by all employers and employees who are members of the employers' organisation and the trade unions, respectively, and who are engaged or employed in the Industry in the Province of Natal, excluding any portions of that area falling within the Self-governing Territory of KwaZulu as it existed immediately prior to the coming into operation of the Constitution of the Republic of South Africa, 1993 (Act No. 200 of 1993).

(2) The terms of this Agreement shall not apply to employers and their employees who are participants with the employers in any scheme providing medical benefits, in existence on 3 January 1986, to which the employer concerned contributes not less than 45 cents per week for each employee who is a member of the scheme and otherwise covered by this Agreement whilst such scheme continues to operate and the said employer and employees continue as participants in the scheme and the employer continues to pay a contribution of not less than 45 cents per week for each such employee.

(3) Notwithstanding the provisions of subclause (2), the terms of this Agreement shall apply to employers and employees in respect of any employee who is not covered by, or ceased to be covered by, a fund or scheme referred to in that subclause.

2. GENERAL PROVISIONS

The provisions contained in clauses 3 to 19, inclusive, of the Agreement published under Government Notice No. R. 2604 of 2 December 1983, as amended and re-enacted by Government Notices Nos. R. 1429 of 13 July 1984, R. 994 of 23 May 1986, R. 2068 of 26 September 1986 and R. 1659 of 19 August 1988 (as amended, re-enacted and extended from time to time), shall apply to employers and employees.

3. CLAUSE 9: CONTRIBUTIONS

Substitute the following for the table appearing in subclause (1):

"M (member): R37,20.

M + 1 (member with one dependant): R40,80.

M + 2 (member with two dependants): R45,60.

M + 3 (member with three dependants): R50,40.

M + 4 + (member with four or more dependants): R55,20.".

4. CLAUSE 10: BENEFITS

In subclause (1), substitute the following for paragraphs (a) to (f):

"(a) 80% of the scale of benefits for expenses, including expenses for confinements, other than expenses for ordinary dental services, optical services, prescriptions, special dental services and medical and surgical accessories, limited to the following maxima per financial year:

Single member (M)	*Member with one or two dependants* (M+1) and (M+2)	*Member with three or more dependants* (M+3) and (M+4+)
R10 850	R14 750	R19 500

(b) 80% of the scale of benefits for ordinary dental services, including plastic dentures, limited to the following maxima per financial year:

Single member (M)	*Member with one or two dependants* (M+1) and (M+2)	*Member with three or more dependants* (M+3) and (M+4+)
R1 550	R1 850	R2 100

(c) 80% of the cost of optical services, including eye-testing and spectacles, limited to the following maxima per financial year:

Single member (M)	*Member with one or two dependants* (M+1) and (M+2)	*Member with three or more dependants* (M+3) and (M+4+)
R600	R750	R850

(d) 80% of the cost of prescriptions. The Fund shall not be liable for the first R15 in respect of each prescription of a medical practitioner or specialist for medicines, drugs, dressings, ointments or lotions. The fund in its entire discretion, notwithstanding the provisions of the Rules of the Fund, may exclude certain specified patent medicine from presented prescriptions. This benefit shall be limited to the following maxima per financial year:

Single member (M)	*Member with one or two dependants* (M+1) and (M+2)	*Member with three or more dependants* (M+3) and (M+4+)
R2 850	R3 400	R3 800

(e) 80% of the scale of benefits for special dental services, i.e. crowns and bridgework, gold inlays, orthodontics, periodontics, prosthodontics and metal base dentures, limited to the following maxima per financial year:

Single member (M)	*Member with one or two dependants* (M+1) and (M+2)	*Member with three or more dependants* (M+3) and (M+4+)
R700	R750	R850

(f) 80% of the cost of medical and surgical accessories, limited to the following maxima per financial year:

Single member (M)	*Member with one or two dependants* (M+1) and (M+2)	*Member with three or more dependants* (M+3) and (M+4+)
R400	R450	R550".

Signed at Durban as authorised, for and on behalf of the parties, this 7th day of November 1995.

B. CARR
Chairman of Council

J. DLADLA
Vice-Chairman of Council

R. E. REDFERN
Secretary of Council

No. R. 1136 **12 Julie 1996**

WET OP ARBEIDSVERHOUDINGE, 1956

ELEKTROTEGNIESE NYWERHEID (KWAZULU-NATAL): WYSIGING VAN MEDIESE HULPFONDSOOREENKOMS

Ek, Tito Titus Mboweni, Minister van Arbeid, verklaar hierby, kragtens artikel 48 (1) (a) van die Wet op Arbeidsverhoudinge, 1956, dat die bepalings van die Ooreenkoms (hierna die Wysigingsooreenkoms genoem) wat in die Bylae hiervan verskyn en betrekking het op die Onderneming, Nywerheid, Bedryf of Beroep in die opskrif by hierdie kennisgewing vermeld, met ingang van die tweede Maandag na die datum van publikasie van hierdie kennisgewing en vir die tydperk wat op 30 Junie 1997 eindig, bindend is vir die werkgewersorganisasie en die vakverenigings wat die Wysigingsooreenkoms aangegaan het en vir die werkgewers en werknemers wat lede van genoemde organisasie of verenigings is.

T. T. MBOWENI

Minister van Arbeid

BYLAE

NYWERHEIDSRAAD VIR DIE ELEKTROTEGNIESE NYWERHEID (KWAZULU-NATAL)

MEDIESE HULPFONDSOOREENKOMS

ooreenkomstig die Wet op Arbeidsverhoudinge, 1956, gesluit deur en aangegaan tussen die

Electrical Contractors' Association (South Africa)

(hierna die "werkgewers" of die "werkgewersorganisasie" genoem), aan die een kant, en die

South African Electrical Workers' Association

en die

Metal and Electrical Workers' Union of South Africa

(hierna die "werknemers" of die "vakverenigings" genoem), aan die ander kant,

wat die partye is by die Nywerheidsraad vir die Elektrotegniese Nywerheid (Natal),

tot wysiging van die Ooreenkoms gepubliseer by Goewermentskennisgewing No. R. 1659 van 19 Augustus 1988 (hierna die herbekragtigingsooreenkoms genoem), soos gewysig en verleng by Goewermentskennisgewings Nos. R. 1214 van 9 Junie 1989, R. 396 van 23 Februarie 1990, R. 1493 van 29 Junie 1990, R. 1872 van 10 Augustus 1990, R. 1232 van 30 Mei 1991, R. 2048 van 23 Augustus 1991, R. 2444 van 28 Augustus 1992, R. 309 van 26 Februarie 1993, R. 892 van 28 Mei 1993, R. 1139 van 2 Julie 1993, R. 202 van 4 Februarie 1994, R. 2042 van 25 November 1994, R. 1006 van 7 Julie 1995 en R. 1232 van 18 Augustus 1995.

1. TOEPASSINGSBESTEK VAN OOREENKOMS

(1) Behoudens andersluidende bepalings in hierdie klousule, is hierdie Ooreenkoms van toepassing op en moet dit nagekom word in die Elektrotegniese Nywerheid (Natal) deur alle werkgewers en werknemers wat lede van onderskeidelik die werkgewersorganisasie en die vakverenigings is en wat berokke is by of in diens is in die Nywerheid in die provinsie Natal, uitgesonderd enige gedeeltes van daardie gebied wat binne die selfregerende gebied KwaZulu val, soos dit bestaan het onmiddellik voor die datum van inwerkingtreding van die Grondwet van die Republiek van Suid-Afrika, 1993 (Wet No. 200 van 1993).

(2) Hierdie Ooreenkoms is nie van toepassing nie op werkgewers en hul werknemers wat saam met die werkgewers deelnemers is aan 'n skema wat mediese voordele verskaf en wat op 3 Januarie 1986 bestaan het en waartoe die betrokke werkgewer minstens 45 sent per week bydra ten opsigte van elke werknemer wat lid van die skema is en andersins deur hierdie Ooreenkoms gedek word terwyl die skema in werking bly en genoemde werkgewer en werknemer voortgaan om deelnemers aan die skema te wees en die werkgewer voortgaan om 'n bydrae van minstens 45 sent per week ten opsigte van elke sodanige werknemer te betaal.

(3) Ondanks subklousule (2) is hierdie Ooreenkoms van toepassing op werkgewers en werknemers ten opsigte van 'n werknemer wat nie deur 'n fonds of skema bedoel in daardie subklousule gedek word nie of wat ophou om daardeur gedek te word.

2. ALGEMENE BEPALINGS

Klousules 3 tot en met 19 van die Ooreenkoms gepubliseer by Goewermentskennisgewing No. R. 2604 van 2 Desember 1983, soos gewysig en herbekragtig by Goewermentskennisgewings Nos. R. 1429 van 13 Julie 1984, R. 994 van 23 Mei 1986, R. 2068 van 26 September 1986 en R. 1659 van 19 Augustus 1988 (soos van tyd tot tyd gewysig, herbekragtig en verleng), is van toepassing op werkgewers en werknemers.

3. KLOUSULE 9: BYDRAES

Vervang die tabel in subklousule (1) deur die volgende:

"M (lid): R37,20.

M + 1 (lid met een afhanklike): R40,80.

M + 2 lid met twee afhanklikes): R45,60.

M + 3 (lid met drie afhanklikes): R50,40.

M + 4 + (lid met vier of meer afhanklikes): R55,20.".

4. KLOUSULE 10: BYSTAND

In subklousule (1), vervang paragrawe (a) tot (f) deur die volgende:

"(a) 80% van die voordeleskaal vir onkoste, met inbegrip van onkoste vir bevallings, uitgesonderd onkoste vir gewone tandheelkundige dienste, gesigkundige dienste, voorskrifte, spesiale tandheelkundige dienste en mediese en chirurgiese bybehore, beperk tot hoogstens die volgende per boekjaar:

Enkele lid (M)	*Lid met een of twee afhanklikes* (M+1) en (M+2)	*Lid met drie of meer afhanklikes* (M+3) en (M+4+)
R10 850	R14 750	R19 500

(b) 80% van die voordeleskaal vir gewone tandheelkundige dienste, met inbegrip van tandestelle van plastiek, beperk tot hoogstens die volgende per boekjaar:

Enkele lid (M)	*Lid met een of twee afhanklikes* (M+1) en (M+2)	*Lid met drie of meer afhanklikes* (M+3) en (M+4+)
R1 550	R1 850	R2 100

(c) 80% van die koste van gesigkundige dienste, met inbegrip van toets van oë en brille, beperk tot hoogstens die volgende per boekjaar:

Enkele lid (M)	*Lid met een of twee afhanklikes* (M+1) en (M+2)	*Lid met drie of meer afhanklikes* (M+3) en (M+4+)
R600	R750	R850

(d) 80% van die koste vir voorskrifte. Die Fonds is nie aanspreeklik vir die eerste R15 ten opsigte van elke voorskrif van 'n geneesheer of spesialis vir medisyne, verdowingsmiddels, verbande, salwe of velmiddels nie. Die Fonds kan, geheel na eie goeddunke, ondanks die bepalings van die reëls van die Fonds, sekere gespesifiseerde patente medisyne uitsluit van voorskrifte wat ingedien is. Hierdie voordeel is beperk tot hoogstens die volgende per boekjaar:

Enkele lid (M)	*Lid met een of twee afhanklikes* (M+1) en (M+2)	*Lid met drie of meer afhanklikes* (M+3) en (M+4+)
R2 850	R3 400	R3 800

(e) 80% van die voordeleskaal vir spesiale tandheelkundige dienste, d.w.s. krone en brugwerk, goudinlegsels, ortodontiek, periodontiek, goudinlegsels, ortodontiek, periodontiek, prostodontiek en tandestelle met 'n metaalbasis, beperk tot hoogstens die volgende per boekjaar:

Enkele lid (M)	*Lid met een of twee afhanklikes* (M+1) en (M+2)	*Lid met drie of meer afhanklikes* (M+3) en (M+4+)
R700	R750	R850

(f) 80% van die koste van mediese en chirurgiese bybehore, beperk tot hoogstens die volgende per boekjaar:

Enkele lid (M)	*Lid met een of twee afhanklikes* (M+1) en (M+2)	*Lid met drie of meer afhanklikes* (M+3) en (M+4+)
R400	R450	R550".

Soos gemagtig, vir en namens die partye by die Raad, op hede die 7de dag van November 1995 te Durban onderteken.

B. CARR
Voorsitter van die Raad

J. DLADLA
Ondervoorsitter van die Raad

R. E. REDFERN
Sekretaris van die Raad

No. R. 1151 **12 July 1996**

LABOUR RELATIONS ACT, 1956

CORRECTION NOTICE

MOTOR INDUSTRY: AMENDMENT OF MOTOR INDUSTRY MEDICAL AID FUND AGREEMENT

The following correction to Government Notice No. R. 1042 appearing in *Government Gazette* No. 17270 of 28 June 1996, is published herewith for general information:

1. In CLAUSE 8: CONTRIBUTIONS: Subclause (12) of the English text, substitute the expression "R24,44" for the expression "R24,24".

2. In "KLOUSULE 8: BYDRAES: Subklousule (12) of the Afrikaans text, substitute the expression "R24,44" for the expression "R24,24".

No. R. 1151 **12 Julie 1996**

WET OP ARBEIDSVERHOUDINGE, 1956

VERBETERINGSKENNISGEWING

MOTORNYWERHEID: WYSIGING VAN MEDIESE HULPFONDSOOREENKOMS VIR DIE MOTORNYWERHEID

Onderstaande verbetering aan Goewermentskennisgewing No. R. 1042 wat in *Staatskoerant* No. 17270 van 28 Junie 1996 verskyn, word vir algemene inligting gepubliseer.

1. In KLOUSULE 8: BYDRAES: Subklousule (12) van die Afrikaanse teks, vervang die uitdrukking "R24,24" met die uitdrukking "R24,44".

2. In "CLAUSE 8: CONTRIBUTIONS: Subclause (12)" van die Engelse teks, vervang die uitdrukking "R24,24" met die uitdrukking "R24,44".

DEPARTMENT OF TRANSPORT
DEPARTEMENT VAN VERVOER

No. R. 1152 **12 July 1996**

1. It is hereby notified that the Minister of Transport, acting in collaboration with the Minister of Finance, in terms of section 3 (7) of the Carriage by Air Act, 1946 (Act No. 17 of 1946), has converted the sums in Francs mentioned in section 22 of the Schedule to the said Act into the currency of the Republic in the following manner:

Sum specified in Schedule to Act—Francs	*Currency of the Republic—Rand*
250 000	R106 701,50
5 000	R 2 134,03
250	R 106,70

2. Government Notice No. R. 1003 of 7 July 1995 is hereby withdrawn.

S. R. MAHARAJ

Minister of Transport

No. R. 1152 **12 Julie 1996**

1. Hierby word bekendgemaak dat die Minister van Vervoer, handelende in oorleg met die Minister van Finansies, kragtens artikel 3 (7) van die Wet op Lugvervoer, 1946 (Wet No. 17 van 1946), die bedrae wat in artikel 22 van die Bylae van daardie Wet vermeld word, in die betaalmiddel van die Republiek op die volgende wyse omgesit het:

Bedrag in Bylae van Wet vermeld—Frank	*Betaalmiddel van die Republiek—Rand*
250 000	R106 701,50
5 000	R 2 134,03
250	R 106,70

2. Goewermentskennisgewing No. R. 1003 van 7 Julie 1995 word hierby herroep.

S. R. MAHARAJ

Minister van Vervoer

No. R. 1170 **12 July 1996**

ROAD TRAFFIC ACT, 1989 (ACT No. 29 OF 1989)

AMENDMENT OF THE ROAD TRAFFIC REGULATIONS

CORRECTION NOTICE

The following correction to regulations 22, 28 and 29, including the headings thereof, of the Twenty-seventh Amendment to the Road Traffic Regulations, 1996, published by Government Notice No. R. 1076 of 28 June 1996, is hereby published for general information:

In regulations 22, 28 and 29 of the Regulations substitute for the expression "30 June 1996", wherever it may occur, of the expression "30 June 1995".

No. R. 1170 **12 Julie 1996**

PADVERKEERSWET, 1989 (WET No. 29 VAN 1989)

WYSIGING VAN DIE PADVERKEERSREGULASIES

VERBETERINGSKENNISGEWING

Onderstaande verbeteringe aan regulasies 22, 28 en 29, met inbegrip van die opskrifte daarvan, van die Sewe-en-twintigste Wysiging van die Padverkeersregulasies, 1996, gepubliseer by Goewermentskennisgewing No. R. 1076 van 28 Junie 1996, word hierby vir algemene inligting gepubliseer:

Deur in regulasies 22, 28 en 29 van die Regulasies die uitdrukking "30 Junie 1996", waar dit ook al voorkom, deur die uitdrukking "30 Junie 1995" te vervang.

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Department of Environment Affairs
Departement van Omgewingsake

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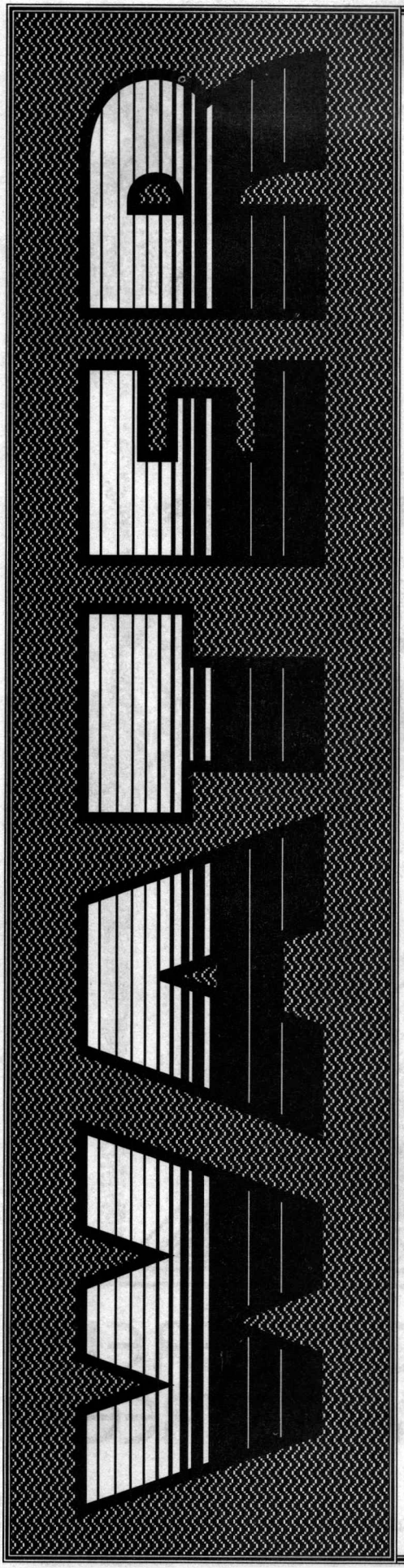

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Department of Environment Affairs

Departement van Omgewingsake

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