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DEPARTMENT OF HEALTH

NO. R. 3258 **24 March 2023**

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

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

The Minister of Health intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and in consultation with the South African Health Products Regulatory Authority (SAHPRA), to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities and Relations Management, mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za) within one month from the date of publication of this Notice.

DR M.J. PHAAHLA, MP

MINISTER OF HEALTH

DATE: 06/03/2023

SCHEDULE

Definitions

1. In these Regulations any expression defined in the Act bears that meaning and, unless the context otherwise indicates –

"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and

"the Regulations" means the General Regulations as published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended —

(*a*) by the substitution of the definition of "complementary medicine" for the following definition:

" "**complementary medicine**" means a Category D medicine;";

(*b*) by the insertion after the definition of "counterfeit medicine" of the following definition:

"**discipline-specific medicine**" means a Category D medicine contemplated in regulation 9(2)(*a*) that is intended for use in humans;";

(*c*) by the substitution of the definition of "health supplement" for the following definition:

"health supplement" means a Category D medicine contemplated in regulation 9(2)(*b*) that is intended for use in humans;"; and

(*d*) by the insertion after the definition of "the Act" of the following definitions:
"veterinary discipline-specific medicine" means a Category D medicine contemplated in regulation 9(2)(*a*) that is intended for use in animals;

(e) by the insertion after the definition of "the Act" of the following definitions:
"**veterinary health supplement**" means a Category D medicine contemplated in regulation 9(2)(*b*) that is intended for use in animals;"

Amendment of regulation 9 of the Regulations

3. Regulation 9 of the Regulations is hereby amended —

(*a*) by the substitution in sub-regulation (1) for paragraph (*d*) of the following paragraph:

"(*d*) Category D = Medicines as classified in sub-regulation (2), intended for use in humans or animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine."

(*b*) by the substitution in sub-regulation (2) for paragraphs (*a*) and (*b*) of the following paragraphs:

"(*a*) medicines identified in class 33 of Annexure 1 and class 28 of Annexure 2; and

(*b*) medicines identified in class 34 of Annexure 1 and class 29 of Annexure 2, excluding medicines or substances listed as Schedule 1 or higher in the Act."

(*c*) by the substitution for sub-regulation (3) of the following sub-regulation:

"(3) Medicines in Categories A and D intended for use in humans are subdivided into classes as per Annexure 1"; and

(*d*) by the substitution for sub-regulation (4) of the following sub-regulation:

"(4) Medicines in Categories C and D intended for use in animals are subdivided into classes as per Annexure 2."

Amendment of regulation 10 of the Regulations

4. Regulation 10 of the Regulations is hereby amended by the substitution in sub-regulation (1)(*cc*) for the words "in the case of complementary medicine" of the words "in the case of a Category D medicine".

Amendment of regulation 11 of the Regulations

5. Regulation 11 of the Regulations is hereby amended —

(*a*) by the substitution in sub-regulation (2)(*t*) for the words "in the case of a complementary medicine" of the words "in the case of a Category D medicine"; and

(*b*) by the addition in sub-regulation (2)(t)(ii) after the word "discipline" of the words "of the medicine".

Amendment of regulation 12 of the Regulations

6. Regulation 12 of the Regulations is hereby amended —

(*a*) by the substitution in sub-regulation (2)(*n*) for the words "in the case of a complementary medicine" of the words "in the case of a Category D medicine"; and

(*b*) by the addition in sub-regulation (2)(*n*)(ii) after the word "discipline" of the words "of the medicine".

Amendment of regulation 13 of the Regulations

7. Regulation 13 of the Regulations is hereby amended —

(a) by the substitution in sub-regulation (1)(*x*) for the words "in the case of a complementary medicine" of the words "in the case of a Category D medicine";

(b) by the substitution for in sub-regulation (1)(*x*)(i) of the following sub-paragraph:

"(i) a statement identifying the discipline of the medicine, or the wording "Veterinary Health Supplement", as the case may be;"

(c) by the insertion in sub-regulation (1)(*x*)(ii) of the word "; and" after the words ""This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.""; and

(d) by the insertion after sub-regulation (1)(*x*)(ii) of the following sub-paragraph:

"(iii) the words "Complementary Medicine"."

Amendment of regulation 14 of the Regulations

8. Regulation 14 of the Regulations is hereby amended —

(a) by the substitution in sub-regulation (2)(*q*) for the words "in the case of a complementary medicine" of the words "in the case of a Category D medicine";

(b) by the substitution for in sub-regulation (2)(*q*)(i) of the following sub-paragraph:
"(i) a statement identifying the discipline of the medicine, or the wording "Veterinary Health Supplement", as the case may be;"

(c) by the insertion in sub-regulation (2)(*q*)(ii) of the word "; and" after the words ""This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.""; and

(d) by the insertion after sub-regulation (2)(*q*)(ii) of the following sub-paragraph:
"(iii) the words "Complementary Medicine"."

Amendment of regulation 42 of the Regulations

9. Regulation 42 of the Regulations is hereby amended —

(*a*) by the substitution in sub-regulation (5)(*c*)(ii) for the words "complementary medicine" of the words "Category D medicine"; and

(*b*) by the substitution in sub-regulation (5)(*c*)(ii)(bb) for the word "complementary" of the words "Category D".

Amendment of Annexure 1 of the Regulations

10. Annexure 1 of the Regulations is hereby amended —

(*a*) by the substitution in the heading of Annexure 1 for the words "CLASSES OF MEDICINES IN CATEGORIES A AND D (HUMAN COMPLEMENTARY MEDICINE)" of the words "CLASSES OF MEDICINES IN CATEGORIES A AND D INTENDED FOR USE IN HUMANS";

(*b*) by the substitution in class 33 for the words "Complementary Medicines: Discipline-Specific Traditional Claims" of the words "Discipline-Specific Medicines"; and

(*c*) by the substitution in class 34 for the words "Complementary Medicines: Health Supplements" of the words "Health Supplements".

Amendment of Annexure 2 of the Regulations

11. Annexure 2 of the Regulations is hereby amended —

(*a*) by the substitution in the heading of Annexure 2 for the words "CLASSES OF MEDICINES IN CATEGORIES C AND D (VETERINARY COMPLEMENTARY MEDICINES)" of the words "CLASSES OF MEDICINES IN CATEGORIES C AND D INTENDED FOR USE IN ANIMALS";

(*b*) by the substitution in class 28 for the words "Veterinary Complementary Medicines: Discipline-Specific Traditional Claims" of the words "Veterinary Discipline-Specific Medicines"; and

(*c*) by the substitution in class 29 for the words "Veterinary Complementary Medicines: Supplements" of the words "Veterinary Supplements".

Short title

12. These Regulations are called General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (Act No. 101 Of 1965): Amendment

DEPARTMENT OF HEALTH

NO. R. 3259 **24 March 2023**

HEALTH PROFESSIONS ACT, 1974, (ACT NO. 56 OF 1974)

REGULATIONS RELATING TO THE CONSTITUTION OF THE PROFESSIONAL BOARD FOR EMERGENCY CARE

The Minister of Health has, in terms of section 15 of the Health Professions Act, 1974 (Act No.56 of 1974), and on the recommendation of the Health Professions Council of South Africa, made the regulations in the Schedule.

.....

DR. M.J PHAAHLA, MP
MINISTER OF HEALTH
DATE: 24/02/2023

SCHEDULE

Definitions

1. In these regulations **"the Act"** means the Health Professions Act, 1974 (Act No. 56 of 1974), and any expression to which a meaning has been assigned in the Act shall bear such meaning, unless the context indicates otherwise -

"board" means the Professional Board for Emergency Care established in terms of Section 15 of the Act;

"designated groups" means black people, women and persons with disabilities who, for purposes of these regulations, shall be protected and advanced in the following order of the levels of disadvantage of the past, which must be taken into consideration in the appointment process:

(a) women,

(b) men of African, Asian or Coloured descent, and

(c) disabled persons, irrespective of descent; and

"Republic" means the Republic of South Africa.

Constitution of the board

2. The board shall consist of the following 21 members who permanently reside in the Republic and appointed by the Minister on the basis of nominations by persons who permanently reside in the Republic:

a) four paramedics, of whom at least two shall be from designated groups and at least one shall be a woman, whose names appear in the register of paramedics;

b) one ambulance emergency assistant, whose name appears in the register of ambulance emergency assistants;

c) one emergency care assistant, whose name appears in the register of emergency care assistants;

d) one basic ambulance assistant, whose name appears in the register of basic ambulance assistants;

e) one emergency care technician whose name appears in the register of emergency care technicians;

f) seven emergency care, of whom at least three shall be from designated groups and at least two shall be a woman, whose names appear in the register of emergency care ;

g) one person registered with the board, and recommended by Universities South Africa to represent educational institutions;

h) one person representing the Department of Health; and

i) four community representatives, of whom at least two shall be from designated groups and at least one shall be a woman.

Repeal

3. The Regulations relating to the Constitution of a Professional Board for Emergency Care Practitioners Published under Government Notice R1254 in Government Gazette 31633 of 28 November 2008 are hereby repealed .

Short Title

4. These Regulations are called Regulations relating to the constitution of the professional board for emergency care.

DEPARTMENT OF HEALTH

NO. R. 3260 **24 March 2023**

THE SOUTH AFRICAN DENTAL TECHNICIANS' COUNCIL

REGULATIONS RELATING TO THE UNDERGRADUATE CURRICULA AND EXAMINATIONS IN DENTAL TECHNOLOGY

The Minister of Health, in terms of section 50(1) of the Dental Technicians Act, 1979 (Act No. 19 of 1979), and on the recommendation of the South African Dental Technicians Council of South Africa, hereby makes the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for attention of the Director: Public Entities Governance; mihloti.mushwana@health.gov.za within three month of the date of publication of this notice.

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 22/02/2023

SCHEDULE

Definitions

1. In these regulations any expression to which a meaning has been assigned in the Act, shall bear that meaning and, unless inconsistent with the context—

"accreditation" means the process conducted by the council or an external and impartial body approved by the council and reporting to council, to grant recognition and approval to the academic and training requirements and professional programme of studies at a training institution;

"curricula" means the academic programmes outlining the academic learning, clinical orientation and the development of dental technology skills, as well as the integration of the students' professional attitude and conduct;

"oral health appliances or prostheses" means any removable or fixed intra- or extra-oral prosthesis;

"programme" means the collective set of activities and assessments through which the curriculum is delivered;

"student" means a person registered as such with the council in terms of the Act;

"the Act" means the Dental Technicians Act, 1974 (Act No, 19 of 1979).

Requirements for undergraduate dental technology curriculum

2. (1) The dental technology curriculum of an approved institution must provide for—

(a) academic learning;

(b) training;

(c) development of dental technology skills; and

(d) development of professional attitudes and conduct.

(2) The curriculum contemplated in subregulation (1) must contribute to the development of students into dental technicians or dental technologists.

(3) The curriculum contemplated in subregulation (1) must—

(a) convey knowledge, skills, attitudes and appropriate modes of professional conduct;

(b) stimulate students to pursue continuous professional development as part of life-long learning;

(c) develop research and management abilities where applicable; and

(d) be relevant for conditions in South Africa while meeting international standards of excellence.

(4) A core curriculum must be developed by each approved institution to ensure that students achieve the minimum core competencies or exit level outcomes as defined from time to time by Rule by the Council acting as a Standards Generating Body, as required by the South African Qualification Authority.

(a) The curriculum shall take cognizance of the resources and technologies currently available in South Africa.

(b) The curriculum must include courses on jurisprudence, bioethics and occupational health and safety.

(c) The curriculum content, teaching methods and assessment methods shall be designed to promote students' ability to—

i. source information;

ii. critically evaluate information;

iii. synthesize information from different sources; and

iv. solve problems.

(d) The curriculum must provide for work integrated learning using the most recent and evidence-based materials, techniques and equipment.

Contents of curriculum

3. (1) The undergraduate dental technology curriculum of an approved institution must provide for—

(a) applied knowledge and understanding of the normal structure, functions and development of the oro-facial region;

(b) applied knowledge and understanding of the dental materials used for oral prostheses;

(c) applied knowledge and understanding of scientific principles and concepts in the creation of oral health appliances or prostheses and the ability to think critically, analytically and creatively with regard to problem-solving;

(d) the ability to use dental and scientific terminology with confidence;

(e) understanding of the principles of therapy and disease management.

(2) The undergraduate dental technology curriculum of an approved institution must include the learning of the following essential skills required for dental technology:

(a) Skills in the creation, repair, and modification of oral health appliances or prostheses in the fields of—
  (i) removable prosthodontics;
  (ii) fixed prosthodontics;
  (iii) maxillofacial prosthodontics;
  (iv) orthodontics;
(b) skills in infection control procedures;
(c) basic computer and, where applicable, management and supervisory skills;
(d) communication skills;
(e) skills to assist in shade taking;
(f) ability to function as a member of a dental team and where appropriate, leadership skills;
(g) ability to operate and clean equipment and knowledge of basic equipment maintenance.

(3) The undergraduate dental technology curriculum of an approved institution must include courses that teach appropriate attitudes and behaviour patterns to ensure the creation of quality oral health appliances.

(4) The courses contemplated in subregulation (3) must include instruction on—
(a) commitment to the oral health care of the community;
(b) recognition of the importance of working together as a team with clinicians;
(c) the establishment of a commitment to life-long learning;
(d) willingness to participate in self and peer evaluations;
(e) awareness of personal limitations and a willingness to seek help when necessary;
(f) recognition of and respect for human and patient rights;
(g) commitment to professional practice with due consideration for the ethics involved.

(5) The undergraduate dental technology curriculum of an approved institution must include all the practical work as per the minimum items and number (quotas) as published by the Council from time to time by Rule.

Duration of study

4. (1) The qualifications in dental technology that may be obtained at an approved institution are—

(a) a Diploma, to be completed within a minimum period of two years and no more than three years;

(b) a Diploma, to be completed within a minimum period of three years and no more than five years;

(c) an Advanced Diploma to be completed within a minimum period of one year and no more than two years;

(d) a Postgraduate Diploma to be completed within a minimum period of one year and no more than two years;

(e) a Bachelor of Health Sciences Degree, to be completed within a minimum period of four years and no more than six years.

(2) Each year of study for the qualifications contemplated in subregulation (1) must be at least 32 weeks in duration excluding assessment time.

Assessment of students in dental technology

5. (1) The affective, cognitive and psychomotor skills of a student must be acquired under supervision and assessed on a continuous basis; the psychomotor skills must be assessed by the use of criterion-referenced rubrics and related to the Minimum Requirements as determined by Council from time to time by Rule.

(2) A student must in a balanced way be assessed on his or her application of knowledge and on his or her—

(a) practical skills;

(b) professional competence;

(c) bioethics; and

(c) social values.

(3) The assessment and examination of prescribed modules may be integrated or divided at the discretion of the approved institution concerned.

(4) In order to ensure continuous assessment, examiners must take into account the student's work throughout the course of study.

(5) A student must pass both the practical and theory components of the assessment. The pass mark shall be as prescribed in the rules of the approved institution: provided that a student's mark for the practical

components of the assessment must not be condoned to a pass on the grounds that other components are satisfactory.

(6) Each discipline or each component of a discipline as the case may be, of the final practical assessment must be passed. Should any discipline be failed and all other aspects of the final assessment have been passed, the failed disciplines must be re-assessed prior to the registration date of the following academic year.

(7) The final student assessment must enable the approved institution to meet its legal obligation to certify that the candidate is competent to practise in a safe and effective manner in relation to the essential skills and competencies as defined by the council for the undergraduate programme.

(8) Council may at its discretion and in line with the Regulations regarding registration and training of student Dental Technicians and student Dental Technologists appoint Council examiners to mark the final exit practical examination to determine suitability for registration.

Standard of education at approved institutions

6. (1) An approved institution must develop programmes that are—

(a) in line with the prescribed council guidelines and Regulations regarding registration and training of student Dental Technicians and student Dental Technologists and taking into account the guidelines of the Department of Education; and

(b) compliant with the principles as determined by the South African Qualifications Authority to qualify for recognition under the National Qualifications Framework Act, 2008 (Act No. 67 of 2008).

(2) An approved institution must establish structures for the internal evaluation of programmes with a view to quality assurance and in preparation for external evaluation/accreditation.

(3) An approved institution must, from time to time as determined by the council, submit progress reports to the council to ensure—

(a) implementation of these regulations and the guidelines referred to in subregulation (1); and

(b) establishment of the structures referred to in subregulation (2).

(4) The council must specify the guidelines for the accreditation of programme, curricula, syllabi, teaching, training and learning processes.

General requirements for training institutions

7. To qualify as an approved institution a training institution must—

(a) make its mission and goals available to the council;

(b) encourage research, in order to advance intellectual creativity, as well as to form a basis for teaching and learning in the undergraduate curriculum;

(c) have systems and structures to ensure that learning systems are grounded in contemporary educational theory and practice;

(d) have adequate learning infrastructure and resources, such as classrooms, lecture theatres, libraries, computer facilities, laboratories, and appropriate equipment, continuously maintained in good working order;

(e) have suitably qualified and registered academic staff in good standing that are involved in dental technology specific research and have had sufficient dental technology professional experience in the discipline to which they are appointed;

(f) engage continuously with the broader dental technology profession via the Advisory Committee structures that will ensure the relevance of what students are taught in terms of theory and practical work; and

(g) provide the required funding and infrastructure that will ensure the quality of work integrated learning that students will receive as part of the prescribed syllabus and specific curriculum.

Withdrawal

8. The Regulations approved on the 27 January 2023 under Notice No.2970 in Government Gazette No 47926 are hereby withdrawn.

Short Title

9. These Regulations are called Regulations relating to the undergraduate curricula and examination in respect of dental technology, 2023.

DEPARTMENT OF HEALTH

NO. R. 3261 **24 March 2023**

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

The Minister of Health has, in terms of section 22A (2) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), on the recommendation of the South African Health Products Regulatory Authority (SAHPRA), made and updated the Schedules.

This Schedule amends the Schedules as inserted by Government Notice R.509 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 24727, 10 April 2003; substituted by Government Notice R.935 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 31387, 5 September 2008; and amended by Government Notice R.1230 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 32838, 31 December 2009; Government Notice R.227 (Medicines and Related Substances Act: Schedules)in Government *Gazette* 35149, 15 March 2012; Government Notice R.674 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 36827, 13 September 2013, Government Notice R.690 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 36850, 20 September 2013,Government Notice R.104 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 37318, 11 February 2014; Government Notice R.352 (Medicines and Related Substances Act, 1965: Schedules) in, Government *Gazette* 37622, 8 May 2014; Government Notice R.234 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 38586, 20 March 2015; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 39815, 15 March 2016; Government Notice R.254 (Medicines and Related Substances Act, 1965:

Schedules) in Government *Gazette* 40041, 03 June 2016; Government Notice No.748 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 41009, 28 July 2017; Government Notice No.1261 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 41256, 17 November 2017; Government Notice No.1262 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 42052, 23 November 2018 and Government Notice No.755 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 42477, 23 May 2019; Government Notice No. R219 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 430151, 28 February 2020, Government Noice No. R586 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 43347, 22 May 2020,Government Notice No. R1375 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 44019, 18 December 2020, Government Notice No. 883 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 45176, 17 September 2021 and Government Notice No. 2685 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 47373, 28 October 2022 using the following convention:

- Words in bold and in square brackets (e.g. **[Gamma benzene hexachloride]** in Schedule 1), indicate omission from a Schedule
- Words underlined with a solid line (e.g. <u>Gamma benzene hexachloride</u>), indicate insertions in a Schedule.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No.101 of 1965)

Note: Where an alternative schedule(s) is included in natural parentheses at any point of an inscription, this is provided to indicate one or more alternative scheduling designation/s. This is for information only and shall not be used in the interpretation of such inscription.

SCHEDULE 1

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(4)*(a)*(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 1 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
Annexure 1C: Basic Ambulance Assistant
Annexure 1D: Ambulance Emergency Assistant
Annexure 1E: Emergency Care Technician
Annexure 1F: Emergency Care Assistant

(ii) Annexure 2: Dental Therapist;

(iii) Annexure 3: Optometrist.

(iv) Annexure 4: Podiatrist

(v) Annexure 5: Oral hygienists

Cetirizine

Diclofenac,

a. when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S3)

b. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)

c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

d. except when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 day; (S2)

e. except when intended for veterinary use (S3).

Ibuprofen

a. when contained in preparations intended for application to the skin, containing 5% m/m or less of ibuprofen, and presented in a pack size exceeding 50 grams; (S0)

b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older;

c. when contained in oral medicinal preparations, intended for human use only, supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12

years and older does not exceed 20 milligrams per kilogram of body weight. (S2, S3).

d. **except** when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)

e. **except** when intended for veterinary use. (S3)

Levocetirizine

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa.

OPTOMETRIST		
OPHTHALMIC PREPARATIONS: OTHER		
Substance	:	Fluorescein
Indication	:	For diagnostic purpose only i.e. In detecting corneal abrasions and foreign bodies in the eye, in applanation tonometry, in assessing the patency of the nasolacrimal duct and in contact lens fitting procedures
Route of Administration	:	Intra-ocular

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) with additional qualifications registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and recognised by the Health Professions Council of South Africa as an authorised prescriber.

ANALGESIC		
Substance	:	Paracetamol
Indication	:	Mild Pain
Route of Administration	:	Oral

ANALGESIC/ ANTI INFLAMMATORY Substance : Ibuprofen Indication : Mild to Moderate Pain Route of Administration : Oral
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER Substance : Loratadine Indication : Atopic dermatitis involving the eyelids Route of Administration : Oral
SYMPATHOMIMETIC Substance : Phenylephrine Indication : Minor ocular irritation Route of Administration : Topical (Drops)

ANNEXURE 5: ORAL HYGIENISTS

Oral hygienists registered with the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Act, 1974 (Act 56 of 1974)

ORAL HYGIENISTS
TOPICAL ANAESTHETIC Substance : Ethyl chloride Indication : Dental surface anaesthesia Route of Administration : Topical

– END SCHEDULE 1 –

SCHEDULE 2

a. All substances referred to in this Schedule are excluded when specifically packed, labeled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within their scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 2 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
Annexure 1C: Basic Ambulance Assistant
Annexure 1D: Ambulance Emergency Assistant
Annexure 1E: Emergency Care Technician
Annexure 1F: Emergency Care Assistant

(ii) Annexure 2: Dental Therapist;

(iii) Annexure 3: Optometrist.

(iv) Annexure 4: Podiatrist

Albendazole,

a. when intended for the treatment of intestinal parasites, as a single oral dose; (S4)

b. except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

[Cetirizine]

Diclofenac,

a. when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S3)

b. when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days;

c. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)

d. except when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S1)

e. except when intended for veterinary use. (S3)

Esomeprazole when indicated for the temporary, short-term relief of heartburn and hyperacidity subject to:

a) a maximum daily dose of 20 milligrams

b) a maximum treatment period of 14 days. (S4)

Ibuprofen,

a. when contained in oral medicinal preparations, intended for human use only in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a

maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight. (S3)

b. when contained in oral medicinal preparations, intended for human use only as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S1, S3)

c. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)

d. **except** when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)

e. **except** when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1);

f. **except** when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

g. **except** when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)

h. **except** when intended for veterinary use. (S3)

[Levocetirizine]

Piroxicam,

a. when intended for the emergency treatment of acute gout attacks, for a maximum treatment period of 5 days; (S3)

b. when intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; (S3)

c. except when intended for veterinary use (S3)

– END SCHEDULE 2 –

SCHEDULE 3

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 3 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

(v) Annexure 4: Podiatrist

Carbimazole

Clevidipine

Diclofenac,

a. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)

b. except when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S1)

c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

d. except when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days. (S2)

Ibuprofen **except:**

a. when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)

b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1)

c. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

d. when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the

Schedule 3

age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

e. when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

f. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

g. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age (S4).

Insulin Lispro

Piroxicam, **except:**

a. when intended for the emergency treatment of acute gout attacks, for a maximum treatment period of 5 days; and

b. when intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S2)

Trifarotene

– END SCHEDULE 3 –

SCHEDULE 4

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

(ii) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(iii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 4 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
Annexure 1C: Basic Ambulance Assistant
Annexure 1D: Ambulance Emergency Assistant
Annexure 1E: Emergency Care Technician
Annexure 1F: Emergency Care Assistant

(ii) Annexure 2: Dental Therapist;

(iii) Annexure 3: Optometrist.

(iv) Annexure 5: Oral Hygienists

Albendazole,

a. except when intended for the treatment of intestinal parasites, as a single oral dose; (S2)

b. except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Amivantamab

Eptinezumab

Esomeprazole, except when indicated for the temporary, short-term relief of heartburn and hyperacidity, subject to:

a) a maximum daily dose of 20 milligrams

b) a maximum treatment period of 14 days. (S2)

Glofitamab

Human C1-esterase inhibitor

Human von Willebrand Factor

Ibuprofen

a. Ibuprofen, when intended for the treatment of a haemodynamically significant patent ductus arterious in infants less than 34 weeks of gestational age;

b. **except** when contained in preparations intended for application to the skin; containing 5 % m/m or less of ibuprofen; (S0, S1)

c. **except** when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1)

d. **except** when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance,

intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

e. **except** when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

f. **except** when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

g. **except** for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

h. **except** when intended for veterinary use (S3).

Icosapent ethyl

Latanoprostene

Mosunetuzumab

Nirmatrelvir

Ponesimod

Rifapentine

Tremelimumab

Vasopressin

Vericiguat

ANNEXURE 5: ORAL HYGIENISTS

Oral hygienists registered with the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Act, 1974 (Act 56 of 1974)

ORAL HYGIENISTS
LOCAL ANAESTHETIC Substance : Lignocaine/Lidocaine hydrochloride with or without Adrenaline or Noradrenaline Indication : Dental surface anaesthesia (local anaesthetic) Route of Administration : Local injection
LOCAL ANAESTHETIC Substance : Mepivacaine with or without Adrenaline Indication : Dental surface anaesthesia (local anaesthetic) Route of administration : Local injection
LOCAL ANAESTHETIC Substance : Articaine with Adrenaline Indication : Dental surface anaesthesia (local anaesthetic) Route of administration : Local injection
LOCAL ANAESTHETIC

ORAL HYGIENISTS	
Substance	: Prilocaine with or without Adrenaline
Indication	: Dental surface anaesthesia (local anaesthetic)
Route of administration	: Local injection

– END SCHEDULE 4 –

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following:

   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

   (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 5 and Specified Schedule 5 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

   (i) Annexure 1A: Emergency Care Provider (Paramedic);

   Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

   Annexure 1E: Emergency Care Technician

c. Specified Schedule 5 substances listed in this schedule are subject to additional control in terms of section 22A of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by **

– END SCHEDULE 5 –

SCHEDULE 6

a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i) as well as the isomers of such esters and ethers, where the existence of isomers of such esters or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients

under his/her care, the Schedule 6 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

– END SCHEDULE 6 –

SCHEDULE 7

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

– END SCHEDULE 7 –

These Schedules as amended come into operation on the date of publication in the Government *Gazette*.

DR MJ PHAAHLA, MP
MINISTER OF HEALTH
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