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CONTENTS

Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 177 2008

COMMENCEMENT OF MEDICINES AND
RELATED SUBSTANCES CONTROL ACT, 2003

Under section 48 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I determine that the Act comes into operation on the date of publication of this notice in the *Gazette*.

R. N. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES Windhoek, 30th June 2008

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 178 2008

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003:
REGULATIONS RELATING TO MEDICINES AND RELATED SUBSTANCES

The Minister responsible for Health, under section 44 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), and after consultation with the Namibia Medicines Regulatory Council, has made the regulations set out in the Schedule.

R. N. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES Windhoek, 30th June 2008

SCHEDULE

ARRANGEMENT OF REGULATIONS

Annexure XVII	Permit to manufacture a Schedule 4 substance or a specified Schedule 3 substance
Annexure XVIII	Application for permit to cultivate or collect plants or a portion of a plant from which a Schedule 4 substance or a specified Schedule 3 substance can be extracted, derived, produced, or manufactured
Annexure XIX	Permit to cultivate or collect plants or a portion of a plant from which a Schedule 4 substance or a specified Schedule 3 substance can be extracted, derived, produced, or manufactured
Annexure XX	Certificate of destruction and disposal of scheduled substances and medicines
Annexure XXI	Application for licence in terms of section 31(1), (2) or (3)
Annexure XXII	Licence issued in terms of section 31(1) of the Act
Annexure XXIII	Licence issued in terms of section 31(2) of the Act
Annexure XXIV	Licence issued in terms of section 31(3) of the Act
Annexure XXV	Application for permit in terms of section 31(4)
Annexure XXVI	Permit issued in terms of section 31(4)
Annexure XXVII	Application for licence in terms of section 31(5)
Annexure XXVIII	Licence issued in terms of section 31(5)
Annexure XXIX	Application for registration of premises used for manufacturing of medicines
Annexure XXX	Licence in respect of registration of premises used for manufacturing of medicines
Annexure XXXI	Application for renewal of licence in respect of registration of premises used for manufacturing of medicines
Annexure XXXII	Scheduled substances for use by registered nurse or midwife
Annexure XXXIII	Application by registered nurse or midwife to purchase, acquire or keep for administration in a midwifery case the scheduled substances set out in Annexure XXIX.
Annexure XXXIV	Permit for scheduled substances for use by registered nurse or midwife
Annexure XXXV	Register of Scheduled substances to be kept by registered nurse or midwife
Annexure XXXVI	Application for sale of unregistered medicine
Annexure XXXVII	Authorisation for the sale of unregistered medicines in terms of section 27 of the Act
Annexure XXXVIII	Fees

Definitions

1. In these regulations, unless the context otherwise indicates, any word or expression to which a meaning is assigned in the Act bears that meaning, and -

"appropriate medicines register" means -

(a) a medicines register referred to in section 17(1)(a) of the Act;

(b) a veterinary medicines register referred to in section 17(1)(b) of the Act;

(c) a complementary medicines register referred to in section 17(1)(c) of the Act; or

(d) any other register referred to in section 17(1)(d) of the Act,

as the case may be;

"approved name", in relation to an active ingredient of a medicine, means the internationally recognised non-proprietary name of such ingredient or such other name as the Council may determine;

"approved package insert," means a package insert approved by the Council upon application made under regulation 4;

"batch", in relation to any medicine, means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogenous properties;

"batch number", means the number or other cypher allocated to a batch of a medicine by the manufacturer;

"business address", in relation to a business carried on in Namibia, means the full physical address of the premises where that business is carried on;

"clinical trial", means any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of a medicine or to study the absorption, distribution, metabolism and excretion of a medicine with the object of ascertaining its safety and efficacy in respect of humans;

"expiry date", in relation to any batch of a medicine, means the date beyond which a manufacturer of that medicine does not guarantee that such medicine will retain its potency, purity, bioavailability and other properties;

"legibility of at least N.6", means the legibility of printing in 6 pt. type size, using 'Times Roman' or 'Helvetica' typeface in black ink on white paper or the equivalent thereof;

"legibility of at least N.12", means the legibility of printing in 12 pt. type size, using 'Times Roman' or 'Helvetica' typeface in black ink on white paper or the equivalent thereof;

"medicines regulatory authority", means the authority in a country responsible for enforcement of the laws relating to the registration and the control of medicines;

"package insert", means the document containing information regarding a medicine referred to in regulation 12 or 15, as the case may be;

"proprietary name", in relation to a medicine, means the name which is unique to a particular medicine and by which it is generally identified and which, in the case of a registered medicine, is the name approved by the Council in respect of that specific medicine in terms of section 19(8) of the Act;

"registered midwife", means a registered midwife as defined in section 1 of the Nursing Act, 2004 (Act No. 8 of 2004);

"scheduling status", in relation to a medicine, means the status of the medicine concerned according to the Schedule that it is classified as, as contemplated in section 29(1) of the Act; and

"the Act", means the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003).

Division of medicines into categories for purpose of registration

2. (1) For the purpose of registration of medicines as contemplated in section 19 of the Act, all medicines are divided into three basic categories, namely -

(a) Category A, in respect of medicines which are intended for use in humans and which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;

(b) Category B, in respect of medicines which cannot normally be administered without further manipulation; and

(c) Category C, in respect of medicines intended for veterinary use and which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.

(2) Medicines falling under the categories referred to in subregulation (1) are further subdivided into the pharmacological classes and into the medicine's principal pharmacological purpose or therapeutic effect, as set out in Annexure I to these regulations.

(3) For the purposes of subregulation (1)(a) and (c) "vehicle" means an inert substance with which a medicine is mixed to facilitate the measurement and administration or application of that medicine.

Persons who may apply for registration of a medicine

3. (1) Only -

(a) a person residing and doing business in Namibia;

(b) the manufacturer of a medicine manufactured in a country outside Namibia by virtue of a registration with the medicines regulatory authority of that country;

(c) a nominee residing in Namibia of a manufacturer referred to in paragraph (b) and authorised by the manufacturer;

(d) a subsidiary of a manufacturer referred to in paragraph (b) doing business in a country outside Namibia, provided the subsidiary -

(i) applies for the registration of medicines owned by the manufacturer; and

(ii) submits proof that the manufacturer partly or wholly owns the subsidiary; or

(e) the holder of a permit issued under section 31(4) of the Act to manufacture and sell a medicine or a scheduled substance,

may apply for the registration of a medicine as contemplated in section 19 of the Act.

(2) An applicant referred to in subregulation (1)(d) must produce satisfactory proof to the Council -

(a) of his or her or its registration as a pharmaceutical manufacturer by the medicines regulatory authority of the country where the medicine is manufactured; and

(b) that he or she or it holds a current certificate of good manufacturing practice issued by that medicines regulatory authority.

(3) With reference to an applicant referred to in subregulation (1)(b) and (d), the Council may make such investigations or cause such investigations to be made, as it considers necessary to establish any fact contemplated in subregulation (2).

(4) An applicant referred to in subregulation (1) must in such application provide the name, business address and telephone number of a pharmacist or other technical representative, with appropriate knowledge of all aspects of the medicine in respect of which registration is applied for, who is responsible for liaising with the Council.

(5) An applicant referred to in subregulation (1) who is not resident in Namibia must appoint a local representative, which may be the nominee contemplated in subregulation (1)(c), who may act in respect of medicines and scheduled substances as contemplated in the Act.

(6) A local representative referred to in subregulation (5) must have legal authorization from the applicant concerned to take responsibility for the medicine in respect of which registration is applied for on behalf of the applicant concerned and will be answerable to the Council in respect of the quality, safety and efficacy of the medicine concerned.

Application for registration of a medicine

4. Subject to regulation 5, an application for the registration of a medicine must be submitted to the Registrar in the form set out in Annexure II to these regulations, together with as many copies thereof as the Council may from time to time determine.

Samples, labels and other things to accompany application for registration of medicines

5. An application for the registration of a medicine must further be accompanied by -

(a) three samples of the medicine in the smallest of each of the package forms available for sale to the public or, if such product is not yet so available, three samples in containers in which the applicant intends to make it available for sale to the public;

(b) samples of all advertising material, package inserts and patient information leaflets which may be in draft form indicating the information which the applicant intends to use;

(c) if so requested by the Council or the Registrar, samples of the raw materials used in the manufacture of the medicine or reference standards used in the testing of the final product;

(d) a proposed label for use on the medicines;

(e) a certified copy of the manufacturing licence together with a current good manufacturing practices certificate from the medicines regulatory authority of the country of origin of the medicine concerned;

(f) proof of existence of a manufacturing site, in the form of a site master file; and

(g) in the case of a Schedule 3 or a Schedule 4 substance, a certified copy of a permit to manufacture such substances.

Reference numbers of applications

6. The Registrar -

(a) must allocate a reference number to each application for the registration of a medicine, and

(b) must record all reference numbers referred to in paragraph (a) in a register to be kept by him or her for that purpose.

Information to appear in appropriate medicines register

7. A -

(a) medicines register relating to medicines which are not veterinary medicines or complementary medicines must be kept in the form as set out in Annexure III to these regulations;

(b) veterinary medicines register relating to veterinary medicines must be kept in the form as set out in Annexure IV to these regulations;

(c) complementary medicines register relating to complementary medicines must be kept in the form as set out in Annexure V to these regulations,

and must contain the particulars required in the Annexure concerned.

Application for amendment of medicines register

8. (1) An application in terms of section 20 of the Act to have an entry in the medicines register amended must be in the form set out in Annexure VI to these regulations and must contain -

(a) the name of the medicine approved by the Council under section 19(8) of the Act;

(b) the registration number allocated to the medicine under section 19(9) of the Act;

(c) the name of the applicant or holder of the certificate of registration;

(d) the date of registration of the medicine;

(e) the entry in the appropriate medicines register for which amendment is being applied for; and

(f) the reasons for the amendment concerned.

(2) The Registrar may make such investigations, or cause such investigations to be made or call for such additional information, as he or she considers necessary to establish whether or not the amendment concerned should be approved.

(3) An amendment contemplated in this regulation may not be introduced to the medicine concerned before -

(a) such amendment has been approved by the Council; and

(b) the appropriate medicines register has been amended accordingly.

Certificate of registration

9. A certificate of registration contemplated in section 19(7)(b) of the Act must be in the form as set out in Annexure VII to these regulations.

Application for transfer of certificate of registration

10. An application contemplated in section 21(1) of the Act for approval to transfer a certificate of registration to a person qualified in terms of that subsection must be in the form as set out in Annexure VIII to these regulations and must contain-

(a) in respect of the holder of the certificate concerned -

(i) the name of the medicine approved by the Council under section 19(8) of the Act;

(ii) the registration number allocated to the medicine under section 19(9) of the Act;

(iii) the name of the holder of the certificate of registration concerned; and

(iv) the date of registration of the medicine concerned in terms of section 19 of the Act; and

(b) in respect of the person to whom the certificate concerned has to be transferred -

(i) the name and business address of the person to whom the certificate is to be transferred;

(ii) if application is made on behalf of a body corporate, the name and business address of such body corporate and proof of its incorporation or registration, as the case may be; and

(iii) proof that such person qualifies in terms of the Act as a person to whom such certificate may be transferred.

Labelling of medicines intended for administration to humans

11. (1) Subject to subregulations (2), (3) and (4), the immediate container of every medicine in which medicine intended for administration to humans is sold must have a label attached thereto, upon which the following particulars pertaining to the contents of such package must appear in clearly legible indelible letters in the official language:

(a) the proprietary name of the medicine, if any;

(b) the registration number of the medicine allocated in terms of section 19(9) of the Act or, in the case of a medicine in respect of which an application for registration has been submitted in accordance with section 19 of the Act, the reference number allocated to such application by the Registrar as contemplated in regulation 6, followed by the expression "(Act No. 13 of 2003)";

(c) the dosage form of the medicine;

(d) the international non-proprietary or approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume unit in lettering which may not be less than -

(i) in the case of a medicine containing only one active ingredient, the size of the largest lettering used for the said proprietary name, and be displayed adjacent to such name; or

(ii) in the case of a medicine which contains more than one active ingredient, one half the size of the largest lettering which is used for the said proprietary name,

but the lettering must have a legibility of at least N.6;

(e) the approved name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;

(f) in the case of a medicine for oral or parenteral administration, the quantity of ethyl alcohol, if any, contained in the medicine, expressed as a percentage of the total volume of the medicine;

(g) the content of the medicine package expressed in the appropriate unit or volume of the medicine;

(h) if practicable, the indications for use of the medicine;

(i) if practicable, the recommended dosage of the medicine;

(j) if applicable, the instruction "Shake the bottle before use";

(k) in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;

(l) in the case of a medicine classified as a scheduled substance as contemplated in section 29(1) of the Act, the letter "NS" followed by the number of the relevant Schedule, in a legibility of at least N.12, and surrounded by a square border, immediately preceding the proprietary name of such medicine or immediately preceding the approved name if there is no proprietary name;

(m) the batch number of the medicine;

(n) the manufacturing date of the medicine;

(o) the expiry date of the medicine;

(p) the manufacturer of the medicine;

(q) the requirements regarding the manner in which the medicine must be stored, with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;

(r) if applicable, the statement "For external use only";

(s) the warning "Keep out of the reach of children";

(t) in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability of the medicine has not been approved by the Council, the warning "Do not use more than 30 days after opening";

(u) any specified warning which, in terms of section 19(11) of the Act, has to be given on the label of a particular medicine as a condition of registration of that medicine;

(v) in the case of a medicine which contains tartrazine, the warning "Contains TARTRAZINE";

(w) in the case of a medicine which contains paracetamol, the warning "Contains PARACETAMOL"; and

(x) in the case of a medicine which contains aspirin, the warning "ASPIRIN should not be administered to children below the age of 16 years.".

(2) If the medicine package bears both an immediate container label and an outer label, subregulation (1) applies to the outer label as well, but it is then sufficient to state on the immediate container label -

(a) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (a), (c), (d), (k), (m), (n) and (o) of subregulation (1);

(b) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (b), (d), (e), (m), (n), and (o) of subregulation (1);

(c) in the case of a liquid, solution or suspension having a total volume more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (a), (b), (c), (d), (l), (m), (n), (o) and (s) of subregulation (1);

(d) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (a) and (o) of subregulation (1); and

(e) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (a), (d), (m), (n) and (o) of subregulation (1), repeated as frequently as is practicable.

(3) The Council may, on application to it by an applicant, authorize -

(a) the inclusion, on the label of a medicine, of any specified information which is not required by this regulation to be so included; or

(b) the deviation, on the label of a medicine, of any specified information which is required by this regulation, or prescribed as a condition of registration, to be so included.

(4) Subregulation (1) does not apply to -

(a) any medicine sold in accordance with section 18(5) of the Act;

(b) any medicine sold by -

(i) a person licenced under section 31(1) of the Act to prescribe and sell a medicine referred to in that section to his or her own patients;

(ii) a pharmacist licenced under section 31(2) of the Act to prescribe and sell a medicine referred to in that section to his or her own patients; or

(iii) a medical practitioner, dentist or veterinarian licenced under section 31(3) of the Act to prescribe and sell a medicine referred to in that section to his or her own patients,

if such medicine is labelled according to regulation 34(4)(e); or

(c) any medicine sold in accordance with a prescription issued by a medical practitioner, dentist or veterinarian for the treatment of a particular patient, if such medicine is sold in a package to which is attached a label containing -

(i) the name and strength of the medicine or the name and strength of each active ingredient or constituent medicine;

(ii) the quantity of the medicine sold;

(iii) the name of the patient;

(iv) the directions with regard to the manner in which such medicine should be used;

(v) the name and business address of the medical practitioner, dentist, veterinarian, pharmacist, pharmacy or hospital or any health facility selling such medicine;

(vi) the dispensing date; and

(vii) a reference number linking the medicine to a patient record.

Package inserts of medicines for human use

12. (1) Subject to such exclusions made by the Minister as contemplated in section 45 of the Act in respect of the medicine concerned and to subregulation (2), each package of a medicine for human use must be accompanied by a package insert approved by the Council, on application made in terms of regulation 4, either as a separate entity or as an integral part of the package and on which is printed in the official language and in type having a legibility of at least N.6, under the headings and in the format specified in this regulation, only the following particulars relating to such medicine -

(a) the scheduling status;

(b) the proprietary name, if any;

(c) the dosage form;

(d) the approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume unit of the medicine;

(e) the approved name and quantity of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;

(f) in the case of a medicine for oral or parental administration, the quantity of ethyl alcohol, if any, included in the medicine, expressed as a percentage of the total volume of the medicine;

(g) in the case of a medicine which contains TARTRAZINE, the warning "Contains TARTRAZINE";

(h) the category and pharmacological classification as contemplated in regulation 2 and Annexure I to these regulations, respectively;

(i) the pharmacological action;

(j) the pharmacokinetic and pharmacodynamic properties;

(k) the indications as approved by the Council in terms of section 19(4) of the Act;

(l) the contra-indications;

(m) the interaction with other drugs;

(n) use during pregnancy and lactation;

(o) the dosage and directions for use;

(p) the side-effects of, and special precautions;

(q) the known symptoms of over dosage and particulars of its treatment;

(r) the conditions of registration;

(s) the identification;

(t) the presentation;

(u) the storage directions, which must be practically formulated and quote storage temperatures as well as indicating the stability of the medicine after opening of the original package;

(v) (i) the specification of the diluent of oral or injectable powder in a bottle

ampoule or vial;

(ii) the specific volume of the diluent to be added;

(iii) the resultant volume of the reconstituted oral solution or injection;

(iv) the period and the temperature at which the reconstituted oral solution or injection should be kept;

(v) the shelf life; and

(vi) the date of reconstitution;

(w) the registration number -

(i) allocated to that medicine in terms of section 19(9) of the Act; or

(ii) in the case of a medicine in respect of which an application for registration has been submitted in accordance with section 19(1) of the Act, the reference number allocated to such application by the Registrar under regulation 6,

followed by the expression "(Act No.13 of 2003)";

(x) the name and business address of the manufacturer, and if a certificate of registration has been issued in respect of such medicine, the name of the holder of such certificate; and

(y) the date of publication of the package insert.

(2) The Council may authorise, on application to it by an applicant, -

(a) the deviation from the format of a package insert prescribed by this regulation as a condition of registration of a medicine;

(b) the inclusion on a package insert of any specified information which is not required by this regulation to be so included; and

(c) that a heading referred to in subregulation (1) may be omitted from the package insert, if the Council determines that there is no applicable information to be submitted under a particular heading.

(3) Subject to subregulation (4), subregulation (1) does not apply to -

(a) any medicine sold in accordance with section 18(5) of the Act;

(b) any medicine sold by -

(i) a person licenced under section 31(1) to prescribe and sell a medicine referred to in that section to his or her own patients;

(ii) a pharmacist licenced under section 31(2) to prescribe and sell a medicine referred to in that section to his or her own patients; or

(iii) a medical practitioner, dentist or veterinarian licenced under section 31(3) to prescribe and sell a medicine referred to in that section to his or her own patients; or

(c) any medicine sold in accordance with a prescription issued by a medical practitioner or dentist or veterinarian for the treatment of a particular patient.

(4) Nothing contained in subregulation (3) is construed as prohibiting the inclusion of a package insert in a package of medicine contemplated in that regulation.

Patient information leaflet

13. (1) Subject to subregulation (2), each package of a medicine must have a patient information leaflet that must contain, in the official language, the following information with regard to the medicine -

(a) the scheduling status;

(b) the proprietary name and dosage form;

(c) the international non-proprietary or approved name of each individual active ingredient;

(d) the approved indications and use;

(e) instructions before taking the medicine which include -

(i) contra-indications;

(ii) precautions to be taken;

(iii) warnings about undesirable effects of the medicine and risks involved with sudden withdrawal of the medicine;

(iv) interactions;

(v) the following general statements:

"If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Consult your doctor or pharmacist or other health care professional for advice."; and

"If you are pregnant or breast feeding your baby while taking this medication, please consult your doctor or pharmacist or other health care professional for advice.";

(f) (i) instructions on how to take the medicine, including the following statements:

"Do not share medicines prescribed for you with any other person."; and

"In the event of over dosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital.";

(ii) advice to the patient in case of a missed dose;

(g) the side effects, including the following general statement:

"Not all side effects reported for this medicine are included in the leaflet. Should your general health worsen while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.";

(h) storage and disposal information, including the following general statement:

"Store all medicines out of the reach of children.";

(i) the presentation, which includes the number, volume or mass per package unit and a

description of the packaging material, such as bottle, blister pack and so forth;

(j) the registration number of the medicine;

(k) the name, business address and telephone number of the holder of the certificate of registration; and

(l) the date of publication of the patient leaflet.

(2) The Council may authorize a deviation from subregulation (1) if it considers it necessary.

(3) A person dispensing or administering a medicine must ensure that a patient information leaflet is made available at the point of such dispensing.

(4) A person who sells a medicine in a package containing more than a quantity needed for the treatment of one patient must supply patient information leaflets equal to the number of patients who can be treated using the quantity of medicine in that package.

(5) The Council may on application in respect of an interchangeable multi-source medicine determine the information to be submitted under a particular heading.

Labelling of veterinary medicines

14. (1) Subject to subregulation (2), (3) and (4), the immediate container of every package in which a veterinary medicine is sold must have a label attached on which the following particulars pertaining to the contents of such package must appear in clearly legible indelible lettering in the official language:

(a) the words "veterinary medicine";

(b) the proprietary name of the medicine;

(c) the registration number of the medicine allocated in terms of section 19(9) of the Act or, in the case of a medicine in respect of which an application for registration has been submitted in accordance with regulation 6, the reference number allocated to such application by the Registrar followed by the expression "(Act No. 13 of 2003)";

(d) the dosage form of the medicine;

(e) the approved name 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 may not be less than -

(i) in the case of a medicine containing only one active ingredient, one half the size of the largest lettering which is used for the said proprietary name;

(ii) in the case of a medicine which contains more than one but less than six active ingredients, one-quarter the size of the largest lettering which is used for the said proprietary name;

(iii) in the case of a medicine containing six or more active ingredients, the minimum type size permitted by this regulation,

but the lettering must in any case not be smaller than the legibility of at least N.6;

(f) the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;

(g) the content of the medicine package expressed in the appropriate unit or volume of

the medicine;

(h) if practicable, the indications for use of the medicine;

(i) if practicable, the recommended dosage of the medicine;

(j) if applicable, the instruction "shake the bottle before use";

(k) in the case of a medicine intended for injection by a particular route of administration, only that route of administration by means of suitable words or abbreviation;

(l) in the case of a medicine classified as a scheduled substance as contemplated in section 29(1) of the Act, the letter "NS" followed by the number of the relevant Schedule, in a legibility of at least N.12, and surrounded by a square border immediately preceding the proprietary name of such medicine;

(m) the batch number of the medicine;

(n) the expiry date of the medicine;

(o) the name of the holder of certificate of registration of the said medicine;

(p) the requirement regarding the manner in which the medicine must be stored, with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;

(q) if applicable the statement "For external use only.";

(r) the warning "Keep out of the reach of children.";

(s) in the case of any medicine intended to be used in food producing animals and involving the possibility of the ingredients of such medicine or metabolites thereof being present in the eggs, milk or tissue of such animals, a warning regarding the withdrawal period of such medicine; and

(t) any specified warning which has to be given, in terms of section 19(11) of the Act, on the label of a particular medicine as a condition of registration of that medicine.

(2) If the medicine package bears both an immediate container label and an outer label, subregulation (1) applies to the outer label as well, but it is then sufficient to state on the immediate container label -

(a) in the case of a medicine intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (a), (b), (e), (k), (l), (m), and (n) of subregulation (1);

(b) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (a), (b), (c), (e), (m), (n), and (o) of subregulation (1)

(c) in the case of a liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (a), (b), (c), (d), (e), (l), (m), (n), and (o) of subregulation (1);

(d) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (a), (e), and (o) of subregulation (1);

(e) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (a), (b), (e), (m), (n) and (o) of subregulation (1), repeated as frequently as is practicable.

(3) The Council may, on application to it by an applicant, authorize the inclusion on the label of a medicine of any specified information, which is not required by this regulation to be so included.

(4) Subregulation (1) does not apply to -

(a) any medicine sold in accordance with section 31(3) of the Act for the treatment of a specific animal;

(b) any medicine sold by a veterinarian or pharmacist in the course of his or her professional activities for the treatment of a particular animal; or

(c) any medicine sold by a pharmacist in accordance with a prescription issued by a veterinarian for treatment of a particular animal,

if such medicine is sold in a package to which is attached a label containing the following information:

(i) the name of the medicine or the name of each active ingredient or constituent medicine;

(ii) the name of the person to whom such medicine has been sold and a description as accurate as possible, of the animals for which the treatment is intended;

(iii) the directions for the use of medicine;

(iv) the name and address of the veterinarian or pharmacist who has sold such medicine;

(v) the reference number allocated to the sale of the medicine as referred to in regulation 24(1)(g), and where applicable the warning, referred to in paragraph (s) of subregulation (1), regarding the withdrawal period of such medicine;

(vi) the date of dispensing;

(vii) the batch number; and

(viii) the expiry date.

Package inserts for veterinary medicines

15. (1) Subject to such exclusions made by the Minister as contemplated in section 45 of the Act in respect of the medicine concerned and subject to subregulation (2), the immediate container of a veterinary medicine that is sold, must be accompanied by a package insert in the official language with the following information with regard to the medicine in legibility of at least N.6 -

(a) the scheduling status;

(b) the proprietary name, if any;

(c) the dosage form;

(d) the approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume unit of the medicine;

(e) the category and pharmacological classification as contemplated in regulation 2 and Annexure I to these regulations, respectively;

(f) the pharmacological action;

(g) the pharmacokinetic and pharmacodynamic properties;

(h) the contra-indications;

(i) warnings of withdrawal period in the case of food producing animals;

(j) the side-effects of, and special precautions;

(k) the known signs of overdose and particulars of its treatment;

(l) the quantity and strength of active ingredients per dosage unit;

(m) the storage directions, which must be practically formulated and quote storage temperatures as well as indicating the stability of the medicine after opening of the original package;

(n) the registration number -

(i) allocated to that medicine in terms of section 19(9) of the Act; or

(ii) in the case of a medicine in respect of which an application for registration has been submitted in accordance with section 19(1) of the Act, the reference number allocated to such application by the Registrar under regulation 6, followed by the expression "(Act No.13 of 2003)";

(o) the name and business address of the manufacturer, and if a certificate of registration has been issued in respect of such medicine, the name of the holder of such certificate; and

(p) any other information as the Council may from time to time determine.

(2) The Council may upon application authorize a deviation from subregulation (1).

Advertising of medicines

16. (1) Subject to subregulation (7), medicines which -

(a) do not contain a scheduled substance; or

(b) contain a Schedule 0 or a Schedule 1 substance,

may be advertised to the public.

(2) Medicines which contain a Schedule 2, Schedule 3 or Schedule 4 substance may be advertised only -

(a) for the information of medical practitioners, dentists, veterinarians, pharmacists and nurses, or

(b) in a publication which is normally or only made available to members of the professions referred to in paragraph (a),

but this paragraph does not prohibit the announcement to the public of the prices of medicines which contains a substance appearing in the Schedules concerned.

(3) Any advertisement of a medicine that contains a statement which -

(a) deviates from;

(b) is in conflict with; or

(c) goes beyond,

the evidence and particulars submitted in the application for registration of such medicine with regard to the safety of the use of the ingredients in human beings or the efficacy of such ingredients in relation to the purpose for which it is intended that they should be used, constitutes an offence as contemplated in section 38(g) of the Act if such evidence and particulars have been accepted and approved by the Council in terms of section 19(1) of the Act in respect of such medicine and have been incorporated into the package insert of such medicine approved by the Council in terms of that section.

(4) An advertisement of a medicine must contain -

(a) the proprietary name and the name of the manufacturer thereof;

(b) the approved name and quantity of each active ingredient of such medicine in letters the size of which may not be less than -

(i) in the case of a medicine containing only one active ingredient, the same size as the largest lettering which is used for the said proprietary name, and be displayed adjacent to such name; or

(ii) in the case of a medicine which contains more than one active ingredient, one half the size of the largest lettering which is used for the said proprietary name;

(c) in the case of a registered medicine, the registration number allocated to it in terms of section 19(9) of the Act; and

(d) in any case where a name other than the proprietary name is also used, such name in lettering the same size as the largest lettering which is used for the said proprietary name in such advertisement.

(5) In the case of an advertisement of a medicine containing more than one active ingredient, no specific reference must be made to the specific properties of any individual active ingredient, unless a reference thereto has been approved by the Council for inclusion in the package insert of such medicine.

(6) If a medicine is advertised verbally for the first time by or on behalf of an applicant to any member of the medical, dental, veterinary, nursing or pharmaceutical profession, the applicant or person who advertises the medicine must simultaneously give written information, which must include at least the information called for in terms of regulation 12, to the person to whom the verbal advertisement is directed, and if the medicine is advertised verbally on subsequent occasions, the information concerned must be available on request.

(7) An advertisement of a medicine must be approved by the Council before such advertisement is used to advertise medicine to the public.

Informing Council of adverse reactions which occur during the use of a medicine and of substandard medicines

17. (1) Every applicant or holder of a certificate of registration in respect of a medicine must within a reasonable time inform the Council of any adverse reaction which occurred during the use of, or which was reported to him or her with regard to the use of a medicine for which he or she holds an application for registration or a certificate of registration.

(2) Every applicant or holder of a certificate of registration referred to in subregulation (1) must without delay inform the Council of the steps which he or she intends to take with regard to an adverse reaction concerned.

(3) For the purpose of this subregulation "adverse reaction" means unwanted effects not reflected to that extent in the package insert of such medicine.

(4) Every applicant or holder of a certificate of registration must -

(a) inform the Council immediately of any formulation, labelling or other error which has occurred with regard to a medicine for which he or she holds an application for registration or a certificate of registration, and which has been released for sale by him or her; and

(b) also inform the Council of steps taken by him or her or which he or she intends to take to rectify the error or with regard to the suspension of the sale of such medicine.

(5) Every authorised prescriber must within a reasonable time inform the Council on the form as set out in Annexure IX to these regulations of any adverse reaction which occurred during the use of any medicine.

(6) A person may report to the Council any medicine the quality of which has deteriorated, rendering it unfit for use.

Notice of particulars of applications received for registration of medicines

18. The Registrar must publish the following particulars in the *Gazette* as contemplated in section 19(12) of the Act -

(a) the proprietary name of the medicine;

(b) the international non-proprietary or approved name and quantity of each active ingredient of the medicine;

(c) the dosage form of the medicine; and

(d) the name of the applicant who lodged the application for registration.

Compounding of medicines by pharmacist for sale in the retail trade

19. (1) A pharmacist compounding a medicine for sale in the retail trade as contemplated in section 18(5)(b) of the Act may only compound a medicine that is -

(a) related to a treatment regimen of a particular patient; and

(b) sufficient to be used by the patient for not more than 30 consecutive days from the date of dispensing.

(2) Any medicine referred to in subregulation (1) must be compounded extemporaneously.

Method of taking samples by inspector and form of certificate where inspector has taken samples

20. (1) Any inspector who takes a sample in terms of section 36(1)(d) of the Act -

(a) must take a sample that is representative of the whole medicine or scheduled substance concerned;

(b) must, if taking samples from bulk medicines or large containers of scheduled substances, take care to reduce the risk of contamination by dust or other substances of the sample and the remaining bulk medicine or scheduled substance;

(c) may, if taking samples in the premises of a manufacturer, cause the personnel of the manufacturer to collect the sample under his or her observation if the taking

of the samples by him or her may increase the risk of contaminating the remaining medicine or scheduled substance;

(d) must in every case take enough quantities of the sample concerned for -

(i) two runs of the intended analysis;

(ii) two runs of parallel testing; and

(iii) a retention sample that is enough for two runs of the intended analysis,

and if the owner of the sample concerned wants to carry out a parallel analysis the sample must include the extra quantity required therefore;

(e) must take care that the container in which the sample of a bulk medicine or scheduled substance is packed does not interact with the medicine or scheduled substance concerned and may not allow contaminants to affect the medicine or scheduled substance in any way that would have a negative effect on the analytical results;

(f) must after taking a sample, label the container of the sample in order to contain the following information -

(i) the name of the medicine or scheduled substance, if known;

(ii) the batch number, if available;

(iii) the quantities of the sample taken;

(iv) the date on which the sample has been taken;

(v) the storage conditions of the sample;

(vi) the handling precautions of the sample;

(vii) his or her name;

(viii) the name of a witness;

(ix) the name of the place from where the sample was taken.

(2) The Council may require any holder of a certificate of registration to supply the Council with a sample of a particular medicine or scheduled substance in order to test, examine or analyse such sample.

(3) A certificate contemplated in section 36(2)(c) of the Act must be in the form set out in Annexure X to these regulations and must contain -

(a) the date on which and the place and time where and when the sample was taken;

(b) a description of the nature and size of each sample taken;

(c) the personal details of the person in whose presence the sample was taken;

(d) the name of the inspector taking the sample; and

(e) the cost of the sample taken.

(4) An inspector must submit to the Registrar a copy of every certificate referred to in subregulation (3) issued by the inspector.

Seizure and disposal of medicine or scheduled substance

21. (1) An inspector may seize any medicine or scheduled substance found in possession, or under the control, of a person not entitled under the Act to keep or use it, if -

(a) the medicine or scheduled substance concerned -

(i) consists of an unregistered medicine and is sold in contravention of the Act;

(ii) is suspected to be counterfeit;

(iii) is misbranded;

(iv) has expired;

(v) is suspected to be stolen;

(vi) is possessed by a person who may not possess it or by a person who may possess it, but who possesses it in quantities exceeding the quantity which he or she may possess;

(vii) belongs to the State and is found in possession of a person who may not possess it; or

(viii) is a biological medicine and is not stored at the specified temperature; or

(b) the Council is of the opinion that it is not in the public interest that the medicine or scheduled substance concerned be made available to the public.

(2) An inspector who has seized a medicine or scheduled substance as contemplated in subregulation (1) must as soon as possible and at the scene of seizure make a written inventory of all medicines or scheduled substances seized, and the inventory must include -

(a) the date, place and time of the seizure;

(b) the name and personal details of the person from whom or in whose presence the medicines or scheduled substances concerned were seized;

(c) the name and quantity of every medicine or scheduled substance seized;

(d) the reason for the seizure; and

(e) the name of the inspector conducting the seizure.

(3) An inspector who has seized a medicine or scheduled substance as contemplated in subregulation (1) may dispose thereof as contemplated in regulation 33.

(4) For the purposes of subregulation (1)(a)(ii), "counterfeit" means in relation to a medicine or a scheduled substance, that a false representation has been made with regard to the contents, identity or source thereof by any means, including the labelling and packing thereof.

Analysis of samples

22. An analyst must -

(a) state in the certificate set out in Annexure XI to these regulations the result of any test, examination or analysis on a sample transmitted to him or her in terms of section 36(2)(c) of the Act; and

(b) submit to the Registrar a copy of every such certificate which has been issued by him

or her.

Requirements for prescription for a medicine or a scheduled substance

23. (1) Every prescription for a medicine or a scheduled substance must be written in legible print and signed in person by the authorised prescriber who wrote it, and must state -

(a) the date of issue of the prescription;

(b) the name, strength and quantity of the medicine or scheduled substance to be supplied in terms of that prescription, and the quantity to be supplied must be expressed in figures as well as in words, but if the authorised prescriber has failed to express the quantity concerned in figures as well as in words, the pharmacist dispensing the prescription may insert, after obtaining confirmation from the authorised prescriber, the words or figures that have been omitted;

(c) the name and address of the patient or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance is to be sold, but if the authorised prescriber who wrote the prescription has omitted to insert thereon the address of the patient or person, the address may be inserted by the person by whom the prescription is dispensed;

(d) the name, qualifications and address of the authorised prescriber who wrote the prescription, which particulars may be printed on the prescription;

(e) in respect of the medicine or scheduled substance, instructions for the administration of the dosage concerned, the frequency of administration and the withdrawal period in the case of veterinary medicines for food producing animals;

(f) the age and gender of the patient and, in the case of a veterinary medicine, the animal species; and

(g) if the prescription may be repeated, the number of times it may be repeated.

(2) A pharmacist dispensing a faxed, e-mailed, telephonic or other electronic transmission of a prescription must -

(a) verify the authenticity of the prescription;

(b) make a permanent copy of the prescription concerned for record purposes; and

(c) obtain the original prescription or order within 7 working days.

(3) An authorised prescriber must keep a record of the diagnosis relevant to a prescription concerned and must indicate the diagnosis on the prescription.

(4) An authorised prescriber may only write an initial prescription after seeing and physically examining the patient in person.

Records of medicines and scheduled substances dispensed on prescription

24. (1) A prescription book or other permanent record must be kept on every premises where prescriptions for a patient to receive a medicine or a scheduled substance specified in that prescription are dispensed, and must be in a form in which the following information relating to every sale of a medicine or a scheduled substance on prescription must be entered for easy reference, namely -

(a) the name of the medicine or scheduled substance;

(b) the date on which the prescription was dispensed;

(c) the dosage, form, strength and quantity of the medicine or scheduled substance sold;

(d) the name and address of the patient or, in the case of a prescription written by a veterinarian, the name and address of the person to whom the medicine or scheduled substance was sold;

(e) the name of the authorised prescriber who wrote the prescription;

(f) the period of validity of the prescription; and

(g) a prescription reference number linking the patient to a patient record.

(2) The seller of a medicine or scheduled substance must retain -

(a) a prescription concerned for at least three years from the date on which the prescription was dispensed;

(b) a prescription book or other permanent record referred to in subregulation (1) at his or her business address for at least three years from the date of the last entry made therein.

Prescription books or other permanent records in respect of sales of Schedule 1, Schedule 2 and Schedule 3 Substances

25. (1) A prescription book or other permanent record in respect of Schedule 1, Schedule 2 or Schedule 3 substances must be kept on all premises where such substances are dispensed or sold and must contain -

(a) the date on which the scheduled substance was sold;

(b) the name of the scheduled substance;

(c) the dosage form, strength and quantity of the scheduled substance;

(d) the name and residential or business address of the person to whom the scheduled substance was sold; and

(e) the name of the seller.

(2) A pharmacist, pharmacist intern or pharmacist assistant who sells a Schedule 1 substance without a prescription in terms of section 29 of the Act must record -

(a) the name of the person to whom it was sold;

(b) the name of the scheduled substance and the quantity; and

(c) his or her own name.

(3) The seller of a scheduled substance contemplated in this regulation must retain a prescription book or other permanent record referred to in subregulation (1) at his or her business address for at least three years after the date of the last entry therein.

Records in respect of Schedule 4 substances and specified Schedule 3 substances for use by manufacturer, wholesaler, importer or exporter

26. (1) Every holder of -

(a) a permit in terms of section 29(15) and (23) of the Act to manufacture, pack and sell, import or export any Schedule 3 or Schedule 4 substance; or

(b) a permit in terms of section 31(4) or a license in terms of section 31(5) of the Act to manufacture, pack and sell, import or export any Schedule 3 or Schedule 4 substance,

must keep a record in respect of each such scheduled substance, in which the following information in respect of every import, export, manufacture, packing and sale, as the case may be, of a Schedule 3 or Schedule 4 substance must be recorded, namely -

(i) in the case of an import or export, the permit or licence number of the relevant import or export permit or licence issued in terms of these regulations in respect of such import or export;

(ii) the name and business address of the person from whom each such scheduled substance has been received or to whom such substance has been sold;

(iii) the date on which such scheduled substance was received, sold, packed, or manufactured; and

(iv) the quantity of such scheduled substance received, sold, packed, or manufactured.

(2) The seller of a scheduled substance contemplated in this regulation must retain a record referred to in subregulation (1) at his or her business address for at least three years after the date of the last entry therein.

Registers and prescription books or other permanent records in respect of Schedule 4 substances

27. (1) The register of Schedule 4 substances and the prescription book or other permanent record referred to in section 29(20) of the Act must be kept in one record, hereinafter referred to as the "register", and must substantially be in the form as set out in Annexure XII to these regulations, and must contain the following information in respect of each receipt or sale, as the case may be, of a Schedule 4 substance -

(a) the name and business address of the person from whom each such substance was received;

(b) the date on which such substance was received;

(c) the quantity of such substance received;

(d) the name and address of the person to whom such substance was sold;

(e) the date of the sale concerned;

(f) in the case of a sale of such a substance on prescription, the name and address of the medical practitioner, dentist or veterinarian who wrote the prescription;

(g) the quantity of such substance sold;

(h) the physical quantity of such substance remaining in stock after each sale or receipt; and

(i) the signature of the person making the entry in the register.

(2) A person required to keep a register referred to in subregulation (1) must retain such register at his or her business address for at least three years after the date of the last entry therein, and if such record is kept in electronic form, it must be held in the form of a computer print-out.

(3) A computer print-out referred to in subregulation (2) must be made monthly, and dated, signed and filed.

(4) Records must be stored separately and in an orderly manner so that they can be accessed easily.

(5) The entry of each receipt or sale of a Schedule 4 substance in the register referred to in subregulation (1) must be made on the date and time the transaction is completed.

Import permits for Schedule 4 substances or specified Schedule 3 substances

28. (1) Any person who intends to apply for a permit referred to in -

(a) section 29(15)(b) of the Act for the importation of a specified Schedule 3 substance; or

(b) section 29(23)(b) of the Act for the importation of a Schedule 4 substance,

must apply therefore to the Permanent Secretary in the form as set out in Annexure XIII to these regulations.

(2) The Permanent Secretary may refuse to issue the permit applied for if, after consultation with the Council, the Permanent Secretary is of the opinion that -

(a) the applicant is not capable of keeping or storing the scheduled substances concerned in a satisfactory manner in order to prevent its loss;

(b) the annual importation quota, if such a quota has been determined by the Council for the scheduled substance concerned, has been exceeded or will be exceeded; or

(c) the scheduled substance concerned, of an acceptable quality, is already available in Namibia.

(3) A permit issued in terms of section 29(15)(b) or (23)(b) of the Act in respect of the importation of a Schedule 3 or Schedule 4 substance -

(a) may only be issued after consultation with the Council; and

(b) must be in the form as set out in Annexure XIV to these regulations.

(4) It must be a condition of every permit referred to in this regulation that there may be no deviation, during the relevant importation of the scheduled substance concerned, from the particulars concerning that importation as set out in the relevant permit.

(5) Notwithstanding any penalty that may be imposed under section 39 of the Act, but subject to subregulation (6), the Permanent Secretary may cancel a permit referred to in subregulation (4), if the Permanent Secretary is of the opinion that subregulation (4) or the conditions contained in the permit concerned have not been complied with.

(6) A permit referred to in subregulation (5) may only be cancelled under section 29(17) or (24) of the Act if the Permanent Secretary has given the person to whom the relevant permit has been issued a prior opportunity to be heard on the matter.

Export permits for Schedule 4 substances or specified Schedule 3 substances

29. (1) A person who intends to apply for a permit referred to in -

(a) section 29(15)(b) of the Act for the exportation of a specified Schedule 3 substance; or

(b) section 29(23)(b) of the Act for the exportation of a Schedule 4 substance,

must apply therefore to the Permanent Secretary in the form as set out in Annexure XV to these regulations.

(2) A permit issued in terms of section 29(15)(b) or (23)(b) of the Act in respect of the exportation of a Schedule 4 substance or a specified Schedule 3 substance must be in the form as set out in Annexure XIV to these regulations.

(3) It must be a condition of every permit referred to in this regulation that there may be no deviation, during the relevant exportation of the scheduled substance concerned, from the particulars concerning that exportation as set out in the relevant permit.

(4) Notwithstanding any penalty that may be imposed under section 39 of the Act, but subject to subregulation (5), the Permanent Secretary may withdraw a permit referred to in subregulation (3), if the Permanent Secretary is of the opinion that subregulation (3) or the conditions contained in the permit concerned have not been complied with.

(5) A permit referred to in subregulation (4) may only be withdrawn as contemplated therein or be cancelled under sections 29(17) or (24) of the Act if the Permanent Secretary has given the person to whom the relevant permit has been issued, a prior opportunity to be heard on the matter.

Manufacturing permits for Schedule 4 substances or specified Schedule 3 substances

30. (1) A person who intends to apply for a permit referred to in -

(a) section 29(15)(a) of the Act to manufacture a specified Schedule 3 substance; or

(b) section 29(23)(a) of the Act to manufacture a Schedule 4 substance,

must apply therefore to the Council in the form as set out in Annexure XVI to these regulations.

(2) A permit issued in terms of section 29(15)(a) or (23)(a) of the Act in respect of the manufacturing of a specified Schedule 3 substance or a Schedule 4 substance must be in the form as set out in Annexure XVII to these regulations.

(3) It must be a condition of every permit referred to in this regulation that there may be no deviation, during the relevant manufacturing process of the scheduled substance concerned, from the particulars concerning that process as set out in the relevant permit.

(4) Notwithstanding any penalty that may be imposed under section 39 of the Act, but subject to subregulation (5), the Council may withdraw a permit referred to in subregulation (3), if the Council is of the opinion that subregulation (3) or the conditions contained in the permit concerned have not been complied with.

(5) A permit referred to in subregulation (4) may only be withdrawn as contemplated therein or be cancelled under sections 29(17) or (24) of the Act if the Council has given the person to whom the relevant permit has been issued, a prior opportunity to be heard on the matter.

Permits for cultivation or collection of plants from which Schedule 4 substances or specified Schedule 3 substances can be extracted, derived, produced or manufactured

31. (1) A person who intends to apply for a permit, referred to in -

(a) section 29(15)(c) of the Act, for the cultivation or collection of plants or portions thereof from which a specified Schedule 3 substance; or

(b) section 29(23)(c) of the Act, for the cultivation or collection of plants or portions thereof from which a Schedule 4 substance,

can be extracted, derived, produced or manufactured must apply therefore to the Council in the form as set out in Annexure XVIII to these regulations.

(2) A permit referred to in sections 29(15)(c) or (23)(c) of the Act must be issued in the form as set out in Annexure XIX to these regulations.

(3) It must be a condition of every permit referred to in this regulation that there may be no deviation, during the relevant cultivation or collection concerned, from the particulars concerning such cultivation or collection as set out in the relevant permit.

(4) Notwithstanding any penalty that may be imposed under section 39 of the Act, but subject to subregulation (5), the Council may withdraw a permit referred to in subregulation (3), if the Council is of the opinion that subregulation (3) or the conditions contained in the permit concerned have not been complied with.

(5) No permit referred to in subregulation (4) may be withdrawn as contemplated therein or be cancelled under sections 29(17) or (24) of the Act, unless the Council has given the person to whom the relevant permit has been issued, a prior opportunity to be heard on the matter.

Returns to be submitted in respect of Schedule 4 substances and specified Schedule 3 substances

32. (1) Every person who imports, exports, produces or manufactures a medicine containing, or consisting of, a Schedule 4 substance or such Schedule 3 substances, as may be specified by the Registrar by notice in the *Gazette*, must submit to the Registrar, on or before 28 February of each year, a return containing -

(a) the quantity of such substance as was held in stock on 31 December of the preceding calendar year;

(b) the quantity of such substance acquired during the preceding calendar year by the importation, production or manufacture of -

(i) any raw material of such substance;

(ii) any preparations of such substance;

(c) the quantity of such substance which was disposed of during the preceding year through the exportation of -

(i) any raw material of such substance;

(ii) any preparations of such substance;

(d) the quantity of such substance which was disposed of during the preceding year through authorised destruction; and

(e) the quantity of such substance utilised during the preceding year in the manufacture of preparations of substances exempted from Schedule 3 or Schedule 4.

(2) For the purposes of subregulation (1) -

(a) all quantities must be expressed in metric units as a percentage base of the relevant substance;

(b) opium, and any preparations containing opium quantities, must be expressed in terms of opium containing 10 per cent anhydrous morphine;

(c) preparations obtained by mixing opium alkaloids, such as omnopon, pantopon and papaveretum, must be expressed as morphine;

(d) if stocks are held or manufacture has been undertaken on behalf of another applicant, it must be indicated;

(e) "manufacture" means the manufacture of Category A and C medicines referred to in regulation 2 and set out in Annexure I to these regulations; and

(f) "produce," means the extraction or synthesis from raw material Category B medicines as referred to in regulation 2.

Destruction and disposal of medicines and scheduled substances

33. (1) Subject to subregulation (2), -

(a) a Schedule 4 and 5 substance and a specified Schedule 3 substance may only be destroyed in the presence of an inspector or a member of the Namibian Police Force Service, and the inspector or member of the Namibian Police Force Service, as the case may be, must issue a certificate in the form set out in Annexure XX to these regulations confirming the destruction of the scheduled substance concerned;

(b) a Schedule 1 and 2 substance and an unspecified Schedule 3 substance may be destroyed by a pharmacist or other person authorised in writing by the Permanent Secretary who is in charge of a place where the substances concerned are kept, and the pharmacist or authorised person concerned must certify such destruction;

(c) medicines or substances which have not been classified as scheduled substances as contemplated in section 29(1) of the Act may be destroyed by any authorised person referred to in paragraph (b) where the medicine or substance concerned is kept.

(2) Notwithstanding subregulation (1)(a), the Council may authorise the destruction of a Schedule 3 and 4 substance by a manufacturer of such substances if an inspector is not present.

(3) No medicine may be disposed of into a sewerage system of a local authority.

(4) The destruction and disposal of scheduled substances and medicines must be conducted in the manner determined by the Council to ensure that they are not retrievable.

(5) A medicine or scheduled substance which has been forfeited to the state as contemplated in section 39(2) and which is according to the court concerned a risk to the public health, must be destroyed in accordance with subregulation (1).

Licences and permits

34. (1) A -

(a) person lawfully performing a health service and who intends to apply, in terms of section 31(1) of the Act, for a licence to acquire, possess, and prescribe, use in respect of or sell to his or her patients any of such Schedule 1, 2 or 3 substances as the Council may from time to time specify for that purpose;

(b) pharmacist who intends to apply, in terms of section 31(2) of the Act, for a licence to prescribe and sell to persons in respect of whom he or she has issued a prescription, any of such Schedule 2 or 3 substances;

(c) medical practitioner, dentist or veterinarian who intends to apply, in terms of section 31(3) of the Act, for a licence to sell any Schedule 1, 2, 3 or 4 substance to his or her patients,

must apply therefore to the Council in the form as set out in Annexure XXI to these regulations.

(2) An application form referred to in subregulation (1) must contain the following information -

(a) the name of the applicant;

(b) the physical and postal addresses of the applicant;

(c) the exact location of the premises where the person, pharmacist, medical practitioner,

dentist or veterinarian, as the case may be, will possess, prescribe, use, sell or dispense, as the case may be, the scheduled substances concerned;

(d) the telephone and fax numbers of the applicant, if applicable;

(e) proof of registration with the relevant professional council;

(f) motivation as to the need for a licence in that particular area; and

(g) any other information that the Council may determine.

(3) In considering an application referred to in subregulation (1) the Council must have regard to the following -

(a) the existence of other health facilities licensed in terms of the Hospitals and Health Facilities Act, 1994 (Act No. 36 of 1994), or the Veterinary and Para-veterinary Professions Proclamation, 1984 (Proclamation No. AG. 14 of 1984), in the vicinity of the premises from where the acquisition, possession, prescription, use, sale or dispensing, as the case may be, of scheduled substances is intended to be carried out;

(b) representations, if any, by other interested persons as to whether a licence should be granted or not;

(c) the geographical area to be served by the applicant;

(d) the estimated number of health care users in the geographical area referred to in paragraph (c);

(e) demographic considerations, including disease patterns and health status of the users to be served; and

(f) any other information that the Council may require.

(4) A person, pharmacist, medical practitioner, dentist or veterinarin referred to in subregulation (1) who has been issued with a licence -

(a) must keep sales records either in hard copy or in electronic format relating to the scheduled substances possessed, prescribed, used, sold or dispensed, as the case may be, for a period of at least three years from the date of sale;

(b) must ensure that the dispensary and premises where the scheduled substances are kept, are suitable for the possession, prescription, use, sale or dispensing, as the case may be, of scheduled substances in accordance with good pharmacy practice and the Pharmacy Act, 2004 (Act No. 9 of 2004);

(c) must keep the scheduled substances under the manufacturers recommended storage conditions as specified on the medicines label or package insert;

(d) may not pre-pack scheduled substances at the premises, unless authorised to do so by the Council;

(e) must label the scheduled substances concerned with -

(i) the name of the patient and a reference number linking the patient to a patient record;

(ii) the name of the practice;

(iii) the date of dispensing;

(iv) the interchangeable multi-source name of the scheduled substances or the international non-proprietary name if the scheduled substance consists of two or more active ingredients;

(v) the quantity of the scheduled substance sold; and

(vi) the directions for use of the scheduled substances;

(f) may not compound and dispense scheduled substances to patients, unless the sale is preceded by a proper diagnosis and a prescription for a particular patient;

(g) may not keep expired scheduled substances on the premises other than in a demarcated area in a sealed container clearly marked "EXPIRED MEDICINES", and such expired scheduled substances must be destroyed as contemplated in regulation 33;

(h) may not allow a person who does not hold a licence, contemplated in section 31(1), (2) or (3) of the Act, to perform at the premises any act pertaining to his or her licence;

(i) must secure the premises where the storage, compounding and dispensing is carried out whenever he or she is not physically present at the premises concerned;

(j) must, in the event of a recall of a scheduled substance, withdraw that substance;

(k) must conspicuously display the licence concerned in the premises concerned; and

(l) must comply with the conditions of the licence concerned.

(5) The Council may exempt from this regulation a scheduled substance requiring preparation for a once off administration to a patient during consultation.

(6) A licence issued in terms of section -

(a) 31(1) of the Act must be in the form as set out in Annexure XXII to these regulations;

(b) 31(2) of the Act must be in the form as set out in Annexure XXIII to these regulations; and

(c) 31(3) of the Act must be in the form as set out in Annexure XXIV to these regulations.

(7) It must be a condition of a licence issued in terms of section 31(1), (2) or (3) of the Act that any act performed under such licence must only be performed in a health facility licensed in terms of the Hospitals and Health Facilities Act, 1994 (Act No. 36 of 1994), or the Veterinary and Para-veterinary Professions Proclamation, 1984 (Proclamation No. AG. 14 of 1984).

(8) A person who is not a pharmacist and who intends to apply in terms of section 31(4) of the Act for a permit referred to therein to manufacture or pack and sell a medicine or a scheduled substance must apply therefore to the Minister in the form as set out in Annexure XXV to these regulations.

(9) A permit referred to in subregulation (8) -

(a) may only be issued after consultation with the Council; and

(b) must be in the form as set out in Annexure XXVI to these regulations.

(10) Any person who may lawfully sell a medicine or a scheduled substance and who intends to apply in terms of section 31(5) of the Act for a licence referred to therein to manufacture,

pack and sell, import or export that medicine must apply therefore to the Council in the form as set out in Annexure XXVII to these regulations.

(11) A licence referred to in subregulation (10) must be issued in the form as set out in Annexure XXVIII to these regulations.

(12) Prior to commencing business a person referred to in subregulation (10) -

(a) must appoint and designate a pharmacist who must control the manufacturing of the medicines and scheduled substances concerned; and

(b) must appoint and designate a pharmacist who resides in Namibia who is responsible to the Council for compliance with the Act.

(13) It must be a condition of every licence or permit contemplated in this regulation that there may be no deviation from the particulars set out in the licence or permit with regard to the subject matter for which the licence or permit concerned was issued.

(14) Subject to subregulation (15) -

(a) the Council may revoke a licence referred to in subregulation (1);

(b) the Minister may revoke a permit referred to in subregulation (8);

(c) the Council may revoke a licence referred to in subregulation (10),

if the Council or the Minister, as the case may be, is of the opinion that subregulation (13) in respect of the licence or permit concerned has not been complied with.

(15) No licence or permit referred to in subregulation (14) may be revoked under section 31(9) of the Act, unless the Council or the Minister, as the case may be, has given the person to whom the relevant licence or permit has been issued a prior opportunity to be heard on the matter.

(16) The holder of a licence referred to in subregulation (1) and the holder of a permit referred to in subregulation (8) -

(a) is personally responsible for the safe-keeping of all scheduled substances he or she has purchased or acquired in terms of the licence; and

(b) must at all times at the request of any inspector produce -

(i) the licence concerned;

(ii) the prescription book, register, other permanent record or record referred to in regulation 25 or 26, as the case may be, in respect of the scheduled substance concerned; and

(iii) all quantities of scheduled substances in his or her possession in terms of the licence.

(17) Upon receipt of a notification of revocation of a licence as contemplated in section 31(9) of the Act the licence holder must personally hand over to the Permanent Secretary or the Council, as the case may be, or to a person duly authorised thereto by the Permanent Secretary or the Council, as the case may be -

(a) the licence concerned;

(b) the prescription book, register, other permanent record or record referred to in regulation 26 or 28, as the case may be, in respect of the scheduled substance concerned; and

(c) in the case of a licence referred to in section 31(1) or (3) of the Act, also any scheduled substances held in his or her possession in terms of the licence.

(18) If a licence holder referred to in subregulation (17) is unable to hand over in person any licence, prescription book, register, record or any scheduled substances in his or her possession as contemplated in that subregulation, the Permanent Secretary or the Council, as the case may be, or any person duly authorised thereto by the Permanent Secretary or the Council, as the case may be, may collect the items concerned from the licence holder.

(19) The Permanent Secretary or the Council, as the case may be, or any person duly authorized thereto by the Permanent Secretary or the Council, as the case may be, must make a written inventory of all items collected as provided in subregulation (18) and the inventory must include -

(a) the place, date and time of collection;

(b) the name and personal details of the person from whom the items are collected;

(c) the name and quantity of every item collected; and

(d) the name of the person collecting the items.

Application for registration of premises used for manufacturing of medicines and renewal of licence

35. (1) An application for the registration of a premises used for the manufacturing of medicines as contemplated in section 37A of the Act must be submitted to the Registrar in the form as set out in Annexure XXIX to these regulations.

(2) An application form referred to in subregulation (1) must contain the information required therein.

(3) A licence in respect of the registration of a premises used for the manufacturing of medicines must be issued in the form as set out in Annexure XXX to these regulations.

(4) An application for the renewal of a licence in respect of the registration of a premises used for the manufacturing of medicines as contemplated in section 37D(2) of the Act must be made -

(a) not later than three months before the expiry thereof, in the form as set out in Annexure XXXI to these regulations; and

(b) must contain the information required therein.

(5) A licence which has been renewed in respect of the registration of a premises used for the manufacturing of medicines must be issued in the form as set out in Annexure XXX to these regulations.

Obtaining of pethidine or preparations or mixtures thereof and other scheduled substances by a registered nurse or a registered midwife

36. (1) A person registered as a nurse or a midwife in terms of the Nursing Act, 2004 (Act No. 8 of 2004), who intends to purchase, acquire or keep for administration in a midwifery case the scheduled substances set out in Annexure XXXII to these regulations, must apply in writing in the form as set out in Annexure XXXIII to these regulations therefore to the Permanent Secretary, stating in such application -

(a) the type of nursing service for which the scheduled substances are required;

(b) the full name of the applicant, together with proof of current registration with the Nursing Council referred to in section 3(1) of the Nursing Act, 2004 (Act No. 8 of

2004);

(c) the registered name and address of the pharmacy from which the applicant intends to obtain the scheduled substances; and

(d) the name, strength, dosage forms and the precise quantities of the maximum supply of all scheduled substances for which the permit is requested.

(2) Subject to subregulation (3), the Permanent Secretary may issue, upon receipt of the application referred to in subregulation (1) and after making such enquiries as he or she may deem necessary, in his or her discretion a permit authorising the permit holder to purchase or acquire or keep or administer the requested scheduled substances.

(3) A permit referred to in subregulation (2) -

(a) may only be issued after consultation with the Council;

(b) must be issued in triplicate in the form as set out in Annexure XXXIV to these regulations; and

(c) (i) the original thereof must be submitted to the pharmacy from which the applicant intends to obtain the scheduled substances;

(ii) the duplicate thereof must be submitted to the permit holder concerned; and

(iii) the third copy thereof must be submitted to the Registrar.

(4) A permit referred to in subregulation (2) is issued subject to the following conditions -

(a) the permit holder must keep a register of scheduled substances in the form as set out in Annexure XXXV to these regulations in which must be recorded in Part A in the appropriate column thereof the following particulars of all the scheduled substances in his or her possession -

(i) the Schedule under which it is classified;

(ii) the name;

(iii) the strength; and

(iv) the stock on hand;

(b) the pharmacist supplying the scheduled substances must with each supply record the following particulars in Part B in the appropriate column of the register of scheduled substances -

(i) the date of supply;

(ii) the number of the permit;

(iii) the quantity supplied;

(iv) the name and address of the pharmacy; and

(v) the name and signature of the pharmacist;

(c) the permit holder must sign in the presence of the pharmacist for receipt of the scheduled substances in the register of scheduled substances;

(d) the permit holder must record, after administration of the scheduled substances, the

following particulars in Part C of the register of scheduled substances -

(i) the date and time of administration;

(ii) the name and address of the patient;

(iii) the quantity administered;

(iv) the reason for administration;

(v) his or her full signature; and

(vi) the balance on hand.

(5) The permit holder -

(a) is personally responsible for the safe-keeping of all scheduled substances he or she has purchased or acquired in terms of the permit; and

(b) must at all times at the request of any inspector produce such permit, the register of scheduled substances and all quantities of scheduled substances in his or her possession.

(6) The Permanent Secretary may at any time withdraw, by notice to the permit holder and after having given him or her an opportunity to be heard, a permit referred to in subregulation (2).

(7) On receipt of a notice of withdrawal the permit holder must personally hand over the permit, the register of scheduled substances and any scheduled substances in his or her possession, to the Permanent Secretary or any person duly authorised by the Permanent Secretary.

(8) If the permit holder is unable to hand over in person the permit, the register of scheduled substances and any scheduled substances in his or her possession as contemplated in subregulation (7), the Permanent Secretary or any person duly authorised thereto by the Permanent Secretary may collect the items concerned from the permit holder.

(9) The Registrar must keep a register of all permits issued to registered nurses and midwives in terms of these regulations.

(10) The Permanent Secretary must inform the Nursing Council of the full name and address of every registered nurse or midwife whose permit has been cancelled or withdrawn as contemplated in subregulation (6), together with the reasons therefore.

(11) A permit issued under subsection (2) must be renewed in January and June of each year.

Import and export of medicines or scheduled substances

37. (1) A person may only import or export a medicine or scheduled substance through -

(a) the Hosea Kutako International Airport near Windhoek;

(b) Eros airport;

(c) the Walvis Bay harbour;

(d) the Ariamsvlei border post near Ariamsvlei;

(e) the Noordoewer border post;

(f) the Buitepos border post;

(g) the Oshikango border post ;

(h) the Wenela border post near Katima Mulilo; or

(i) any post office in Namibia.

(2) A person may only import or export a scheduled substance if such person -

(a) is the holder of a license issued in terms of the Act to import scheduled substances; or

(b) in the case of an unregistered medicine contemplated in section 27, is authorised by the Council to import such unregistered medicine.

(3) The Council may require any person who imports any medicine or scheduled substance into Namibia to take a sample of each batch of that medicine or scheduled substance and analyse that sample or cause it to be analysed against the specifications of that medicine or scheduled substance to ensure that the quality thereof has not been affected during transportation.

Possession of certain scheduled substances by persons entering or departing from Namibia

38. Notwithstanding anything to the contrary in the Act or these regulations contained, any person entering or departing from Namibia who is in possession of -

(a) a prescription for a Schedule 4 substance or a specified Schedule 3 substance, signed by a medical practitioner, dentist or veterinarian; or

(b) a certificate by a pharmacist to the effect that the scheduled substance concerned was prescribed by a medical practitioner, dentist or veterinarian for such person,

may be in possession for personal medicinal use of a quantity of the scheduled substance concerned which does not exceed a reasonable quantity required for use for a period of not more than one month.

Transmission of Schedule 4 substances and specified Schedule 3 substances by post

39. Subject to regulation 27, if a Schedule 3 substance specified by the Registrar by notice in the *Gazette* or any Schedule 4 substance is to be conveyed into Namibia by letter post, the scheduled substance concerned may be sent or conveyed only by registered parcel post.

Transmission of scheduled substances through Namibia

40. (1) Scheduled substances that are transmitted through Namibia -

(a) if offloaded from the carrier while in Namibia, must be stored in a customs and excise warehouse contemplated in section 19 of the Customs and Excise Act, 1998 (Act No. 20 of 1998); and

(b) may not be manipulated in any way while in Namibia, unless authorised by the Council.

(2) The name, form of preparation and quantity of the scheduled substances referred to in subregulation (1) must be declared to staff members of the Office of the Commissioner for Customs and Excise at the port or place of entry and of exit.

(3) Every person who has made a declaration referred to in subregulation (2) must forward a copy thereof to the Council.

Control of medicines and scheduled substances in hospitals

41. (1) The -

(a) pharmacist in charge of a hospital pharmacy; or

(b) in the absence of that pharmacist, any other person licensed in terms of section 31(1) of the Act or any person authorised in terms of the Pharmacy Act, 2004 (Act No. 9 of 2004),

must supervise the safety, security, purchasing, storage and dispensing of medicines and scheduled substances in a hospital.

(2) Medicines and scheduled substances in hospitals must -

(a) be kept according to the storage conditions indicated on the label thereof;

(b) in the case of narcotics and psychotropic substances, be kept under lock and key if not dispensed; and

(c) be stored locked in such a manner that only a person referred to in subregulation (1) has access thereto.

(3) If the pharmacist or the other persons contemplated in subregulation (1)(a) and (b) are not available, the pharmacy concerned must be closed.

Re-packing of medicines into patient ready packs

42. (1) The re-packing of medicines into patient ready packs may only be carried out by -

(a) a pharmacist, or a pharmacist's assistant, a pharmaceutical technician or a pharmacist intern, acting under the personal supervision of a pharmacist; or

(b) any other person authorised in terms of the Pharmacy Act, 2004 (Act No. 9 of 2004.

(2) Every person re-packing medicines as contemplated in subregulation (1) -

(a) must use a batch numbering system; and

(b) must do the re-packing concerned -

(i) under the required temperature and humidity conditions specified by the manufacturer;

(ii) in an area of the premises concerned specially used for re-packing only; and

(iii) in accordance with the procedures relating to good manufacturing and distribution practices recommended by the World Health Organisation.

(3) The date of re-packing of any medicine must appear on the label of each container containing the repacked medicines.

Minimum standards for good manufacturing practices to be followed in the manufacture of medicines

43. (1) Any person manufacturing medicines in Namibia must follow and comply with the standards of good manufacturing practices as contained in the World Health Organisation guidelines on current good manufacturing practices.

(2) The Council must ensure through regular inspections -

(a) that all medicines registered in Namibia as contemplated in this Act are manufactured according to the World Health Organisation guidelines on current good manufacturing practices; and

(b) that conditions mentioned in the World Health Organisation guidelines are maintained at all manufacturing premises all the time.

Purchase, acquisition, keeping or use of scheduled substances by master of a vessel or officer in charge of an aircraft

44. (1) Subject to subregulation (2), the Permanent Secretary, a medical practitioner or a veterinarian designated by the Permanent Secretary may authorize, on the written request of the master of a vessel or the officer in charge of an aircraft, the purchase, acquisition, keeping or use of a Schedule 2, 3 or 4 substance.

(2) The quantity of scheduled substances which the master of a vessel or the officer in charge of an aircraft may purchase, acquire, keep or use as contemplated in subregulation (1) must in the opinion of the person who authorised the purchase, acquisition, keeping or use concerned, be within reasonable limits and subject to the condition that the scheduled substance is intended for medicinal use.

Expedited registration process for medicines for human use

45. (1) The Council may consider an expedited registration process for medicines for human use in the case -

(a) of an application for essential medicines which is accompanied by a declaration by the applicant that such a medicine is listed in the prevailing Namibian Essential Medicines List published by the Ministry responsible for health;

(b) subject to subregulation (3), of any medicine containing new chemical entities that is considered essential for national health and which is accompanied by a written notification to that effect from the Minister, but which do not appear on the Namibian Essential Medicines List referred to in paragraph (a);

(c) of any medicine tendered internationally to the State for supply to state hospitals and state health facilities.

(2) A medicine contemplated in subregulation (1)(c) may be supplied on condition -

(a) that the manufacturing facilities where the medicine is manufactured, have prior to the supply thereof been approved by a good manufacturing practice inspection according to the guidelines of the World Health Organisation; and

(b) that the application for registration has been submitted to the Registrar prior to the supply thereof; or

(c) that a registration has been granted by other medicines regulatory authorities recognised by the Council.

(3) An application in respect of a medicine referred to in subregulation (1)(b) must be accompanied by a summary of the registration application which must be in such format and contain such information as the Council may determine.

(4) Subject to subregulation (3), the Council may subject certain applications in respect of a medicine referred to in subregulation (1)(b) to an abbreviated medicine review process as determined by the Council if registration has been granted by other medicines regulatory authorities for the purpose applied for.

(5) The Council must within three months review an application for registration submitted in accordance with subregulation (2)(b) and must inform the applicant of the outcome within three months.

(6) The Council may request any information with respect to an application under consideration, and the information concerned must be submitted by the applicant within the period indicated by the Council, failing which the Council may reject an application.

Application for sale of an unregistered medicine in terms of section 27 of the Act

46. (1) An application for the sale of an unregistered medicine as contemplated in section 27(1) of the Act must be submitted to the Registrar in the form as set out in Annexure XXXVI to these regulations and must contain the information required therein.

(2) Authorisation to sell an unregistered medicine in terms of section 27(1) of the Act must be in the form as set out in Annexure XXXVII to these regulations.

Fees

47. (1) The fees set out in Annexure XXXVIII to these regulations are payable to the Registrar in respect of the act, matter or thing mentioned therein.

(2) Every application contemplated in these regulations must be accompanied by the appropriate application fee, if any.

Penalties

48. A person who contravenes or fails to comply with regulations 12, 16(1), (2), (4), (5), (6) and (7), 17, 20, 22(b), 23, 24, 25, 26, 27, 32, 34(1), (5), (8), (9), (11), (13), (17) and (18), 36(1), (4), (5) and (7), 37, 39, 40 and 44 commits an offence and is liable upon conviction to a fine not exceeding N$4 000 or to imprisonment for a period not exceeding one year, or to both such fine and such imprisonment.

Procedures at meetings of Council

49. (1) The Registrar must -

(a) sign notices convening ordinary and special meetings of the Council;

(b) specify in the notice concerned the business to be transacted at a meeting;

(c) send the notice concerned by post or deliver the notice by hand to each member of the Council -

(i) in the case of an ordinary meeting of the Council, at least ten days before the date for which the meeting concerned is convened, but if all members agree any meeting may be convened at shorter notice;

(ii) in the case of a special meeting of the Council, within such period as the chairperson of the Council may consider necessary, and may be given by e-mail, telegram, telephone or telefax.

(2) Only business specified in the notice relating thereto may be transacted at a meeting of the Council, except such matters as the Council has resolved by vote to deal with as urgent.

(3) The Council may adjourn a meeting thereof to any day or hour, but only business as was set out in the notice convening the meeting may be transacted at a reconvened meeting.

(4) The Registrar must keep an attendance register of all members attending a meeting of the Council.

(5) A member of the Council who intends to bring any matter for discussion before the Council must give written notice to the Registrar, at least 30 days before the date for which a meeting of the Council is to be convened, that he or she intends to raise a matter for discussion at such meeting and such matter for discussion must -

(a) be reflected in the notice convening the meeting; and

(b) unless adjourned, be considered at such meeting.

(6) Only matters of which due notice has been given in accordance with subregulation (5) may be considered at a meeting of the Council, unless the meeting permits the matter to be brought forward as a motion.

(7) A motion which finds no seconder may not be further considered.

(8) The Registrar must as far as possible refer all matters within the terms of reference of the executive committee or any other committee established in terms of section 13 of the Act, as the case may be, to the committee concerned and the committee must, as far as is practicable, make the necessary recommendations and report thereon to the meeting of the Council immediately following on such referral.

(9) The Registrar must refer all matters within the terms of reference of the veterinary medicines committee to that committee and that committee must as far as is practicable, make the necessary recommendations and report thereon to the meeting of the Council immediately following on such referral.

(10) The Registrar must forward, if practicable, copies of reports of committees to each member of the Council together with the notice convening the meeting at which such reports are to be considered.

(11) The record of the proceedings of every meeting of the Council contemplated in section 8(9) of the Act must be signed, after confirmation at the next meeting of the Council, by the chairperson of the Council.

(12) The Registrar must forward a copy of the record of proceedings of each meeting of the Council to all members thereof as soon as reasonably possible after the meeting has been held.

(13) The chairperson of the Council must at the opening of each separate session of the Council give opportunity to members thereof to put questions with regard to the work of the Council, and the questions must be answered forthwith if possible, or if not, at a later session by the chairperson or by such member of the Council or staff member as the chairperson may direct.

(14) The Registrar must compile, in consultation with the chairperson of the Council, the agenda for every meeting of the Council, and the agenda must include -

(a) confirmation of the record of proceedings of the previous meeting;

(b) matters arising from the record of proceedings of the previous meeting;

(c) reports of standing committees;

(d) motions;

(e) correspondence; and

(f) general.

(15) A member of the Council may move, at a particular meeting thereof, that any item appearing on the agenda thereof be advanced in the agenda.

(16) Subject to subregulation (18) and unless otherwise permitted by the chairperson of

the Council, all motions and amendments must be in writing and signed by the mover.

(17) The chairperson of the Council or the Registrar, acting under the authority of the chairperson, must read any motion or amendment referred to in subregulation (16), and obtain a seconder therefore before the motion or amendment is spoken to by other members of the Council.

(18) All formal amendments must be framed as independent motions.

(19) An amendment -

(a) must be relevant to the motion it is intended to amend;

(b) may not alter the original motion in such a way as to make it virtually a new motion, and

(c) must be so framed as -

(i) to add or insert certain words;

(ii) to omit certain words; or

(iii) to omit, add or insert certain words.

(20) Unless permitted by the Council, no motion or amendment may be withdrawn after having been read by the chairperson of the Council or by any other member acting under the authority of the chairperson.

(21) The seconder of a motion or an amendment may reserve his or her speech for any period of the debate.

(22) If an amendment -

(a) is proposed, it may be followed by other amendments, and the last amendment must be considered first;

(b) is rejected, the original motion must be put to the vote;

(c) is carried, it must be regarded as a substantive motion and must, as to further amendments, in all other respects be treated as an original motion;

(d) is under debate, only one of the further proposals may be received -

(i) an amendment, namely "that the motion be amended as follows:";

(ii) the postponement of the question, namely "that the meeting proceeds to the next business";

(iii) the closure, namely "that the question be now put";

(v) the adjournment of the debate, namely "that the debate on the motion be adjourned"; or

(v) the adjournment of the meeting, namely, "that the Council now adjourns".

(23) A proposal for the postponement of the question, which may specify a date for the further consideration of the question, -

(a) must be made and seconded without debate; and

(b) may be moved at any time, even during debate on an amendment, and if the proposal -

(i) is carried, the question must be dropped from the agenda of business; or

(ii) is lost, the debate must proceed.

(24) A proposal for the closure must -

(a) be made and seconded without debate; and

(b) must be put forthwith,

and if the proposal is carried, the motion or amendment under debate must at once be voted on by the Council.

(25) If a proposal for the adjournment of the debate -

(a) is carried -

(i) the Council must move to the next item on the agenda of business; and

(ii) the debate must be resumed at the next ordinary meeting of the Council,

when the proposer of the adjournment is entitled, on the resumption of the debate, to speak first;

(b) is proposed and seconded, the chairperson of the Council may ask, before putting the question, the opinion of the Council as to whether it will, before rising, proceed to the transaction of unopposed business.

(26) A motion to rescind a resolution which has been passed at a previous meeting -

(a) may be considered only if notice thereof has been given in terms of subregulation (6);

(b) must be passed if a majority of the votes recorded is in its favour.

(27) A motion to rescind a resolution which has been passed during a session of the Council -

(a) may be considered, notwithstanding subregulation (26)(a), at the same session of the Council, if written notice thereof has been given that the matter be considered on a subsequent day of that session;

(b) must be passed only if two thirds of the votes recorded are in its favour.

(28) The Registrar must record any ruling of the chairperson of the Council on the interpretation of this regulation, if so requested by a member of the Council at the time of the ruling.

(29) Notice may be given of a motion to review any ruling of the chairperson of the Council -

(a) on the interpretation of this regulation as contemplated in subregulation (28); and

(b) the notice must constitute an instruction to the executive committee contemplated in section 11 of the Act to consider and report to the Council on such ruling, and such report must be placed on the agenda for consideration.

(30) Any member of the Council who dissents from the opinion of the majority of the Council and who wishes to have his or her dissent recorded, may request that such dissent be entered into the record of the proceedings concerned.

Procedures at meetings of executive committee

50. (1) The Registrar must -

(a) sign notices convening meetings of the executive committee;

(b) specify in the notice concerned the business to be transacted at a meeting; and

(c) send the notice concerned by post or deliver the notice by hand to each member of the executive committee at least ten days before the date for which the meeting concerned is convened, but if all members agree, a meeting may be convened at shorter notice.

(2) Only business specified in the notice may be transacted at a meeting of the executive committee, except such matters as the executive committee has resolved by vote to deal with as urgent.

(3) The executive committee may adjourn a meeting thereof to any day or hour, but only business as was set out in the notice convening the meeting may be transacted at a reconvened meeting.

(4) The Registrar must keep an attendance register of all members of the executive committee attending a meeting thereof.

(5) A member of the executive committee who intends to bring any matter before the committee must give written notice to the chairperson of the Council, at least 30 days before the date for which a meeting of the committee is to be convened, that he or she intends to raise a matter for discussion at such meeting and such matter for discussion must -

(a) be reflected in the notice convening the meeting; and

(b) unless adjourned, be considered by the committee in that meeting.

(6) Only matters of which due notice has been given in accordance with subregulation (5) may be considered at a meeting of the executive committee, unless the meeting permits the matter to be brought forward as a motion.

(7) A motion which finds no seconder may not be further considered.

(8) A majority of the members of the executive committee constitutes a quorum at a meeting thereof.

(9) The record of the proceedings of every meeting of the executive committee must be preserved in the form of typewritten minutes and must be signed, after confirmation at the next meeting of the executive committee, by the chairperson of the Council.

(10) The minutes of each meeting of the executive committee must contain-

(a) a resume of the subject matter dealt with; and

(b) such motions and amendments as have been proposed and adopted or rejected, with the names of the proposer and seconder, but without any comments or observations of members of the executive committee.

(11) The Registrar must compile the agenda for each meeting of the executive committee, and the agenda must include -

(a) confirmation of the record of proceedings of the previous meeting;

(b) matters arising from the record of proceedings of the previous meeting;

(c) reports of standing committees;

(d) motions;

(e) correspondence; and

(f) general.

(12) A member of the executive committee may move at a particular meeting thereof that any item appearing on the agenda thereof be advanced in the agenda.

Procedure at meetings of veterinary medicines committee

51. (1) The chairperson of the veterinary medicines committee must keep an attendance register of all members attending a meeting of the veterinary medicines committee.

(2) A member of the veterinary medicines committee who intends to bring any matter before the committee must give written notice to the chairperson of the veterinary medicines committee, at least 30 days before the date for which a meeting of the committee is to be convened, that he or she intends to raise a matter for discussion at such meeting and such matter for discussion must -

(a) be reflected in the notice convening the meeting; and

(b) unless adjourned, be considered by the committee in that meeting.

(3) Only matters of which due notice has been given in accordance with subregulation (2) may be considered at a meeting of the veterinary medicines committee, unless the meeting permits the matter to be brought forward as a motion.

(4) A motion which finds no seconder may not be further considered.

(5) A majority of the members of the veterinary medicines committee constitutes a quorum at a meeting thereof.

(6) The record of the proceedings of every meeting of the veterinary medicines committee must be preserved in the form of typewritten minutes and must be signed, after confirmation at the next meeting of the executive committee, by the chairperson of the veterinary medicines committee.

(7) The minutes of each meeting of the veterinary medicines committee must contain -

(a) a resume of the subject matter dealt with; and

(b) such motions and amendments as have been proposed and adopted or rejected, with the names of the proposer and seconder, but without any comments or observations of members of the veterinary medicines committee.

Procedure at meetings of other committees

52. (1) A majority of the members of any committee contemplated in section 13 of the Act constitutes a quorum at a meeting thereof.

(2) The record of the proceedings of every meeting of a committee contemplated in section 13 of the Act must be preserved in the form of typewritten minutes and must be signed, after confirmation at the next meeting of the committee, by the chairperson of the committee.

(3) The minutes of each meeting of a committee contemplated in section 13 of the Act must contain -

(a) a resume of the subject matter dealt with; and

(b) such motions and amendments as have been proposed and adopted or rejected, with the names of the proposer and seconder, but without any comments or observations of members of the committee.

Appeal against decision of Council

53. (1) A person who wants to appeal against a decision of the Council must within 30 days from the date on which the decision appealed against was communicated to him or her, send a notice by registered post to: The Minister, Ministry of Health and Social Services, Private Bag 13198, Windhoek.

(2) A notice referred to in subregulation (1) must -

(a) contain the full names, business and postal address of the appellant;

(b) set out the decision of the Council which is appealed against;

(c) state the date on which the decision concerned was communicated to the appellant; and

(d) set out clearly and succinctly the grounds for the appeal.

Repeal of regulations

54. Government Notices R.352 of 21 February 1975, R.1188 of 9 July 1976 and No. 47 of 15 March 2001 are hereby repealed.

ANNEXURE I

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
PHARMACOLOGICAL CLASSIFICATION OF CATEGORISED MEDICINES
(regulation 2(2))

(A) MEDICINES IN CATEGORY A ARE SUBDIVIDED INTO THE FOLLOWING PHARMALOGICAL CLASSES:

1. Central nervous system stimulants -
1.1 Central analeptics;
1.2 Psychoanaleptics (anti-depressants);
1.3 Special anti-depressant combinations;
1.4 Respiratory stimulants;
1.5 Hallucinogenic medicines; and
1.6 Other central nervous system stimulants.

2. Central nervous system depressants -
2.1 Anaesthetics;
2.2 Sedatives;
2.3 Hypnotics;
2.4 Barbiturates;
2.5 Non-barbiturates;
2.6 Anticonvulsants, including anti-epileptics;
2.7 Tranquillisers;
2.7.1 Phenothiazines and their derivatives;
2.7.2 Rauwolfia: Alkaloids and combinations;
2.7.3 Diphenylmethane and its derivatives;
2.7.4 Alkyl diols and their derivatives;
2.7.5 Miscellaneous structures;
2.8 Antipyretics or antipyretic and anti-inflammatory analgesics;
2.9 Analgesic combinations;
2.10 Other analgesics;
2.11 Centrally acting muscle relaxants; and
2.12 Other central nervous system depressants.

3. Connective Tissue Medicines -
3.1 Antirheumatics (anti-inflammatory agents);
3.2 Non-hormonal preparations;
3.3 Anti-gout preparations; and
3.4 Combinations with corticosteroids.

4. Local anaesthetics.

5. Medicines affecting autonomic function -
5.1 Adrenomimetics (sympathomimetics);
5.2 Adrenolytics (sympatholytics);
5.3 Cholinomimetics (cholinergics);
5.4 Cholinolytics (anticholinergics);
5.4.1 Anti-Parkinsonism preparations;
5.4.2 General;
5.5 Ganglion blockers;
5.6 Histamine;
5.7 Antihistaminics, anti-emetics and antivertigo preparations;
5.7.1 Antihistaminics;
5.7.2 Anti-emetics and antivertigo preparations;
5.8 Preparations for the common cold including nasal decongestants;
5.9 Hydroxytryptamine (serotonin); and
5.10 Serotonin antagonists.

6. Cardiac medicines -

6.1 Cardiac stimulants;
6.2 Cardiac depressants; and
6.3 Cardiac glycosides.

7. Vascular medicines -

7.1 Vasodilators and hypotensive medicines;
7.1.1 Rauwolfia and combinations;
7.1.2 Rauwolfia: Diuretic combinations;
7.1.3 Other hypotensives;
7.1.4 Vasodilators - coronary and other medicines used in angina pectoris;
7.1.5 Vasodilators - peripheral;
7.2 Vasoconstrictors, pressor medicines;
7.3 Migraine preparations;
7.4 Lipotropic agents; and
7.5 Serum-cholesterol reducers.

8. Medicines acting on blood and haemopoietic system -
8.1 Coagulants, haemostatics;
8.2 Anticoagulants;
8.3 Erythropoietics (haematinics); and
8.4 Plasma expanders.

9. Medicines against alcoholism.

10. Medicines acting on respiratory system -
10.1 Antitussives and expectorants;
10.2 Bronchodilators; and
10.3 Inhalants.

11. Medicines acting on gastro-intestinal tract -
11.1 Digestants;
11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics);
11.3 Anorexigenics;
11.4 Antacids;
11.4.1 Acid neutralisers;
11.4.2 Acid neutralisers with antispasmodics;
11.5 Laxatives;
11.6 Lubricants and faecal softeners;
11.7 Cholagogues;
11.8 Suppositories and anal ointments;
11.9 Antidiarrhoeals;
11.9.1 Antidiarrhoeals in combination with anti-infective agents; and
11.9.2 Special combinations.

12. Anthelmintics, bilharzia medicines and filaricides.

13. Dermatological preparations -
13.1 Antiseptics, disinfectants and cleansing agents;
13.2 Antiscabies medicines;
13.3 Surface anaesthetics;
13.4 Antipruritics;
13.4.1 Corticosteroids with or without anti-infective agents;
13.4.2 Emollients and protectives;
13.5 Rubefacients;
13.6 Counterirritants;
13.7 Keratolytics;
13.8 Special combinations;
13.8.1 Preparations for psoriasis'

13.8.2 Fungicides;
13.9 Radiation protectants;
13.10 Melanin inhibitors and stimulants; and
13.11 Acne preparations.

14. Preparations for treatment of wounds -
14.1 Wound disinfectants; and
14.2 Wound dressings.

15. Ophthalmic preparations -
15.1 Ophthalmic preparations with antibiotics and/or sulphonamides;
15.2 Ophthalmic preparations with corticosteroids; and
15.3 Combination antibiotics.

16. Ear, nose and throat preparations -
16.1 Nasal decongestants;
16.2 Aural preparations;
16.3 Surface anaesthetics; and

16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.

17. Medicines acting on muscular system -
17.1 Peripherally acting muscle relaxants; and
17.2 Muscle activators.

18. Medicines acting on genito-urinary system -
18.1 Diuretics;
18.2 Antidiuretics;
18.3 Ion-exchange preparations;
18.4 Urolitholytics;
18.5 Urinary tract antiseptics;
18.6 Vaginal preparations;
18.7 Contraceptive preparations;
18.8 Ovulation controlling agents; and
18.9 Uterine antispasmodics.

19. Oxytocics.

20. Antimicrobial (chemotherapeutic) agents -
20.1 Antibiotics and antibiotic combinations;
20.1.1 Broad and medium spectrum antibiotics;
20.1.2 Penicillins;
20.1.3 Penicillin-streptomycin combinations;
20.1.4 Antibiotic-sulphonamide combinations;
20.1.5 Streptomycin and combinations;
20.1.6 Topical antibiotics;
20.1.7 Antifungal antibiotics;
20.2 Other than antibiotics;
20.2.1 Sulphonamides;
20.2.2 Fungicides;
20.2.3 Tuberculostatics;
20.2.4 Leprostatics;
20.2.5 Germicides;
20.2.6 Medicines against protozoa;
20.2.7 Spirochaeticides; and
20.2.8 Antiviral agents.

21. Hormones, antihormones and oral hypoglycaemics -
21.1 Insulin preparations;
21.2 Oral hypoglycaemics;
21.3 Thyroid preparations;

21.4 Parathyroid preparations;
21.5 Corticosteroids;
21.5.1 Corticosteroids and analogues;
21.5.2 Analgesic combinations;
21.5.3 Anti-infective combinations;
21.6 Anabolic steroids;
21.7 Male sex hormones;
21.8 Female sex hormones;
21.8.1 Oestrogens;
21.8.2 Progesterones with or without oestrogens;
21.9 Androgen-oestrogen combinations;
21.10 Trophic hormones;
21.11 Hyperglycaemic hormones; and
21.12 Hormone inhibitors.

22. Vitamins -
22.1 Multivitamins and multivitamins with minerals;
22.1.1 Vitamins for paediatric use;
22.1.2 Vitamins for pre natal use;
22.1.3 Vitamins for geriatric use; and
22.1.4 Vitamin B-complex with vitamin C.

23. Amino-acids.

24. Mineral substitutes and electrolytes.

25. Special foods -
25.1 Infant foods and other formulae, excluding foods used solely as a substitute for human milk.

26. Cytostatic agents.

27. Chelating agents (versenates) as heavy metal antidotes.

28. Contrast media.

29. Diagnostic agents.

30. Biologicals -
30.1 Antibodies;
30.2 Antigens; and
30.3 Blood fractions.

31. Enzymatic preparations.

32. Other substances or agents -
32.1 Tonics;
32.2 Other;
32.3 Slimming preparations;
32.4 Water for injection;
32.5 Artificial tear and contact lens solutions;
32.6 Preparations of boracic acid, borax and zinc, starch and boracic powder;
32.7 Topical applications of delousing agents;
32.8 Topical applications of insect repellents;
32.9 Intra-uterine devices;
32.10 Dental preparations;
32.11 Solutions for haemo- or peritoneal dialysis;
32.12 Preparations for which the expressions "medicated", "medicinal", "for medical use" or expressions with similar connotations are used;
32.13 Preparations intended to promote hair growth;
32.14 Sales packs containing two or more medicines with different indications; and

32.15 Radiopharmaceuticals.

(B) MEDICINES IN CATEGORY C ARE SUBDIVIDED INTO THE FOLLOWING PHARMALOGICAL CLASSES:

1. Central And Peripheral Nervous System -
1.1 Central nervous system stimulants;
1.1.1 Central analeptics;
1.1.2 Respiratory stimulants;
1.2 Anaesthetics;
1.2.1 Inhalation anaesthetics;
1.2.2 Parenteral anaesthetics;
1.2.3 Local anaesthetics;
1.3 Narcotic analgesics;
1.3.1 Opioid agonists;
1.3.2 Opioid antagonists;
1.4 Sedatives;
1.4.1 Sedative hypnotics;
1.4.2 Sedative analgesics;
1.4.3 Sedative antagonists;
1.5 Anticonvulsants including anti-epileptics;
1.6 Tranquillisers;
1.6.1 Phenothiazine derivatives;
1.6.2 Butyrophenone derivatives;
1.6.3 Tricyclics;
1.7 Neuroleptanalgesics;
1.8 Analgesic antipyretics; and
1.9 Drugs used for euthanasia.

2. Autonomic Nervous System -
2.1 Sympathomimetics;
2.2 Sympatholytics;
2.3 Cholinergics; and
2.4 Antimuscarinics.

3. Musculo-Skeletal System and Joints -
3.1 Anti-inflammatory;
3.1.1 Steroidals;
3.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs);
3.1.2.1 COX inhibitors;
3.1.2.2 Non selective COX2 inhibitors;
3.1.2.3 Selective COX2 inhibitors;
3.1.3 Topical agents;
3.1.4 Combinations;
3.2 Analgesics;
3.2.1 Opioids
3.2.2 NSAIDs;
3.2.3 Topical agents;
3.2.4 Combinations;
3.3 Muscle relaxants;
3.3.1 Centrally acting; and
3.3.2 Peripherally-acting.

4. Autacoids -
4.1 Histamine inhibitors;
4.1.1 Antihistamines;
4.1.2 Histamine release inhibitors; and
4.2 Serotonin antagonists.

5. Cardio-Vascular System -
5.1 Positive inotropic agents;

5.1.1 Cardiac glycosides;
5.1.2 Methylxanthines;
5.2 Anti-arrhythmics;
5.3 Vasodilators;
5.3.1 Peripheral-acting vasodilators;
5.3.2 Angiotensin inhibitors; and
5.3.3 Calcium channel inhibitors.

6. Blood And Haemopoeitic System -
6.1 Coagulants, haemostatics;
6.2 Anticoagulants;
6.3 Haematinics;
6.4 Plasma expanders.

7. Respiratory System -
7.1 Antitussives and expectorants;
7.2 Mucolytics;
7.3 Bronchodilators; and
7.4 Combinations.

8. Gastro-Intestinal System -
8.1 Mouth washes;
8.2 Emetics;
8.3 Anti-emetics;
8.4 Acid-reducers;
8.4.1 Antacids and combinations;
8.4.2 Histamine-2 receptor antagonists;
8.4.3 Proton pump inhibitors;
8.4.4 Cytoprotective agents;
8.5 Motility enhancers;
8.5.1 Lubricants and faecal softeners;
8.5.2 Laxatives and purgatives;
8.6 Antispasmotics;
8.7 Antidiarrhoeals;
8.7.1 Plain;
8.7.2 With anti-microbial agents;
8.7.3 Antimicrobial agents;
8.7.4 Biologicals;
8.8 Analgesics;
8.9 Digestants;
8.10 Preparations used in the rumen;
8.10.1 Ruminotorics; and
8.10.2 Anti-bloat remedies.

9. Hepatic System -
9.1 Cholagogues and cholerectics; and
9.2 Liver protectants and lipotropics.

10. Urinary System -
10.1 Diuretics;
10.2 Urolitholytics and antispasmodics;
10.3 Urinary tract antiseptics;
10.4 pH modifiers;
10.4.1 Urinary acidifiers; and
10.4.2 Urinary alkalinisers.

11. Reproductive System -
11.1 Intravaginal and intra-uterine preparations;
11.2 Sex hormones;
11.2.1 Testosterone;
11.2.2 Oestrogens;

11.2.3 Progesterones and progestogens;
11.2.4 Combinations;
11.3 Prostaglandins;
11.4 Trophic hormones;
11.5 Myometrial stimulants (Ecbolics);
11.6 Myometrial relaxants (Tocolytics); and
11.7 Ovulation controlling agents.

12. Endocrine System -
12.1 Insulin preparations;
12.2 Thyroid preparations;
12.3 Corticosteroids;
12.4 Growth hormone; and
12.5 Anabolic steroids.

13. Dermatologicals -
13.1 Disinfectants and cleaning agents;
13.2 Antiseptic and antimicrobial preparations;
13.3 Antipuritics;
13.3.1 Topical corticosteroids with or without anti-infective agents;
13.3.2 Topical antihistamines with or without anti-infective agents;
13.4 Emollients and protectives;
13.5 Rubefacients and counter irritants;
13.6 Keratolytics;
13.7 Antifungals; and
13.8 Anti-parasitics.

14. Ophthalmic And Aural Preparations -
14.1 Anti-infectives;
14.2 Corticosteroids; and
14.3 Combinations (anti-infective with corticosteroids).

15. Wounds -
15.1 Wound antiseptics;
15.2 Wound dressings; and
15.3 Desloughing agents.

16. Mammary Gland -
16.1 Intra-mammary preparations; and
16.2 Preparations for the care of teats and udders.

17. Antimicrobials -
17.1 Antibacterials;
17.1.1 Beta-lactams;
17.1.1.1 Penicillins;
17.1.1.2 Cephalosporins;
17.1.2 Tetracyclines;
17.1.3 Aminoglycosides;
17.1.4 Macrolides, lincosamides and pleuromutulins;
17.1.5 Amphenicols;
17.1.6 Ouinolones;
17.1.7 Sulphonamides and potentiators;
17.1.8 Nitrofurans;
17.1.9 Polypeptides;
17.1.10 Antibacterial combinations;
17.2 Antifungals;
17.3 Antivirals;
17.4 Anti-protozoals;
17.4.1 Anticoccidials;
17.4.2 Antibabesials; and
17.4.3 Spirochaeticides.

18. Antiparasitic Agents -
18.1 Endoparasiticides;
18.1.1 Benzimidazoles and probenzimidazoles;
18.1.2 Macrocyclic lactones;
18.1.3 Halogenated salicylanilides and itrophenols;
18.1.4 Midazoles;
18.1.5 Tetrahydropyrimidines;
18.1.6 Piperazines;
18.1.7 Organophosphores;
18.1.8 Combinations;
18.2 Endectocides;
18.3 Ectoparasiticides;
18.3.1 Organochlorines;
18.3.2 Organophosphores and Carbamates;
18.3.3 Pyrethrins and Pyrethroids;
18.3.4 Formamidines;
18.3.5 Nitroquanidines;
18.3.6 Phenylpyrazoles;
18.3.7 Insect growth hormones;
18.3.8 Chitin synthesis inhibitors; and
18.3.9 Combinations.

19. Vitamins, Minerals And Geriatric Preparations -
19.1 Vitamins only;
19.2 Vitamin and mineral combinations;
19.3 Minerals and electrolytes; and
19.4 Vitamins, electrolytes and aminoacid combinations.

20. Cytostatic Agents.

21. Immune Modulating Agents.

22. Chelating Agents.

23. Contrast Media.

24. Biologicals -
24.1 Dogs vaccines;
24.2 Cats vaccines;
24.3 Poultry vaccines;
24.4 Ruminants vaccines;
24.5 Swine vaccines;
24.6 Horse vaccines;
24.7 Other species vaccines;
24.8 Other vaccines;
24.9 Other biologicals.

25. Production Enhancers -
25.1 Antimicrobials;
25.2 Hormones;
25.2.1 Sex hormones;
25.2.2 Growth hormones; and
25.3 Beta agonists.

26. Fish Medicines.

27. Game medicines.

28. Reptile medicines.

29. Other animals medicines.

ANNEXURE II

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR REGISTRATION OF A MEDICINE
(regulation 4)

APPLICATION NUMBER

PART 1 ADMINISTRATIVE INFORMATION

PART 1A ADMINISTRATIVE PARTICULARS

(a) Particulars of the Applicant/Prospective holder of the certificate of registration (PHCR)

Name: .....

Business address: .....

.....

Postal address: .....

Telephone no: ..... Fax no.……

E-mail address: .....

Site/Applicant Master File Number: .....

Person responsible/authorised to communicate with Council:

Name: .....

Business address: .....

.....

Telephone no: ..... Fax no.……

E-mail address: .....

(Attach a letter of authorisation signed by the person responsible for the overall management and control of the business)

(b) PARTICULARS OF THE MEDICINE

Category: .....

Proprietary name: .....

Pharmacological classification: .....

Dosage form: .....

Approved name: .....

Strength(s) per dosage unit: .....

Descriptive name of Biological medicine: .....

Route of administration: .....

Country of origin (country in which the original development was carried out): .....

Manufacturer(s): .....

Physical address of site(s): .....

Site Master File reference number(s): .....

Packer(s): .....

Physical address of site(s): .....

Site Master File reference number(s): .....

Finished product release control (FPRC)(s): .....

Physical address of site(s): .....

Site Master File reference number(s): .....

Finished product release responsibility (FPRR)(s): .....

Physical address of site(s): .....

Site/Applicant Master File number(s): .....

The undersigned hereby declares that all the information herein, and in the PARTS hereto, are correct and true and are relevant to this particular medicine.

.....
Signature of responsible person

.....
Signature of pharmacist
(if responsible person is not a pharmacist)

....
Name in block letters Date of application

....
Designation Date of current amenment
(Post registration only)

(c) Amendment history (Post-registration only)

Date of letter of amendment application	Summarised details of amendment	Date of Council response

PART 1B TABLE OF CONTENT

A comprehensive table of content of the dossier, including the SUB-PARTS of each PART, must be provided.

PART 1C LABELLING

(a) Package insert

The under-mentioned information with regard to this medicine must appear on the package insert. The information must be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to regulation 12(2)).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition
4. Pharmacological classification
5. Pharmacological action (Pharmacokinetics, pharmacodynamics and summary of clinical studies, where applicable)
6. Indications
7. Contra-indications
8. Warnings
9. Interactions
10. Pregnancy and lactation
11. Dosage and directions for use
12. Side effects and special precautions
13. Known symptoms of overdosage and particulars of its treatment
14. Identification
15. Presentation
16. Storage instructions
17. Registration number
18. Name and business address of the holder of the certificate of registration
19. Date of publication of the package insert.

(b) Patient information leaflet

The under-mentioned information with regard to this medicine must appear on the patient information leaflet. The information must be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to regulation 13(2)).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition of the medicine, that is, what this medicine contains
4. Approved indication and use, that is, what this medicine is used for
5. Instruction before taking the medicine
6. Instructions on how to take the medicine
7. Side effects
8. Storage and disposal information
9. Presentation
10. Identification
11. Registration number
12. Name and business address of the holder of the certificate of registration
13. Date of publication of the Patient Information Leaflet.

(c) Label

A facsimile of the immediate container label and, if applicable, the outer label must be included here. This must conform to regulation 11.

PART 1D FOREIGN REGISTRATION

(a) A list of countries in which an application has been lodged and the status of these applications must be furnished, detailing approvals, deferrals, withdrawals and rejections.

(b) If the medicine has been registered by the regulatory authorities with which Council aligns itself, i.e. RSA (MCC), USA (FDA), European Union (EMEA), UK (MHRA), Sweden (MPA), Canada (Health Canada), Australia (TGA), and Japan (MWH), include -

- a copy of the certificate of registration,
- the conditions of registration and
- the approved package insert (data sheet) translated into English where relevant.

(c) Details of any negative decision by any regulatory authority reflected in PART 1D (b) must be provided.

PART 2 BASIS FOR REGISTRATION AND OVERVIEW OF APPLICATION

PART 2A PHARMACEUTICAL AND BIOLOGICAL AVAILABILITY

(a) The following is an overview with special reference to the purpose of the study(ies), the reference product(s) and the overall conclusion.

(b) The methods and experimental details and results of, and the conclusions drawn from studies/tests carried out to confirm the pharmaceutical and/or biological availability are as follows:

Partial or total exemption from the requirements of this Part may be applicable if efficacy and safety are intended to be established by clinical data (or for other reasons as determined by the Council), provided that clinical trials have been conducted with the same formulation as the one being applied for.

PART 2B SUMMARY BASIS FOR REGISTRATION APPLICATION (SBRA)

The following is a summary of the core data in support of the clinical safety and efficacy.

In cases concerning well-known active pharmaceutical ingredients, or if non-clinical and clinical overviews are submitted, the Council may grant exemption from the submission of an SBRA.

PART 2C PHARMACEUTICAL EXPERT REPORT (PER)

The following is an independent, objective and encompassing report in light of current scientific knowledge addressing all the quality aspects of the product.

In cases concerning well-known active pharmaceutical ingredients, the Council may grant exemption from the submission of the above report.

PART 2D PRE-CLINICAL EXPERT REPORT (PCER)

The following is an independent, objective and encompassing report in light of current scientific knowledge addressing all the non-clinical aspects of the development of the product and of the relevant aspects referred to in the package insert.

In cases concerning well-known active pharmaceutical ingredients, or if an SBRA is submitted, the Council may grant exemption from the submission of the above report.

PART 2E CLINICAL EXPERT REPORT (CER)

The following is an independent, objective and encompassing report in light of current scientific knowledge on all the clinical aspects of the development of the product and of the relevant aspects referred to in the package insert.

In cases concerning well-known active pharmaceutical ingredients, or if an SBRA is submitted, the Council may grant exemption from the submission of the above report.

PART 3 PHARMACEUTICAL AND ANALYTICAL

PART 3A(i) ACTIVE PHARMACEUTICAL INGREDIENT (API)

(a) The name(s), structural formulae, empirical formulae, molecular mass, solubility and storage requirements are tabulated as follows:

International Non-Proprietary Name (INN) or approved name or chemical name/description	Structuralformula, empiricalformula,molecular mass	Solubility	Storage requirements	Retest period

(b) The API is obtained from the following sources (names and business addresses of the manufacturers):

(c) The API File (APIF) must be included.

PART 3A(ii) BIOLOGICAL MEDICINE: PRIMARY PRODUCTION LOT/BATCH

(a) Description of the preparation and production of the primary production lot

The following is a complete description of the preparation and manufacturing process of the primary production or bulk lot, the tests performed and the stages at which such tests are performed to confirm its integrity.

The name and address of the manufacturing facility in which the production of the primary production lot takes place must be provided.

(b) Specifications of ingredients used in the primary production lot

The following are the specifications (titles and limits/criteria) that apply to the ingredients used in the primary production or bulk lot.

If the test corresponds to a recognised pharmacopoeia, this must be mentioned.

(c) Tests carried out on ingredients in the primary production lot and details of the laboratories involved

The following is a complete description of the tests carried out on all the ingredients used in the primary production, or bulk lot.

The name and address of the laboratory(ies) in which such tests are carried out must be specified.

PART 3B FORMULATION

(a) Pharmaceutical medicine: final dosage form
Biological medicine: final filling lot/batch

Below is a schedule of the names and quantities of each active and inactive

pharmaceutical ingredient contained in a dosage unit. If no dosage unit exists, another suitable unit of mass or volume of the medicine may be used as long as the relevant particulars regarding the active pharmaceutical ingredients correspond in the package insert and on the label.

The purpose(s) of each inactive ingredient in the formulation must be specified, including that of those ingredients used during manufacturing but which are not present in the final product.

Approved name	Quantity per dosage unit	Active or inactive	Purpose of inactive

(b) Pharmaceutical medicine: **diluent** (if applicable)
Biological medicine: **final filling lot reconstituting liquid/diluent**

Below is a schedule of the names and quantities of each pharmaceutical ingredient contained in a dosage unit.

The purpose of each ingredient must be specified, including those used but which are not present.

Approved name	Quantity	Purpose

PART 3C SPECIFICATIONS AND CONTROL PROCEDURES FOR PHARMACEUTICAL INGREDIENTS

(a) Pharmacopoeial ingredients

Pharmaceutical Ingredient		Pharmacopoeial reference*	Any additional specifications (e.g. particle size)	Any additional control procedures
Active				
Inactive				

*The latest edition of the pharmacopoeia is implied, unless otherwise specified and justified.

(b) Non-pharmacopoeial ingredients

Pharmaceutical Ingredient		Title of Specification	Limits	Control procedures
Active				
Inactive				

(c) Laboratory

The identification and assay of the API and identification of the inactive pharmaceutical ingredients (IPIs) are tested by the following laboratory (name and business address of the laboratory).

PART 3D CONTAINERS AND PACKAGING MATERIALS

(a) Immediate container

The following is a description of the immediate container(s), the nature of the material, closure, pack sizes, specifications and the control procedures performed by the manufacturer/ packer of the final product. The tests performed by the supplier are indicated.

(b) Outer container

The following is a brief description of the outer container.

(c) Bulk container

The following is a brief description of the bulk container.

(d) Applicator and administration sets

The following is a description of the applicator and administration sets (if applicable), the type of material and dimensions including sketches.

PART 3E MANUFACTURING PROCEDURE

Pharmaceutical medicine: manufacturing procedures of final product
Biological medicine: final filling lot and diluent

The comprehensive procedure of manufacture, detailing the

- various stages of manufacture;
- packaging procedure;
- batch manufacturing formulations(s) and batch size(s);
- in-process control procedures and the frequency with which they are carried out during the manufacturing and packaging process; and
- names and addresses of the different manufacturing and packaging facilities/sites where the various stages of manufacturing and packaging are carried out if more than one site is involved,

are as follows:

PART 3F FINAL PRODUCT SPECIFICATIONS AND CONTROL

Pharmaceutical medicine: final product

Biological medicine: final filling lot and diluent

(a) Specifications (titles and limits)

List the specifications (titles and limits) for the following, if applicable:

(i) In-process control.
(ii) Final product control.
(iii) Stability testing.
(iv) Reconstituted/diluted final product.

Title of Specification	Limits

(b) Control

	Final release criteria
FPRC	
FPRR	

(c) Control procedures and validation

The control procedures for the specifications and validation of the analytical assay methods in section (a) and a final product certificate of analysis are included.

PART 3G STABILITY DATA FOR THE FINISHED PHARMACEUTICAL PRODUCT (FPP)

(a) Stability programme

Describe the stability programme to be followed and include the following:

(i) Conditions (temperature, humidity).
(ii) Time points of determination, e.g. 0, 3, 6, 9 months, etc.

(b) Discussion and motivation of shelf-life for each type of container

(c) Stability data

(d) Stability test control procedures and validation if different to those of the final product.

PART 3H PHARMACEUTICAL DEVELOPMENT

The following is a description of the pharmaceutical development of the product addressing the choice of formulation, ingredients and containers, overages, manufacture, stability and tests carried out during the development clearly identifying the clinical trial formulations.

PART 3I EXPERTISE AND PREMISES USED FOR THE MANUFACTURE OF A BIOLOGICAL MEDICINE

(a) Details relating to the premises where the primary production is undertaken and the staff involved in the production and testing of biological medicines

(b) Name and address of the facility where the final filling lot is stored if imported and/or different to that given in (a).

PART 4 PRE-CLINICAL STUDIES

(a) Pre-clinical Expert Report

(b) The following are results obtained and conclusions drawn from tests performed pre-clinically to demonstrate all aspects of the toxicity of the medicine and to prove the safety of its use, with special reference to -

(i) acute toxicity;
(ii) subacute toxicity studies;
(iii) chronic toxicity studies;
(iv) reproduction toxicity and teratogenicity studies;
(v) carcinogenicity studies;
(vi) mutagenicity studies; or
(vii) other tests to substantiate the safety of the medicine; and
(viii) pharmacokinetic studies.

(c) The methods and experimental results of, and the conclusions drawn from tests performed pre-clinically with reference to the efficacy of the medicine, with special emphasis on the relationship between the tests performed and the purpose for which the medicine is, or will be used or for which it will be propagated, and further, with regard to the dosage and method of administration of the medicine, are as follows:

In cases concerning well-known active pharmaceutical ingredients, the Council may grant exemption from the submission of some or all of the above information.

PART 5 CLINICAL STUDIES

(a) Clinical Expert Report

(b) The clinical trials performed on human volunteers and patients with regard to the safety of the medicine, with special reference to the particular dosage, routes of administration and the side effects observed, are as follows:

(c) The particulars of clinical trials conducted to establish the efficacy of the medicine are as follows:

(d) Experimental details and results of the studies performed to establish the correlation between the applicable blood and other suitable physiological levels, and the pharmacological action claimed for the medicine, are as follows:

(e) Periodic Safety Update Report for medicines for human use

In cases concerning well-known active pharmaceutical ingredients, the Council may grant exemption from the submission of some or all of the above information.

APPLICATION FOR REGISTRATION OF A VETERINARY MEDICINE

PART 1 ADMINISTRATIVE INFORMATION

PART 1A ADMINISTRATIVE PARTICULARS

(a) Particulars of the Applicant/Prospective holder of the certificate of registration (PHCR)

Name: .....

Business address: .....

Postal address: .....

Telephone No: .....

Fax No: .....

E-Mail address: .....

Site/Applicant Master File Number: .....

Person responsible/ authorised to communicate with Council: .....

Name: .....

Business address: .....

.....

Telephone No: .....

Fax No.: .....

E-mail: .....

(Attach a letter of authorisation signed by the person responsible for the overall management and control of the business)

(b) Particulars of the veterinary medicine

Proprietary name: .....

Pharmacological Classification: .....

Dosage form: .....

Approved name: .....

Strength(s) per dosage unit: .....

Descriptive name of veterinary biological: .....

Route of administration: .....

Country of origin (country in which the original development was carried out):

Indicate with an X in the appropriate block if the application is for a

☐ New product with new active ☐ new product with existing active
☐Amendment to existing product - Registration no. .....
☐Parallel product ☐ daughter product ☐ multi-source product ☐ veterinary biological

Manufacturer(s): .....

Physical address of site(s): .....

Site Master File reference number(s): .....

Packer(s): .....

Physical address of site(s): .....

Site Master File reference number(s): .....

Final product release control (FPRC) (s): .....

Physical address of site(s): .....

Site Master File reference number(s): .....

Final product release responsibility (FPRR) (s): .....

Physical address of site(s): .....

Site/Applicant Master File number(s): .....

The undersigned hereby declares that all the information herein, and in the PARTS hereto, are correct and true and are relevant to this particular medicine.

_____ _____

Signature of responsible person **Signature of pharmacist**
(if responsible person is not a pharmacist

_____ _____

Name in block letters Date of application

_____ _____

Designation Date of current amendment (Post-registration only)

(c) Amendment history (Post-registration only)

Date of letter of amendment application	Summarised details of amendment	Date of Council response

PART 1B TABLE OF CONTENT

A comprehensive table of content of the dossier, including the SUB-PARTS of each PART, must be provided.

PART 1C LABELLING

(a) Veterinary Medicine Scientific Package insert

The under-mentioned information with regard to this medicine must appear on the package insert. The information must be presented in the format stipulated, provided that the Council may authorize any deviation from such information or such format (refer to regulation 15(2)).

1. The words "**Veterinary Medicine**"
2. Scheduling status
3. Proprietary name and dosage form
4. Composition
5. Pharmacological classification
6. Pharmacological action (Pharmacokinetics, pharmodynamics and summary of clinical studies where applicable)
7. Indications per species
8. Contra-indications
9. Warnings or withdrawal period in the case of food-producing animals
   Safety in pregnancy and lactation
10. Dosage and directions for use including per age and species dosage
11. Side effects and special precautions for use per species.
12. Interactions
13. Known signs of overdosage and particulars of its treatment per species
14. Identification
15. Presentation
16. Storage instructions
17. Registration number (or reference number)
18. Name and business address of the holder of the certificate of registration
19. Date of notification of approval of this scientific package insert

(b) Label

A facsimile of the immediate container label and, if applicable, the outer label must be included here. This must conform to regulation 14.

PART 1D FOREIGN REGISTRATION

(a) A list of countries in which an application has been lodged and the status of these applications must be furnished, detailing approvals, deferrals, withdrawals and rejections.

(b) If the medicine has been registered by the regulatory authorities with which Council aligns itself, i.e. RSA (MCC), USA (FDA), European Union (EMEA), UK (MHRA), Sweden (MPA), Canada (Health Canada), Australia (TGA), and Japan (MWH), include -

- a copy of the certificate of registration,
- the conditions of registration and
- the approved package insert (data sheet) translated into English where relevant.

(c) Details of any negative decision by any regulatory authority reflected in PART 1D(b) must be provided.

PART 2 BASIS FOR REGISTRATION AND OVERVIEW OF APPLICATION

PART 2A BIOEQUIVALENCE AND BIOAVAILABILTY

(a) State the purpose of the study

(i) As comparison of formulation to be marketed versus formulation used in clinical trials, or
(ii) As proof of efficacy for a multi-source application, or
(iii) As proof of efficacy of new formulation (formulation change)

(b) Reference product used

(i) Clinical trial formulation
(ii) Innovator product
(iii) Current formulation (for change of formulation)

The following must be indicated:

	Reference product	**Formulation applied for**
Name of product		
Batch no.		
Holder of certificate of registration		
Country where purchased		
Assay results		
Source of Active Pharmaceutical Ingredient		

(c) Method used

Describe the method in full, e.g. bioavailability, dissolution, etc.

(d) Validation

Validation data for all quantitative assay methods must be included.

(e) Studies

Include protocol, final report, assay validation report, pharmacokinetic report (including individual animal data) and statistical report.

(f) Discussion and Conclusion

Attach documents (where applicable).

Partial or total exemption from the requirements of this PART may be applicable if efficacy and safety are intended to be established by clinical data (or for other reasons determined by Council), provided that clinical trials have been conducted with the same formulation as the one being applied for.

PART 2B SUMMARY BASIS FOR REGISTRATION APPLICATION FOR A VETERINARY MEDICINE (SBRAV)

The following is a summary of the core data in support of the clinical safety and efficacy.

In cases concerning well-known active pharmaceutical ingredients, or if Non-clinical and Clinical Overviews are submitted , the Council may grant exemption from the submission of an SBRAV.

PART 2 C PHARMACEUTICAL EXPERT REPORT (PER)

The following is an independent, objective and encompassing report in light of current scientific knowledge addressing all the quality aspects of the product.

In cases concerning well-known active pharmaceutical ingredients, the Council may grant exemption from the submission of the above report.

PART 2D PRE-CLINICAL EXPERT REPORT (PCER)

The following is an independent, objective and encompassing report in light of current scientific knowledge addressing all the non-clinical aspects of the development of the product and of the relevant aspects referred to in the package insert.

In cases concerning well-known active pharmaceutical ingredients, or if an SBRAV is submitted, the Council may grant exemption from the submission of the above report.

PART 2E CLINICAL EXPERT REPORT (CER)

The following is an independent, objective and encompassing report in light of current scientific knowledge on all the clinical aspects of the development of the product and of the relevant aspects referred to in the package insert.

In cases concerning well-known active pharmaceutical ingredients, or if an SBRAV is submitted, the Council may grant exemption from the submission of the above report.

PART 3 QUALITY CONTROL

PART 3A(i) ACTIVE PHARMACEUTICAL INGREDIENT (API) VETERINARY PHARMACEUTICALS

(a) The name(s), structural formulae, empirical formulae, molecular mass, solubility and storage requirements are tabulated as follows:

International Non-proprietary Name (INN) or approved name or chemical name/description	Structural formula, empirical formula, molecular mass	Solubility	Storage requirements	Retest period

(b) The API is obtained from the following sources (names and business addresses of the manufacturers):

(c) Active Pharmaceutical Ingredient File (APIF) or Drug Master File (DMF - open part) or certificate of suitability (CEP) must be included

PART 3A(ii) VETERINARY BIOLOGICALS

PRIMARY PRODUCTION LOT/BATCH

1. Description of the preparation and production of the primary production lot.

(a) Name and address of the manufacturing facility in which production of the primary production lot takes place.

(b) Master seed identification, description and control.

(c) The complete description of the preparation and manufacturing process of the primary production or bulk lot, the tests carried out on the product and the stages at which such tests are carried out to confirm the integrity of the product must be submitted.

2. Specifications of ingredients used in the primary production lot.

The following are the specifications that apply to the ingredients used in the primary production or bulk lot of a veterinary biological medicine, including the titles of the tests and the limits and criteria of acceptance of each parameter contained in the specification. (Where the test mentioned corresponds to a recognised pharmacopoeia, the source must be mentioned):

3. Tests carried out on ingredients in the primary production lot and details of the laboratories involved

The following is a complete description of the tests carried out on all the ingredients used in the primary production or bulk lot, specifying the name and address of the laboratory(ies) in which such tests are carried out.

PART 3 B FORMULATION

(a) Veterinary medicine: final dosage form
Veterinary biological: final filling lot/batch

Below is a schedule of the names and quantities of each active and inactive pharmaceutical ingredient contained in a dosage unit. If no dosage unit exists, another suitable unit of mass or volume of the veterinary medicine may be used as long as the relevant particulars regarding the active pharmaceutical ingredients correspond in the package insert and on the label.

The purpose(s) of each inactive ingredient in the formulation must be specified, including that of those ingredients used during manufacturing but which are not present in the final product.

Approved name	Quantity per dosage unit	Active or inactive	Purpose of inactive

(b) Veterinary medicine: diluent (if applicable)
Veterinary biological: final filling lot reconstituting liquid/diluent

Below is a schedule of the names and quantities of each pharmaceutical ingredient contained in a dosage unit.

The purpose of each ingredient must be specified, including those used but which are not present.

Approved name	Quantity	Purpose

PART 3C SPECIFICATIONS AND CONTROL PROCEDURES FOR PHARMACEUTICAL INGREDIENTS

(a) Pharmacopoeial ingredients

Pharmaceutical Ingredient		Pharmacopoeial reference*	Any additional specifications (e.g. particle size)	Any additional control procedures
Active				
Inactive				

*The latest edition of the pharmacopoeia is implied, unless otherwise specified and justified.

(b) Non-pharmacopoeial ingredients

Pharmaceutical Ingredient		Title of Specification	Limits	Control procedures
Active				
Inactive				

(c) Laboratory

The identification and assay of the API and identification of the inactive pharmaceutical ingredients (IPIs) are tested by the following laboratory (name and business address of the laboratory).

PART 3 D CONTAINERS AND PACKAGING MATERIALS

(a) Immediate container

The following is a description of the immediate container(s), the nature of the material, closure, pack sizes, specifications and the control procedures performed by the manufacturer/ packer of the final product. The tests performed by the supplier are indicated.

(b) Outer container

The following is a brief description of the outer container.

(c) Bulk container

The following is a brief description of the bulk container.

(d) Applicator and administration sets

The following is a description of the applicator and administration sets (if applicable), the type of material and dimensions including sketches.

PART 3E MANUFACTURING PROCEDURES

Veterinary medicine: **manufacturing procedures of final product**
Veterinary biological: **final filling lot and diluent**

The comprehensive procedure of manufacture, detailing the

- various stages of manufacture
- packaging procedure,
- batch manufacturing formulations(s) and batch size(s),
- in-process control procedures and the frequency with which they are carried out during the manufacturing and packaging process, and the
- names and addresses of the different manufacturing and packaging facilities/sites where the various stages of manufacturing and packaging are carried out if more than one site is involved,

are as follows:

PART 3F FINAL PRODUCT SPECIFICATIONS AND CONTROL

Veterinary medicine: **final product**
Veterinary biological: **final filling lot and diluent**

(a) Specifications (titles and limits)

List the specifications (titles and limits) for the following, if applicable:

(i) In-process control
(ii) Final product control
(iii) Stability testing
(iv) Reconstituted/diluted final product

Title of Specification	Limits

(b) Control

	Final release criteria
FPRC	
FPRR	

(c) Control procedures and validation

The control procedures for the specifications and validation of the analytical assay methods in section (a) and a final product certificate of analysis are included.

PART 3G STABILITY DATA FOR THE FINISHED PRODUCT

(a) Stability programme

Describe the stability programme to be followed and include the following:

(i) Conditions (temperature, humidity)

(ii) Time points of determination, e.g. 0, 3, 6, 9 months, etc.

(b) Discussion and motivation of shelf-life for each type of container

(c) Stability data

(d) Stability test control procedures and validation if different to those of the final product.

PART 3H PHARMACEUTICAL DEVELOPMENT

The following is a description of the pharmaceutical development of the product addressing the choice of formulation, ingredients and containers, overages, manufacture, stability and tests carried out during the development clearly identifying the clinical trial formulations.

PART 3I EXPERTISE AND PREMISES USED FOR THE MANUFACTURE OF VETERINARY BIOLOGICALS

(a) Details relating to the premises where the primary production is undertaken and the staff involved in the production and testing of veterinary biologicals

(b) Name and address of the facility where the final filling lot is stored if imported and/or different to that given in (a).

PART 4 PRE-CLINICAL STUDIES

(a) Pre-clinical Expert Report

(b) The following are results obtained and conclusions drawn from tests performed pre-clinically to demonstrate all aspects of the toxicity of the medicine and to prove the safety of its use, with special reference to -

(i) acute toxicity

(ii) subacute toxicity studies

(iii) chronic toxicity studies

(iv) reproduction toxicity and teratogenicity studies

(v) carcinogenicity studies

(vi) mutagenicity studies, or

(vii) environmental impact studies

(viii) pharmacokinetics studies

(ix) neurological studies

(x) other tests to substantiate the safety of the veterinary medicine

(c) The following are results obtained of and conclusions drawn from tests performed pre-clinically to demonstrate all aspects of the efficacy of the veterinary medicine, with special reference to:

(i) The methods and experimental results of and the conclusions drawn from tests performed pre-clinically with reference to the efficacy of the veterinary medicine ;
(ii) the relationship between the tests performed and the purpose for which the veterinary medicine is or will be used, or for which it will be propagated, and
(iii) the dosage and method of administration of the veterinary medicine:

In cases concerning well-known active pharmaceutical ingredients, the Council may grant exemption from the submission of some or all of the above information.

PART 5 CLINICAL STUDIES

(a) Clinical Expert Report

(b) The field trials performed on target species with regard to the safety of the use of the veterinary medicine, with special reference to the particular dosage, routes of administration used and the side-effects observed per species, are as follows:

(c) The particulars of clinical or field trials conducted to establish the efficacy of the use of the veterinary medicine, are as follows:

(d) Experimental details and results of the studies performed to establish the correlation between the applicable blood and other suitable physiological concentrations and the pharmacological action claimed for the veterinary medicine, are as follows:

(e) Veterinary medicines for food-producing animals: Residue depletion studies and recommended withdrawal periods, are as follows:

(f) Periodic Safety Update report for medicines for veterinary use
In cases concerning well-known active pharmaceutical ingredients, the Council may grant exemption from the submission of some or all of the above information.

ANNEXURE III

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
MEDICINES REGISTER FOR MEDICINES WHICH ARE NOT VETERINARY MEDICINES OR COMPLEMENTARY MEDICINES
(section 17(1)(a) of the Act)
(regulation 7(a))

Name of medicine	Registration Number	Approved name of each active ingredient	Dosage form	Applicant/ certificate holder	Date of registration	Conditions of registration

ANNEXURE IV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
VETERINARY MEDICINES REGISTER
(section 17(1)(b) of the Act)
(regulation 7(b))

Name of medicine	Registration number	Approved name of each active ingredient	Dosage form	Applicant/ certificate holder	Date of registration	Conditions of registration

ANNEXURE V

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
COMPLEMENTARY MEDICINES REGISTER
(section 17(1)(c) of the Act)
(regulation 7(c))

Name of medicine	Registration number	Approved name of each active ingredient	Dosage form	Applicant/ certificate holder	Date of registration	Conditions of registration

ANNEXURE VI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR AMENDMENT OF ENTRY IN REGISTER
(section 20 of the Act)
(regulation 8(1))

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

FROM:
...……...
……..
……..
……..
……...
(Name and address of applicant)

I,…… (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being the holder of a certificate of registration in respect of ……
……
(name of medicine approved by the Council under section 19(8)) of the Act) with ……
……
(registration number allocated to the medicine under section 19(9) of the Act) and registered on ……
……. …….. (date of registration of the medicine)
hereby apply for the amendment of the following entry in the register with respect to that medicine:
……. ……
to the following entry: ……..……
……
due to the following reasons: …….....……
……
……
……

……. ……
Signature of applicant Date

ANNEXURE VII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
CERTIFICATE OF REGISTRATION
(section 19(7) of the Act)
(regulation 9)

It is hereby certified that the Namibia Medicines Regulatory Council has approved in terms of section 19(4) of the Medicines and Related Substances Control Act, 2003 (Act No 13 of 2003), the registration of the medicine described below subject to the conditions set out below.

Registered name (proprietary name) of medicine: ……
Registration number: ……
Date of registration: ……
Approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume unit of medicine: ……
……
……
Dosage form: ……
Registered in the name of (name and business address of applicant): ……
……
……
……
Name and address of manufacturer and the manufacturing facility: ……
……
……
……

Name of the final product release controller: ……
……
Name of the final product release responsibility: ……

Conditions of registration (Attached):

Issued at …….. on ……...

Registrar of Medicines Stamp

ANNEXURE VIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR APPROVAL OF TRANSFER OF CERTIFICATE OF REGISTRATION
(section 21 of the Act)
(regulation 10)

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

FROM: (Name and address of applicant)

I,…… (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being the holder of a certificate of registration in respect of ……..……
……..……..……
(name of medicine approved by the Council under section 19(8)) with ……
……..…
(registration number allocated to the medicine under section 19(9) of the Act) and registered on ……..…. (date of registration of the medicine) hereby apply for approval for the transfer of the certificate of registration attached hereto to: ……. (full names and surname of the person to whom the certificate is to be transferred) of ……..……
……..……
(postal and physical business address)* / ……
or (name of body corporate) of ……..…
(postal and physical business address)*

…….
Signature of applicant

……
Date

*Delete whichever is not applicable.

Note: Please attach proof -

(a) of incorporation or registration of the body corporate, as the case may be; and

(b) that the person or body corporate concerned qualifies in terms of the Medicines Control Act, 2003, as a person to whom the certificate concerned may be transferred.

ANNEXURE IX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
REPORT OF ADVERSE DRUG REACTION
(regulation 17(5))

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

Full names and surname or record number of patient: ……..……..…..…*
Age: ……..…… Gender: ……..…….……. Weight: ……..……..

ADVERSE REACTION DESCRIPTION Date: ……
……..……
……..……
……
……
…..…….…..

DRUG THERAPY Indicate suspected drug(s): Trade Name and Batch No.	Daily dosage and route	Date therapy started	Date therapy stopped	Reasons for use

Treatment of reaction

OUTCOME	Recovered	Not yet recovered	Unknown	Fatal

(This matter will be followed up and you will be informed of the outcome)
Comments: (e.g. relevant history, allergies, previous exposure)
……
……
……
……..……

Profession of reporting authorised prescriber: (e.g. medical practitioner, dentist, veterinarian, nurse or pharmacist): ……..…….....…….....……
Full names and surname: …….....….
Business address: …….....…….
Telephone:……....…….....…….(w) Cell: ……....…….

…….....… .....
Signature Date

* (The identity of the reporter and the patient will be strictly confidential)

ANNEXURE X

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
CERTIFICATE BY INSPECTOR
(section 36(2)(c) of the Act)
(regulation 20(3))

I, (full names and surname) hereby certify that the accompanying is/are a sample/samples of a medicine or a scheduled substance taken on …… at (full address) ……
……
from the stocks under the control of (full names and surname and business address) ……
……
……
in the presence of (full names and surname and business address of witness): ……
……
……
The following particulars relate to the sample/samples:

(a) Proprietary name (if any): ……
(b) Dosage form: ……
(c) Estimated quantity: ……
(d) Particulars on label: ……
  (i) Name and business address of applicant: ……
  (ii) Batch number: ……
  (iii) Expiry date: ……
  (iv) Other marks of identification (claims, indications, trade marks): ……
  ……
  ……
(e) This sample is submitted for analysis/testing/examination/identification/other action (specify) ……
  ……
(f) The cost of the sample taken amounts to N$ ……

…… ……
Signature of Inspector Date

…… ……
Signature of Witness Date

ANNEXURE XI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
CERTIFICATE BY ANALYST
(section 36(4) of the Act)
(regulation 22)

I, (full names and surname), ……..……..……..... duly authorized in terms of section 37 of the Medicine and Related Substances Control Act, 2003, (Act No. 13 of 2003), as analyst hereby declare -

(a) that I have received a sample described as ……..……
……
…….....…
on ……..……. from (full names and surname)……
……
…….....……;

(b) that I have carried out the instructions of the inspector on …….....……; and

(c) that my findings were as indicated in the report attached hereto.

Remarks with regard to results of analysis: ……
……..…….....
.....……

…… ……
Signature of Analyst Date

ANNEXURE XII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
SCHEDULE 4 SUBSTANCES REGISTER AND PRESCRIPTION BOOK
(section 29(20) of the Act)
(regulation 27(1))

SUBSTANCE …..…… FORM ……. DOSE, MASS OR VOLUME UNIT ……..……...

Date received or issued	Supplier's name and address	Supplier's Invoice No or Import permit No	Purchaser's name and address	Ref. No	Prescriber's Name and address	Units received	Units issued	Balance	Signature

ANNEXURE XIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR PERMIT TO IMPORT A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE
(section 29(15)(b) and (23)(b) of the Act)
(regulation 28(1))

APPLICATION NUMBER

TO:	FROM:
The Permanent Secretary	……..
Ministry of Health and Social Services	……..
Private Bag 13198	……..
WINDHOEK	……..
	(Name and address of applicant)

I,…… (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered ……..…..... practising/conducting* a business at ……..…….....……..… (physical address) hereby apply for a permit authorising me/it to import a Schedule 4/specified Schedule 3* substance/preparation* in respect of which the following details are given:

(a) the name of the substance/preparation:* …….....…….

(b) the quantity of the substance/preparation:* …….....….
……...……...……
……..……
……..……

(c) the name and content of the active ingredients of the substance/preparation* (per unit and total): …….....……..
……..……
……..……
…….....…….

(d) the dosage form of the substance/preparation*: …….....……...…

I declare that the quantities required are reasonably required by me for purposes authorised by law. I estimate that these quantities will meet my requirements for a period of ……. months from the date of application.

The consignment will be imported from ……..…..……
…….....……..
(full names and surname and address of person in exporting country from whom the drug is to be obtained).

The consignment will be imported through ……...…….. ……
…….....……. (border post, airport or harbour).

I declare that the quantities applied for are appropriate for the purpose applied for.

……. …….
Signature of Applicant Date

* Delete whichever is not applicable.

ANNEXURE XIV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
IMPORT/EXPORT PERMIT* FOR A SCHEDULE 4 OR
A SPECIFIED SCHEDULE 3 SUBSTANCE
(section 29(15)(b) and 23(b) of the Act)
(regulations 28(1) and 29(2))

I, (full names and surname …….... the Permanent Secretary: Ministry of Health and Social Services, hereby authorise ……..…… …… (name of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered …… …… ……practising/conducting *business at ……. ……..(physical address) to import/export* the following Schedule 4/specified Schedule 3* substance/preparation,* subject to the conditions, if any, set out herein:

(a) the name of the substance/preparation:* …….....…….
(b) the quantity of the substance/preparation* (calculated as a base) ……...…… ……..…..
(c) the dosage form of the substance/preparation:* …….....……..

Conditions, if any: ……..…….…….....…. ……..…… ……..……..…… The consignment will be imported/exported* through …… …… ……..……(border post, airport or harbour).

Issued at ……..…….....…….. on ……..……..

Period of validity of permit: ……..…….....……

……
Signature of Permanent Secretary: Ministry of Health and Social Services

*Delete whichever is not applicable.

ANNEXURE XV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR PERMIT TO EXPORT A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE
(section 29(15)(b) and 23(b) of the Act)
(regulation 29(1))

APPLICATION NUMBER

TO:	FROM:
The Permanent Secretary	……..
Ministry of Health and Social Services	……..
Private Bag 13198	……..
WINDHOEK	……..
	(Name and address of applicant)

I,…… (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered …….. practising/conducting* a business at ……..… (physical address) hereby apply for a permit authorising me/it to export to…… ……..…… (name and address of the firm or person in the importing country to which or to whom the substance/ preparation* is to be supplied) the Schedule 4/specified Schedule 3* substance/preparation in respect of which the following details are given:

(a) In the case of the exportation of a raw material or a semi-finished product only:
  (i) the name of the substance: ……..……..……
  (ii) the quantity of the substance (calculated as a base): …..…….....……

(b) In the case of the exportation of a preparation (finished product):
  (i) the name and quantity of the active ingredient(s) of the preparation (per unit and total): ……..……..……
  (ii) the quantity of the preparation ……..…….
  (iii) the dosage form of the preparation: ……..…….

I declare that the quantities applied for are appropriate for the purpose applied for.

The consignment will be exported through …… …… ……..…… (border post, airport, harbour or post office).

…… ……..
Signature of applicant Date

Note: The permit concerned may only be issued if the applicant submits with the application concerned a copy of an importation authorisation issued by the medicines regulatory authority of the country to which exportation of the relevant substances is contemplated.

ANNEXURE XVI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR PERMIT TO MANUFACTURE A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE
(section 29(15)(a) and 23(a) of the Act)
(regulation 30(1))

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

FROM:……..
……..
……..
……..
……..
……..
(Name and address of applicant)

I,…….…… (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered ……...……..practising/conducting* a business at ……..…. ……..……(physical address) hereby apply for a permit authorising me/it to manufacture …… the Schedule 4/specified Schedule 3* substance/preparation* in respect of which the following details are given:

(a) In the case of the manufacturing of a raw material or a semi-finished product only:

(i) the name of the substance …….....……

(ii) the quantity of the substance (calculated as a base) …….…....……...

(b) In the case of the manufacturing of a preparation (finished product) -

(i) the name and quantity of the active ingredients of the preparation (per unit and total): …….....……..
…….....……
…….....….....…

(ii) the quantity of the preparation: …….....……..

(iii) the dosage form of the preparation: …….....……

…… ……
Signature of applicant Date

*Delete whichever is not applicable.

ANNEXURE XVII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
PERMIT TO MANUFACTURE A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE
(section 29(15)(a) and 23(a) of the Act)
(regulation 30(2))

The Namibia Medicines Regulatory Council hereby authorizes ……...…… ……..……. (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered …… ……..…….. practising/conducting* business at ……...……...…… ……..…….....…. (physical address) to manufacture the following Schedule 4/specified Schedule 3* substance, subject to the conditions set out herein:

(a) the name of the Schedule 4/specified Schedule 3* substance/preparation: * ……...…….....……

(b) the quantity of the substance/preparation *(calculated as a base) …… …….....……

(c) the name and content of the active ingredients of the substance/preparation *(per unit and total) …….....……...……. ……..…...… ……...……...……...…

(d) the dosage form of the substance/preparation * …….....……..

Conditions: ……..... ……..... ……..…….....

Issued at…….....…….. on …….....……...

Period of validity of permit: ….…….....……...

…….
Registrar of Medicines

*Delete whichever is not applicable.

ANNEXURE XVIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR PERMIT TO CULTIVATE OR COLLECT PLANTS OR A PORTION OF A PLANT FROM WHICH A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE CAN BE EXTRACTED, DERIVED, PRODUCED OR MANUFACTURED
(section 29(15)(c) and 23(c) of the Act)
(regulation 31(1))

APPLICATION NUMBER

TO:	FROM: (Name and address of applicant)
The Registrar of Medicines	……..
Namibia Medicines Regulatory Council	……..
Ministry of Health and Social Services	……..
Private Bag 13198	……..
WINDHOEK	……..

I,……...…… (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered ……...…….....……practising/conducting* a business at ……..……..…….....…….(physical address) hereby apply for a permit authorising me/it" to cultivate or collect plants or portions of plants from which a Schedule 4/specified Schedule 3* substance can be extracted/derived/ produced /manufactured,* and in respect of which the following details are given:

(a) the names of the plants or portions thereof to be cultivated/collected:* ……..……
……
…….....……

(b) the names of the Schedule 4/specified Schedule 3* substance to be extracted/derived/ produced/manufactured* and the purpose for which it will be used:
…….....……
…….....……
…….....

(c) the place(s) where the cultivation/collection* will take place:
…….....……

…….. ……
Signature of applicant Date

*Delete whichever is not applicable.

ANNEXURE XIX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
PERMIT TO CULTIVATE OR COLLECT PLANTS OR A PORTION OF A PLANT FROM WHICH A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE CAN BE EXTRACTED, DERIVED, PRODUCED OR MANUFACTURED
(section 29(15)(c) and 23(c) of the Act)
(regulation 31(2))

The Namibia Medicines Regulatory Council hereby authorises ……..…… …….. (full names and surname of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered …….. ……practising/conducting* a business at ……..... ……..……..……..(physical address) to cultivate or collect the plants or portions of plants as set out below, on the conditions as determined herein:

(a) the names of the plants or portions thereof to be cultivated/collected:*
……..……..……
……..……

(b) the names of the Schedule 4/specified Schedule 3* substances to be extracted/derived/produced/manufactured* and the purpose for which it will be used:
……..……
……..……
……..……

(c) the place(s) where the cultivation/collection* will take place:
……..……

Conditions: ……..……
……..……
……..……
……..……
……..……

Period of validity of the permit: ……..…….

……. ……
Registrar of Medicines Date

*Delete whichever is not applicable.

ANNEXURE XX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
CERTIFICATE OF DESTRUCTION AND DISPOSAL OF SCHEDULED SUBSTANCES AND MEDICINES
(regulation 33(1))

1. Details of premises where the scheduled substances or medicines were found:

Name: …….....…….....…….

Postal address: …….....…

Physical address: …….....……

Name of person in charge: …….....……

2. Items destroyed:

Name of scheduled substance or medicine	Quantity	Reason for destruction

3. Method of destruction and disposal: ……..……
……..……
……..……
……..……

4. Name of inspector / Authorised person: …….....……

…….....…. …….
Signature of Inspector/Authorised person Date

…….....…. …….
Signature of person in charge of premises Date

ANNEXURE XXI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR LICENCE IN TERMS OF SECTION 31(1), (2) OR (3) OF THE ACT
(regulation 34 (1))

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

A. General Information:

1. Name of applicant: ……..……..
2. Qualifications of applicant: …….……
3. Postal address of applicant: …….……
4. Telephone No.: …….…… Fax No:…….……
   E-mail address: …….……
5. Residential address of applicant: …….…….
   ……..……
6. State whether the type of licence applied for is under section 31(1), (2) or (3) of the Medicines and Related Substances Control Act, 2003): ……
   ……..……
   ……..……

B. Please attach the following:

1. Certified copies of certificates of qualification.
2. Certificate of current registration with the relevant professional board.
3. Motivation as to the need to for the licence concerned.

C. Other information:

1.1 Physical address of premises where the applicant intends to store, compound, and dispense medicines: ……..……
……..……

1.2 Area in Namibia within which the applicant intends to perform his or her service (for example, municipality, town, village, settlement area, rural area): ……..……
……..……
……..……
……..……

2. Catchment area to be served by the applicant: ……..……
……..……
……..……

3. Estimated population in the geographical area: …….....……..

4. Particulars of the premises

	Yes	No	For official use only
1. Is there a separate facility for washing hands?			
2. Is there a separate facility for cleaning equipment?			
3. Is the temperature in the dispensary below 25°C?			
4. Is there a suitable means of counting tablets and capsules?			
5. Is there a suitable range of dispensing containers for medicinal products available?			
6. Is there a suitable and adequate means of waste disposal available?			
7. Is there a fridge for heat sensitive pharmaceuticals and vaccines available?			
8. Are there security measure in place to prevent unauthorized entry?			
9. Are all working surfaces finished with a smooth impermeable and washable material?			
10. Is there sufficient and adequate lighting?			
11. Is the floor surface of impermeable material?			
12. Are all scheduled medicines stored/displayed in areas inaccessible to the public?			
13. Are all cupboards and shelves finished with a smooth impermeable and washable material?			

…… ……

Signature of applicant Date

ANNEXURE XXII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
LICENCE ISSUED IN TERMS OF SECTION 31(1) OF THE ACT
(regulation 34(7)(a))

PART A

The Namibia Medicines Regulatory Council hereby authorises -…….....……..
…….(full names and surname) of ….....……
(business postal address) ……..…….....…….
(physical business address) being a ..…….....……
……..……(occupation)
to acquire, possess and prescribe, use in respect of, or sell to, his or her patients in terms of section 31(1) of the Medicines and Related Substances Control Act, 2003, the Schedule 1, Schedule 2 or Schedule 3 substances specified in Part B to this licence, subject to the conditions, if any, set out in Part C to this licence.

Period of validity of licence: …….....……...

…… ……..
Registrar of Medicines Date

PART B

SPECIFIED SCHEDULED SUBSTANCES

MEDICINE	DOSAGE FORM	INDICATIONS

PART C

CONDITIONS SUBJECT TO WHICH THE SCHEDULED SUBSTANCES SPECIFIED IN PART B MAY BE ACQUIRED, POSSESSED AND PRESCRIBED, USED IN RESPECT OF, OR BE SOLD TO PATIENTS ……

……

……

……

……

ANNEXURE XXIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
LICENCE ISSUED IN TERMS OF SECTION 31(2) OF THE ACT
(regulation 34(7)(b))

PART A

The Namibia Medicines Regulatory Council hereby authorises -…….....……..
……..(full names and surname) of …….....……
(business postal address) …….....…….
(physical business address) being a …….....…….
…….…… (occupation)
to prescribe, and sell to persons in respect of whom he or she has issued a prescription under paragraph (a) of section 31(2) of the Medicines and Related Substances Control Act, 2003, the Schedule 2 or Schedule 3 substances specified in Part B to this licence, subject to the conditions, if any, set out in Part C to this licence.

Period of validity of licence: …….....……...

…… ……..
Registrar of Medicines Date

PART B

SPECIFIED SCHEDULED SUBSTANCES

MEDICINE	DOSAGE FORM	INDICATIONS
……		
……		
……		
……		
……		
……		
……		
…….....……		
……		

PART C

CONDITIONS SUBJECT TO WHICH THE SCHEDULED SUBSTANCES SPECIFIED IN PART B MAY BE ACQUIRED, POSSESSED AND PRESCRIBED, USED IN RESPECT OF, OR BE SOLD TO PATIENTS

……
……
……
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……
……

ANNEXURE XXIV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
LICENCE ISSUED IN TERMS OF SECTION 31(3) OF THE ACT
(regulation 34(7)(c)

PART A

The Namibia Medicines Regulatory Council hereby authorises -……..……
……. (full names and surname) of …….....…..……
……(business postal address) ….……..……
(physical business address) being a ……..…… (occupation) to sell to his or her patients in terms of section 31(3) of the Medicines and Related Substances Control Act, 2003, Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substances, subject to the conditions, if any, set out in Part B to this licence.

Period of validity of licence: ….……..……...

…… ……..
Registrar of Medicines Date

PART B

CONDITIONS SUBJECT TO WHICH SCHEDULE 1, SCHEDULE 2, SCHEDULE 3 OR SCHEDULE 4 SUBSTANCES MAY BE SOLD TO PATIENTS

……
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ANNEXURE XXV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR PERMIT IN TERMS OF SECTION 31(4) OF THE ACT
(regulation 34(9))

APPLICATION NUMBER

TO:
The Minister of Health and Social Services
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK.

I, (full names and surname) ……..…… being a ..…
…….....…….....…… (occupation) and holding the following qualifications
……..……
(attach certified copies of qualifications) of …….…….....……..……
(postal address), telephone no. ……..fax no. …….. e-mail address…….....…….....……....
.....……..
hereby applies in terms of section 31(4) of the Medicines and Related Substances Control Act, 2003, for a licence to manufacture*/pack and sell* the medicine or scheduled substances set out below:

Scheduled Substance/ Medicine	Scheduled substances/medicine, strength and dosage form	Quantity

Physical address of facility where the intended manufacturing*/packing and selling* will be done:
……..……
……..……

……. …….
Signature of Applicant Date

*Delete whichever is not applicable

ANNEXURE XXVI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
PERMIT ISSUED IN TERMS OF SECTION 31(4) OF THE ACT
(regulation 34(10))

I, ……..…… the Minister responsible for health, hereby authorise in terms of section 31(4) of the Medicines and Related Substances Control Act, 2003, ……
…….....…….. (full names and surname) of ….....……
…….....
…….....……
(physical and postal business address), being a …….....……..
……..…… (occupation) and holding the following qualifications …….....…… to manufacture*/ pack and sell* the medicine or scheduled substance specified below:

Schedule/Medicine	Schedule substances, medicine, strength and dosage form	Quantity

Conditions :…….....…….
…….....……
…….....……
…….....……

Period of validity of licence: …….....…….....…...

…… ……
Minister Responsible for Health Date

ANNEXURE XXVII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR LICENCE IN TERMS OF SECTION 31(5) OF THE ACT
(regulation 34(11))

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

I, (full names and surname) ……..……. being a … ……..……..…. (occupation) and holding the following qualifications ……..……. ……..……. (attach certified copies of qualifications) of …… (postal address), telephone no. ……..... fax no. ……..…….....…… e-mail address …… hereby applies in terms of section 31(5) of the Medicines and Related Substances Control Act, 2003, for a licence to manufacture*/pack and sell*/import*/export* the medicine or scheduled substances set out below: ……..……...
…….....……
…….....……
…….....……
…….....……
…….....…….
(please attach, if applicable, a copy of the permit issued in terms of section 31(4) of the Medicines and Related Substances Control Act, 2003)

Physical address of facility where the intended manufacturing and selling */packing and selling* will be done: ……..……..……

…….
Signature of Applicant

…….
Date

*Delete whichever is not applicable.

ANNEXURE XXVIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
LICENCE ISSUED IN TERMS OF SECTION 31(5) OF THE ACT
(regulation 34(12))

The Namibia Medicines Regulatory Council hereby authorises in terms of section 31(5) of the Medicines and Related Substances Control Act, 2003, ...……..... ……. (full names and surname) of …….....…….
(postal business address) …….....…….
(physical business address), being a …….....……
(occupation) and holding the following qualifications …… ……
…….....……
to manufacture*/pack and sell*/import*/export* the following medicine or scheduled substances:
….…….....……....
……..……
…….…….…….....……
Conditions: ……..……..
…….....……
Period of validity of licence: …….....……...

……. …….
Registrar of Medicines Date

*Delete whichever is not applicable.

ANNEXURE XXIX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR REGISTRATION OF PREMISES USED FOR MANUFACTURING OF MEDICINES
(regulation 35)

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

1. Name of applicant: ……..…..
2. Postal address of applicant: ……..……
3. Telephone No.:…….....……Fax No: …….....……..
   E-mail address of applicant: ……..……
4. Residential address of applicant: ……..……
   ……..……
5. Physical address of premises: ……..……..……..
   ……..……
6. Name of pharmacist, or person contemplated in section 31(4) of the Act, as the case may be, under whose personal supervision the premises will be: ……..
   .....…

…… ……
Signature of applicant Date

Note: Attach qualification certificates of applicant and proof of registration with the Pharmacy Council.

ANNEXURE XXX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

LICENCE IN RESPECT OF REGISTRATION OF PREMISES USED FOR MANUFACTURING OF MEDICINES
(regulation 35(3))

The Namibia Medicines Regulatory Council has approved the registration of the premises below for the manufacturing of medicines and issues the following licence in respect thereof.

Name of licence holder: ……..……..
Telephone number: ……..……. Fax number: ……..……..
Residential address: ……..……..
……..……
Name of premises: ……..
Physical address of premises: ……..……..……..
……..……
Name of pharmacist, or person contemplated in section 31(4) of the Act, as the case may be, under whose personal supervision the premises will be: ……
……
Expiry date: ……..…….
Applicable conditions (if any): ……..…
……..…
……..…
……..…

....
Registrar of Medicines Date

ANNEXURE XXXI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

APPLICATION FOR RENEWAL OF LICENCE IN RESPECT OF REGISTRATION OF PREMISES USED FOR MANUFACTURING OF MEDICINES

(regulation 35)

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

1. Name of applicant: ……..……..
2. Postal address of applicant: ……..…….
3. Telephone No.: ……..…… Fax No: …….....…….
   E-mail address of applicant: …….....……
4. Residential address of applicant: …….....…….
   …….....……
5. Physical address of premises:……..…….....……
   …….....…
6. Name of pharmacist, or person contemplated in section 31(4) of the Act, as the case may be, under whose personal supervision the premises will be: …….....……...
7. Date of expiry of existing licence: …….....…..

…… ……
Signature of applicant Date

Note: Attach qualification certificates of applicant and proof of registration with the Pharmacy Council.

ANNEXURE XXXII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
SCHEDULED SUBSTANCES FOR USE BY REGISTERED NURSE OR MIDWIFE
(regulation 36(1))

Schedule	Medicine	Strength	Dosage	Maximum stock permitted
S2	Phytomenadione injection (Vit K1)	1 mg/0.5 ml	1 mg IM	10x0.5 ml ampoules
S2	Ergometrine tartrate injection	0.5 mg / ml	0.5 mg IM	50x1 ml ampoules
S2	Naloxone hydrochloride injection (neo-Natal)	0.02 mg / ml	0.01 mg/kg IM or subcutaneous. May be repeated	10x2 ml ampoules
S2	Lignocaine hydrochloride solution	1% 2%	15-20 ml 1% solution per patient 5 ml 2% solution per patient	10 x 20 ml vials 10 x 20 ml vials
S2	Chloramphenicol eye casules (applicaps)	-	One capsule per treatment	50 capsules
S2	Oxytocin	10 IU / ml	-	20 ampoules
S4	Pethidine hydrochloride injection	50 mg / ml	50 mg IM. Additional 50 mg may be given	20 x 1 ml ampoules (1000 mg)

ANNEXURE XXXIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION BY REGISTERED NURSE*/MIDWIFE *TO PURCHASE, ACQUIRE OR KEEP FOR ADMINISTRATION IN A MIDWIFERY CASE THE SCHEDULED SUBSTANCES SET OUT IN ANNEXURE XXIX
(regulation 36(1))

APPLICATION NUMBER

TO:
The Permanent Secretary
Ministry of Health and Social Services
Private Bag 13198
Windhoek

I, (full names and surname) …….. being a nurse*/midwife* registered in terms in terms of the Nursing Act, 2004 (Act No. 8 of 2004), hereby apply to acquire the scheduled substances mentioned in the column below, being scheduled substances set out in Annexure XXIX:

Name of scheduled medicine/ substance	Strength and dosage forms	Maximum quantity

The other required particulars are as follows:
Business postal address: ……..……..
Physical business address: ……..……..
Date of registration as registered nurse/midwife:* ……..
(Please attach copy of certificate of registration concerned).
The scheduled substances concerned will be obtained from ……...……
…… (name of pharmacy) of ……
…… (postal address) and ……
…….....… (physical address).

…….. ……
Signature of Applicant Date

ANNEXURE XXXIV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
PERMIT FOR SCHEDULED SUBSTANCES FOR USE BY REGISTERED NURSE*/MIDWIFE*
(regulation 36(3))

I, ……... the Permanent Secretary: Ministry of Health and Social Services, hereby authorise in terms of regulation 36(2) ……..... (full names and surname) of ……..……. (physical and postal business address), who is practising as a registered nurse*/midwife* in his or her own midwifery practice*/in a clinic practice *currently registered in terms of the Nursing Act, 2004 (Act No. 8 of 2004), to purchase, acquire or keep for administration the scheduled substances mentioned in the column below after the deletion note:
To: …… (name) ……
…….....…….
(postal and physical business address of pharmacy from whom scheduled substances concerned will be obtained).
Permit Number: …….....……...

…….. ……
Permanent Secretary: Date
Ministry of Health and Social Services

Note: The permit must be issued in triplicate, the original to the pharmacy, the duplicate copy to the applicant (registered nurse and midwife) and the third copy to the Registrar.

* Delete whichever is not applicable

Schedule	Medicine	Strength	Dosage	Maximum Stock permitted
S1	Soluble aspirin tablets and codeine phophate tablets	-	One or two tablets, may be repeated after four hours	100 tablets
S2	Phytomenadione injection (Vit. K1)	1 mg/0,5 ml	1 mg IM	10 x 0,5 ml ampoules
S2	Ergometrine tartrate injection	0,5 mg IM	0,5 mg IM	50 x 1 ml ampoules
S2	Naloxonehydrochloride injection (neonatal)	0,02 mg/ml	0,01 mg/kg IM or subcutaneous; may be repeated	10 x 2 ml ampoules
S2	Lignocaine hydrochloride solution	1% 2%	15-20 ml 1% solution per patient 5 ml 2% solution per patient	10 x 20 ml vials 10 x 20 ml vials

S2	Chloramphenicol eye capsules (applicaps)	-	One capsule per treatment	50 capsules
S2	Oxytocin	10 IU/ml	-	20 ampoules
S4	Pethidine hydrochloride injection	100 mg/2 ml	100 mg IM	12 x 2 ml ampoules (1 200 mg)

ANNEXURE XXXV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

REGISTER OF SCHEDULED SUBSTANCES TO BE KEPT BY REGISTERED NURSE OR MIDWIFE
(regulation 36(4))

PART A
(To be completed by the pharmacist and the permit holder)

Schedule	Name of substance or medicine	Strength	Stock on hand (Permit holder to complete)	New stock acquired (Pharmacist to complete)	Maximum stock permitted

I, the permit holder, acknowledge receipt of the scheduled substances.

Name: ……..…… Permit No.: …….....…..
Name and business address of the pharmacy: …….....…….
…….....……

…..……
Signature of permit holder

Name of the pharmacist: …….....

…..…… ……
Signature of pharmacist Date

PART B

Date	Number of permit	Quantity	Name and address of pharmacy	Issued by	Received by
Brought forward					
New stocks acquired					

PART C
IN RESPECT OF ADMINISTRATION OF SCHEDULED SUBSTANCE
(To be completed by permit holder after use)

Date	Time	Name and address of patient	Quantity administered	Administered by		Reason for adminis-tration	Balance on hand
				Signature	Qualification		

ANNEXURE XXXVI

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
APPLICATION FOR SALE OF UNREGISTERED MEDICINE
(Section 27 of the Act)
(regulation 46)

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

PART A
PARTICULARS OF APPLICANT

Name: .....
Qualifications: .....
Business Address: .....
Postal Address: .....
Telephone No.: ..... Fax No:.....
E-mail address: .....

PART B
PARTICULARS OF THE MEDICINE TO BE SOLD

Proprietary name: …….…….

Pharmacological classification: ……....

Dosage form: …….……

Dosage unit: ……..

Approved names of the active pharmaceutical ingredient(s): …….. ….....

……...

Strengths per dosage unit: ……..……...

Descriptive name of biological medicine: ……

Country of origin: ……..……...

Manufacturer: ……...

Business address: …….....…….....

.....……..

Is the medicine registered in the country of origin?: ……..…… (YES/NO)
Name other countries where the medicine is registered: …….....….
……..……
Has the manufacturer or representative applied for registration of the medicine in Namibia?:……..
(YES/NO).

If the medicine is not registered in any country, what is the stage of development of the medicine?:
…….....……...
…….....……

Indications for use of the medicine: …….....……
……..……
…….....……

Explain in detail the purpose for which the medicine is required: ……...……
…….....……
…….....……
…….....……..……

Patient details if the medicine is for an individual patient:
Name of patient: …….....……..
Age: …….....…… Sex: ….…….....……
Diagnosis: …….....……
…….....……
Dosage: …….....……
Expected duration of treatment: …….....……..

Are there any registered alternatives of the medicine in Namibia?:…….…….....……. (YES/NO)
If "Yes", explain why the alternative cannot be used? :……...…….....
.....
……..…
…….....…

The undersigned hereby declares that all the information submitted above is true and correct, and that a full report on the use of this medicine will be provided to the Namibia Medicines Regulatory Council on completion of the treatment.

.....….....
Signature of applicant

.....….....
Name in block letters

.....….....
Date of application

ANNEXURE XXXVII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
AUTHORISATION FOR THE SALE OF AN UNREGISTERED MEDICINE
IN TERMS OF SECTION 27 OF THE ACT
(regulation 46)

The Namibia Medicines Regulatory Council hereby authorises in terms of section 27 of the Act the use of the unregistered medicine(s) listed below:

Name of medicine: ……..……..
Dosage form: ……..……...
Strength per dosage unit: ……..…….
Quantity: ……..……..
Manufacturer: ……..……..
For the treatment of: ……..……
Name of patient: ……..…..
Age: ……..……..…… Sex: ……..……..……
Diagnosis:……..
.....
Dosage and duration of treatment: ……..……...
……..……
Name and address of hospital: ……..……
……..……
Name of medical practitioner: (Applicant): ……..……

…… ……..
Registrar of Medicines Date

ANNEXURE XXXVIII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

FEES
(regulation 47)

1. In respect of an application for registration of a Category A medicine -

(a) in respect of a medicine compounded in its entirety in Namibia -

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa) per application: N$3000-00;

(bb) for registration: N$1000-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: N$1000-00;

(bb) for registration: N$ 500-00;

(iii) for a line extension of a medicine -

(aa) per application: N$1000-00;

(bb) for registration: N$ 500-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: N$1000-00;

(bb) for registration: N$ 500-00;

(v) annually, in respect of the retention of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council: * N$ 500-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): N$ 500-00;

(bb) the transfer of a certificate of registration (whether approved or not): N$ 250-00;

(b) in respect of a medicine, not compounded in its entirety in Namibia -

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa) per application: N$3500-00;

(bb) for registration: N$1050-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: N$1750-00;

(bb) for registration: N$ 700-00

(iii) for a line extension of a medicine -

(aa) per application: N$1750-00;

(bb) for registration: N$ 700-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: N$1750-00;

(bb) for registration: N$ 700-00;

(v) annually, in respect of the retention of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council:* N$1050-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): N$1050-00;

(bb) transfer of a certificate of registration (whether approved or not): N$ 700-00.

2. In respect of an application for registration of a Category C medicine -

(a) in respect of a medicine compounded in its entirety in Namibia -

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa) per application: N$1500-00;

(bb) for registration: N$ 500-00;

(ii) for an interchangeable multi-source

medicine -

(aa) per application: N$ 500-00;

(bb) for registration: N$ 250-00;

(iii) for a line extension of a medicine -

(aa) per application: N$ 500-00;

(bb) for registration: N$ 250-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: N$ 500-00;

(bb) for registration: N$ 250-00;

(v) annually, in respect of the retention of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council: * N$ 250-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): N$ 250-00;

(bb) the transfer of a certificate of registration (whether approved or not): N$ 125-00;

(b) in respect of a medicine, not compounded in its entirety in Namibia -

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa) per application: N$2100-00;

(bb) for registration: N$ 7100-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: N$ 875-00;

(bb) for registration: N$ 350-00

(iii) for a line extension of a medicine -

(aa) per application: N$ 875-00;

(bb) for registration: N$ 350-00;

(iv) for a medicine not referred to in

			subparagraphs (i), (ii), or (iii) -	
		(aa)	per application:	N$ 875-00;
		(bb)	for registration:	N$ 350-00;
	(v)		annually, in respect of the retention of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council:*	N$ 525-00;
	(vi)		in respect of an application for -	
		(aa)	the amendment of an entry in the register (whether approved or not):	N$ 525-00;
		(bb)	transfer of a certificate of registration (whether approved or not):	N$ 350-00.
3.			In respect of any licence issued in terms of section 31 of the Act:	N$1000-00.
4.			In respect of an authorisation granted for the sale of an unregistered medicine -	
	(a)		registered outside Namibia but not registered in Namibia	N$4000-00;
	(b)		not registered at all	N$6000-00;
	(c)		not registered at all, but forming part of a clinical trial	N$6000-00;
	(d)		registered in Namibia, but forming part of a clinical trial for purposes of other indications	N$2000-00;
	(e)		prescribed for a specific patient	N$ 50-00.
5.			In respect of an application for the registration of a premises used for the manufacturing of medicines:	N$1000-00.
6.			For the performance of an inspection to determine whether a premises referred to in item 5 are suitable to be registered as such -	
	(a)		in respect of the premises of a manufacturer of medicines in Namibia	N$400-00 per hour.
	(b)		in respect of the premises of a manufacturer of medicines outside Namibia	N$9000-00 per site, plus travelling and accommodation costs for two inspectors.

* Please note:

(a) The fees referred to in paragraph 1(a)(v) and (b)(v) payable during a particular calendar year must be paid on or before the last working day of March of that year, failing which the

Registrar must cancel the registration of the medicines concerned as contemplated in terms of section 22(4) of the Act.

(b) For the purposes of this Annexure "line extension of a medicine" means any additional strength to the pharmaceutical form, excluding novel dosage forms or delivery systems.

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 179 2008

EXEMPTION OF PERSON OR CLASS OF PERSON
FROM APPLICATION OF SECTION 29:
MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under subsection (33)(e) of section 29 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I –

(a) exempt any person who manufactures or compounds, packs or sells, imports or exports any medicine or substance specifically packed, labeled or used –

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

(ii) for analytical laboratory purposes,

from the application of that section, if such medicine or substance is classified as a Schedule 0, Schedule 1, Schedule 2 or Schedule 3 substance; and

(b) exempt any person who manufactures or compounds, packs or sells, imports or exports any medicine or substance specifically packed, labeled or used –

(i) as a foodstuff, cosmetic or disinfectant as contemplated and approved, for such use, in terms of the Foodstuffs, Cosmetics and Disinfectants Ordinance, 1979 (Ordinance No. 18 of 1979); or

(ii) as an agricultural remedy, farm feed, fertilizer or stock remedy as contemplated and registered for use in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947 (Act No. 36 of 1947),

from the application of that section, if such medicine or substance is classified as a Schedule 0 substance.

R. N. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES Windhoek, 17th June 2008

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 180 2008

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003:
CLASSIFICATION OF MEDICINES AND OTHER SUBSTANCES
AS SCHEDULED SUBSTANCES

Under section 29(1) of the Medicines and Related Substances Control Act, 2003 (Act No.13 of 2003), and on the recommendation of the Namibia Medicines Regulatory Council and for the purpose of the control of medicines and other substances, I classify the medicines and other substances as Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, as set out in the Schedule below.

R. N. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES Windhoek, 30th June 2008

SCHEDULE

Definitions

1. (1) In this Notice, unless the context otherwise indicates, any word or expression to which a meaning is assigned in the Act bears that meaning, and -

"dosage unit" means -

(a) a tablet;

(b) a capsule; or

(c) 5 millilitres in the case of liquid oral preparations and mixtures,

as the case may be;

"Schedule" means Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5, as the case may be; and

"the Act" means the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003).

(2) In any Schedule contained in this Notice a reference to 'S' with a number next to it in brackets, means that the medicine or other substance in the description concerned also occurs in the Schedule to which the abbreviation refers.

General

2. Unless expressly excluded or unless listed in another Schedule, all substances referred to in any Schedule include the following:

(a) the isomers of such substances, if the existence of such isomers is possible within the specific chemical designation;

(b) the esters and ethers of such substances and of the isomers referred to in paragraph (a), as well as the isomers of such esters and ethers, if the existence of such esters, ethers and isomers is possible;

(c) the salts of such substances and of the isomers referred to in paragraph (a), as well as the salts of the esters and isomers referred to in paragraph (b), if the existence of such salts is possible;

(d) the isomers of any of the salts referred to in paragraph (c), if the existence of such isomers is possible; and

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

SCHEDULE 0

This Schedule includes all substances which are subject to registration in terms of the Act and which are not listed in any of the other Schedules.

SCHEDULE 1

Acetanilide and alkyl acetanilides.
Acetarsol, including preparations intended for human vaginal use.
Acetylcysteine.
Acetyldihydrocodeine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S4).
Aconite alkaloids; substances, preparations and mixtures containing 0,02 per cent or more thereof.
Acrivastine.
Acyclovir, if intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S2)
Adrenaline (epinephrine), preparations not intended for injection and ophthalmic preparations not intended for glaucoma. (S2)
Alkaloids and glycosides, all poisonous alkaloids and glycosides, and salts of such poisonous alkaloids and glycosides not specifically named in any other Schedule.
Alverine.
Aminopentamide.
Amorolfine.
Amyl nitrate.
Anethole trithione.
Anticoagulants, if intended for application to the skin. (S2)
Antihistamines, irrespective of indication or dosage form, except - (a) Astemizole and Terfenadine (S2); (b) if listed separately in Schedules 2 and 3; and (c) except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947 (Act No. 36 of 1947).
Antimalarials, preparations containing substances in the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds, if intended specifically for malaria prophylaxis. (S2)
Antimicrobial substances, namely bacitracin, gramicidin, polymyxin B, tyrothricin, griseofulvin, mupirocin and natamycin if intended for topical application to the skin, nares and external ear, as well as nystatin preparations intended for application to the cavity, nares and external ear and excluding nystatin if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, as excluded from the conditions of Schedule 2. (S2)
Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and mixtures containing 1.0 per cent or more thereof.
Antipyrine (phenazone), including preparations and mixtures, if intended for application to the skin.
Apomorphine; preparations and mixtures thereof except if indicated for the treatment of erectile dysfunction. (S2)
Aptocaine.
Arecoline.
Arsenic; substances, preparations and mixtures containing arsenic trioxide.
Atropine, substances, preparations and mixtures thereof except ophthalmic preparations. (S2)
Azelaic acid.
Azelastine.
Bambuterol.

Beclomethasone propionate (See corticosteroids).
Bee venom, if intended for application to the skin. (S2)
Belladonna alkaloids, substances and preparations thereof.
Benproperine.
Benzethonium chloride, including preparations intended for human vaginal use.
Benzydamine, preparations and mixtures containing - (a) 3 per cent or less of benzydamine, if intended for application to the skin; and (b) 0.15 per cent or less of benzydamine if intended for use as a mouth rinse or for topical application in the mouth and throat, but the total daily dose may not exceed 36 milligrams of benzydamine. (S2)
Beta-aminopropylbenzene and beta-aminoisopropylbenzene, as excluded from the conditions of Schedule3. (S3)
Bevonium methylsulphate.
Bifonazole, including preparations intended for application to the skin.
Bioallethrin.
Biologicals, if intended for human medicinal use including polyvalent snake antivenom, but not injectable preparations thereof. (S2)
Bismuth, including prerations intended for oral issue.
Bitolterol.
Bromhexine.
Bromides, preparations and mixtures thereof containing less than 80 milligrams of bromine as bromide per recommended daily dose. (S3)
Bufexamac, including preparations intended for application to the skin.
Bunamidine.
Butinoline.
Calabar bean alkaloids; substances, preparations and mixtures thereof.
Calcium salts, preparations thereof, if intended for injection, unless listed in another Schedule, but not if registered in terms of the Fertilizers, Farm Feeds, and Agricultural Remedies Act, 1947.
Camphorated Opium Tincture BP.
Camylofin.
Cantharidin.
Canthaxanthin, if intended for medicinal purposes.
Carbocisteine.
Carbuterol, if not contained in respirator solutions and if not intended for injection. (S2)
Carisoprodol.
Cathine ((+)-norpseudeophedrine), preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S4)
Cetirizine
Chlorhexidine, if intended for human vaginal use.
Chlormezanone, mixtures thereof if the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S2)
Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne, preparations and mixtures containing 5,0% or less of chlorodyne in combination with other active medicinal ingredients. (S4)
Chloroform, substances, preparations and mixtures containing less than 20% of chloroform. (S3)

Chlorprenaline.
Chlorzoxazone.
Cholestyramine
Cimetidine, if intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to - (a) a maximum dose of 200 milligrams; (b) a maximum daily dose (per 24 hours) of 800 milligrams; and (c) a maximum treatment period of 2 weeks. (S2).
Clidinium bromide.
Clonidine, if intended for the treatment of migraine. (S2)
Clotrimazole, if intended for application to the skin and if intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Codeine (methylmorphine), preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S4)
Colchicine, in cases of emergency. (S2)
Contrast media.
Corticosteroids (natural or synthetic) if contained in preparations intended for inhalation - (1) Beclomethasone dipropionate, if intended for nasal administration (other than by aerosol), in the treatment of the symptoms of seasonal allergic rhinitis (hayfever) in adults and children over the age of 12 years, subject to - (a) a maximum dose of 100 micrograms per nostril; (b) a maximum daily dose of 200 micrograms per nostril; (c) a pack size limit of 200 doses (S2). (2) Flunisolide, if intended for nasal administration, other than aerosol, in a strength not exceeding 0.025 per cent (w/w) indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over the age of 12 years, if in the case of adults and children over the age of 16 years, the maximum dose per nostril in 50 micrograms and the maximum daily dose per nostril is 100 micrograms and in the case of children 12 to 16 years, the maximum dose per nostril is 25 micrograms and the maximum daily dose per nostril is 75 micrograms and the pack size is limited to 240 doses. (3) Fluticasone propionate, if intended for nasal administration, other than by aerosol, in the short-term treatment (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over the age of 12 years, if the maximum daily dose per nostril in 100 micrograms and the pack size is limited to 120 doses. (S2).
Cyclandelate.
Cyclopentolate, but not ophthalmic preparations thereof. (S2)
Desloratidine.
Dextromethorphan.
Dialysate preparations.
Dichlorophen, preparations and mixtures intended for application to the skin (S2), except if intended for use and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Diclophenac, if intended for application to the skin, for emergency treatment of acute gout attacks and for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Dicyclomine.
Difenoxin (or diphenoxylic acid), mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0% of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S4)
Dihydrocodeine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit, and liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S4)

Dimethothiazine; if intended solely as an antihistamine. (S2)
Diosmine.
Diphenoxylate, preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S4)
D-norpseudoephedrine (See Cathine)
Dithiazanine.
Domperidone.
Econazole, if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Emedastine.
Emepronium.
Enilconazole if intended for application to the skin. (S2)
Ephedra alkaloids (natural or synthetic), other than ephedrine preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1.0 per cent or less of ephedra alkaloids, and other preparations and mixtures containing not more than 30 milligrams of ephedrine or ephedra alkaloids per dose. (S3)
Ephedrine contained in products registered in terms of the Act, except preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1.0 per cent or less of ephedrine, and other oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose. (S3)
Ergot alkaloids (natural or synthetic), if intended for the treatment of migraine. (S2)
Escin (aescin), medicinal preparations and mixtures thereof intended for application to the skin and containing 1,0% or less of escin. (S2)
Ethacridine.
Ether (diethyl ether), all substances, preparations and mixtures containing less than 20% of ether. (S3)
Ethylmorphine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S4)
Ethylphenylephrine.
Etofenamate, including preparations intended for application to the skin. (S2).
Etilefrine.
Etodroxizine, except preparations and mixtures thereof if used solely as an antihistamine. (S3)
Exalamide.
Famotidine, if intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to - (a) a maximum dose of 10 milligrams; (b) a maximum daily dose (per 24 hours) of 20 milligrams; and (c) a maximum treatment period of 2 weeks. (S2).
Fedrilate.
Felbinac, including preparations intended for application to the skin.
Fenbendazole, except if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Fenoprofen, if intended for the emergency treatment of acute gout attacks and for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Fenoterol, if not contained in respirator solutions (S2) and if not intended for injection or for the prevention or delay of labour. (S2)
Fenticonazole, including preparations intended for application to the skin.
Flavoxate.

Flubendazole, except if intended and registered as an anthelmintic for pigs in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Flucytosine, if intended for application to the skin. (S2)
Flufenamic acid, if intended for application to the skin. (S2)
Flunisolide, (See corticosteroids)
Fluorescein, if intended for ophthalmic use. (S2)
Fluorides, oral medicinal preparations and mixtures thereof containing 0.25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another schedule. (S2)
Flurbiprofen - (1) if intended for application to the skin, including by transdermal patch, provided that in the case of application by transdermal patch indications are for use by adults and children of the age of 12 years and older and the treatment period is limited to 4 weeks (S2); (2) if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Fluticasone propionate, (See corticosteroids).
Formoterol.
Fusafungine.
Gadopentetic acid.
Gamma benzene hexachloride, human medicinal preparations and mixtures if intended for application to the skin.
Gelsemium alkaloids.;substances, preparations and mixtures thereof.
Glycopyrronium.
Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester) if intended for application to the skin. (S2)
Halogenated hydroxyquinolines, if intended for application to the skin. (S2)
Hexametazine.
Hexoprenaline, if not contained in respirator solutions (S2) and if not intended for injection or for the prevention or delay of labour. (S2)
Homatropine, preparations and mixtures thereof, but not ophthalmic preparations. (S2)
Hormones (natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, if intended for - (a) human vaginal use; (b) oral contraception; (c) specific emergency post coital contraception (S2); (d) zeranol, natural estrogen, and progestrogen, if intended and registered in terms of the Act as a veterinary production improver (S2); and (e) BST(Bovine somatropin) if intended and registered in terms of the Act for veterinary use. (S2)
Hydrocortisone and hydrocortisone acetate, if used as a single active ingredient in a maximum concentration of 1,0% in preparations intended for application to the skin, and hydrocortisone in a maximum concentration of 1.0 per cent used in combination with miconazole for topical application in the treatment of athlete's foot. (S2)
Hydroquinone; preparations and mixtures containing 2 per cent or less thereof, if intended for application to the skin. (S2)
O-(□-hydroxyethyl) rutosides.
Hyoscine; substances and mixtures thereof including transdermal preparations if intended for the prevention of the symptoms of motion sickness.

Ibuprofen in oral medicinal preparations - (a) if the recommended daily dose for adults does not exceed 1,2 grams and that for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of bodyweight; (b) if intended for emergency treatment of acute gout attacks; (c) if intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days, but not if specifically intended for the treatment of inflammatory joint diseases; (d) if contained in preparations intended for application to the skin. (S2)
Idoxuridine, if intended for application to the skin. (S2)
Indanazoline.
Indomethacin, if intended for application to the skin and for the emergency treatment of acute gout attacks. (S2).
Injections, unless listed in another Schedule, except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Insulin, in cases of emergency. (S2)
Iopromide.
Ipecacuanha alkaloids, substances, preparations and mixtures thereof containing less than 0,2% alkaloids, calculated as emetine. (Also see Schedule 2 under “Emetine”.)
Ipratropium bromide.
Irrigation fluids.
Isoaminile.
Isoconazole, if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Isoprenaline (isoproterenol), if not contained in respirator solutions (S2) and if not intended for injection. (S2)
Isopropamide.
Isosorbide, in cases of emergency. (S2)
Ketoconazole, if intended for application to the skin except preparations and mixtures containing not more than 1.0 per cent ketoconazole if intended for the prevention and treatment of dandruff. (S2)
Ketoprofen, if intended for - (a) the short-term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 100 milligrams of ketoprofen in 24 hours; (b) for the emergency treatment of acute gout attacks and for the treatment of post-traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 100mg of ketoprofen for a maximum period of 5 days. (S2); (c) application to the skin. (S2)
Lactobacillus acidophilus and Lactobacillus bifidus, if intended for therapeutic purposes, except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Lansoprazole, if intended for the temporary short-term relief of heartburn and hyperacidity, subject to - (a) a maximum daily dose of 15mg; (b) a maximum treatment period of 14 days. (S2)
Lead acetate, but not if registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.
Lead plaster and its combinations.
Levocetirizine
Lithium salts, if intended for application to the skin. (S2)
Lobelia alkaloids; substances, preparations and mixtures thereof except if intended for ophthalmic use and parenteral use.
Local anaesthetics, but not if intended for ophthalmic and for parenteral use. (S2)
Lodoxamide.

Loperamide.
Loratadine.
Lufenuron.
Luxabendazole, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Lysozyme, if intended for application to the skin. (S2)
Macrogolethers, if intended for human vaginal use, but not if intended for spermicidally lubricated condoms.
Malathion, if not intended and registered as an ectoparasiticide in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.
Manganese salts, preparations thereof for injection, if intended for veterinary use.
Mebendazole, except if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Mebeverine.
Mefenamic acid, if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days, and preparations containing mefenamic acid as the only therapeutically active substance, if intended for the treatment of primary dysmenorrhoea, if the maximum daily dose is 500 milligrams 3 times a day and the maximum treatment period is 3 days. (S2)
Mepenzolate bromide.
Mephenesin.
Mercuric ammonium chloride.
Mercuric chloride.
Mercuric iodide.
Mercuric oxides, substances, preparations and mixtures thereof, but not those containing less than 3,0% of mercury.
Mercury organic compounds, substances, preparations and mixtures in the form of aerosols intended for application to the skin and mucous membranes and substances, preparations and mixtures containing less than the equivalent of 0,6% of elemental mercury, intended for application to the skin and mucous membranes, except phenylmercuric nitrate if registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies Act, 1947.
Mesna, preparations thereof not intended for injection. (S2)
Metacresol sulphonic acid formaldehyde, includining preparations intended for human vaginal use.
Metaproterenol (orciprenaline), if not contained in respirator solutions (S2) and if not intended for injection or for the prevention or delay of labour. (S2)
Methenamine (hexamine), if not intended for application to the skin; except if intended and registered in terms of the Act as an urinary tract antiseptic for veterinary use. (S1)
Methionine, if intended for medicinal purposes.
Methixene.
Methocarbamol; if intended for medicinal purposes.
Methoxyphenamine.
Miconazole, if intended for application to the skin, for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis and for human use in preparations containing 2,0% or less of miconazole, for the topical treatment of fungal infections of the mouth (oral candidiasis). (S2)
Microfibrillar collagen hydrochloride.
Minoxidil, if intended for application to the scalp. (S2)
Morantel citrate, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.

Morphine, mixtures containing 0,2% or less of morphine, calculated as anhydrous morphine. (S4)
N-acetyl-aspartyl-glutamic acid.
Nabumetone, if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Naphazoline, including preparations intended for nasal use.
Naproxen - (a) if intended for application to the skin (S2); (b) as a sodium salt, if intended for the short-term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with common cold and fever, at a maximum dose of 600mg naproxen (660 milligrams naproxen sodium) in 24 hours; (c) if intended for emergency treatment of acute gout attacks and for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Nedocromil.
Nicergoline.
Nicotine, if intended for human medicinal use, except - (a) nicotine gum containing 4mg or less of nicotine per piece if the pack size does not exceed 30 pieces per pack if these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only; (b) nicotine transdermal patches for continuous application to the skin in strengths up to and including 15mg/16 hours if these medicines are used for the relief of nicotine withdrawal as an aid to smoking cessation only.
Nicotinic acid, oral medicinal preparations and mixtures thereof containing more than 30 milligrams per recommended daily dose, except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Nitrofurantoin, if intended for application to the skin. (S2)
Nitrofurazone, if intended for application to the skin. (S2)
Nitroglycerine, if intended for medicinal use in cases of emergency.(2)
Nitroscanate.
Nizatidine, if administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to - (a) a maximum dose of 150 milligrams; (b) a daily dose of 300 milligrams; (c) a maximum treatment period of two weeks. (S2)
Norcodeine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit (S4)
Noscapine.
Nux vomica, substances, preparations and mixtures.
Nystatin, if intended for application to the skin and if intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S2)
Octatropine methylbromide.
Oleoresin of aspidium (Filix Mas.)
Olopatadine
Opium, mixtures containing not more than 0,2% of morphine, calculated as anhydrous morphine. (S4)
Ornidazole, if intended for application to the skin. (S2)
Orphenadrine.
Orthodichlorobenzene, if intended for topical human medicinal use.
Otilonium bromide.

Oxibendazole, except if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Oxybuprocaine, if contained in eye drops intended for emergency treatment of arc eyes. (S2)
Oxymetazoline, including preparations intended for nasal use.
Oxyphencyclimine.
Oxyphenonium.
Pancreatic enzyme-containing preparations, unless listed in another Schedule.
Pancrelipase.
Papaverine, substances, preparations and mixtures thereof.
Paracetamol - (1) substances, preparations and mixtures, except - (a) in tablets or capsules containing 500 milligrams or less or paracetamol, if - (i) packed in a primary pack containing not more than an aggregate of 12.5 grams of paracetamol in such tablets or capsules; (ii) packed in blister strip packaging or in containers with child resistant closures; (b) in individual wrapped powders or in sachets containing 1000 milligrams or less of paracetamol, if packed in a primary pack containing not more than an aggregate of 12.5 grams of paracetamol in such powders or sachets; (c) in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres, if - (i) packed in a primary pack containing not more than 100 millilitres in the case of the liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 mililitres; (ii) packed in a primary pack containing not more than 20 millilitres in the case of the paediatric dosage form (drops) containing 120 milligrams or less of paracetamol per 1.2 millilitres; (2) if contained in rectal suppositories.
Paradichlorobenzene, if intended for topical human medicinal use.
Penciclovir, if intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S2)
Pentaerythritol tetranitrate, in cases of emergency. (S2)
Pentosan polysulfate sodium except if intended for the treatment of interstitial cystitis. (S2)
Pentoxifylline.
Phenazopyridine.
Phenylephrine, but not ophthalmic preparations containing 0,2% or less of phenylephrine.
Phenylpropanolamine; preparations and mixtures if the recommended daily dose for adults does not exceed 100 milligrams and for children if the age of 6 to 12 years does not exceed 50 milligrams id intended for symptomatic relief of nasal and sinus congestion.
Pholedrine.
Pholcodine, preparations and mixtures if compounded with one or more therapeutically active substances containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodine (calculated as base) per 5 millitre dosage unit. (S4)
Phospholipids, if applied for therapeutic purposes.
Pinaverium.
Pipenzolate.
Piperonyl butoxide, if not intended and registered as an ectoparasiticide in terms of the Fertilizers, Farm Feeds, Agricultural Remedies Act, 1947.
Pipoxolan.
Pirbuterol, if not contained in respirator solutions. (S2)
Piroxicam, if intended for the emergency treatment of acute gout attacks and for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Pizotifen, preparations and mixtures, if intended for prophylaxis of migraine. (S3)
Podophyllum resin, preparations and mixtures containing 20% or less thereof. (S2)
Poldine methylsulphate.
Polyvalent snake antivenom.
Potassium chloride, if intended for intravenous infusion or for injection, and if the recommended dose is more than 20 millimol of potassium (1 500 milligrams of potassium chloride) per 24 hours, but not if contained in oral rehydration preparations.
Povidone iodine, if intended for human vaginal use.
Prifinium bromide.
Procaine hydrochloride, when intended for oral administration.
Procaterol, if not contained in respirator solutions.(S2)
Procyclidine.
Proglumide.
Proguanil; if used in combination with chloroquine if intended specifically for malarial prophylaxis (S2).
Promethazine; preparations and mixtures if intended for use as an antihistamine, for application to the skin and if intended specifically for the treatment of travel sickness. (S3)
Propantheline bromide.
Propentofylline, if intended for veterinary use. (S2)
Propylhexedrine, if used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S2)
Propyphenazone.
Proteolytic (fibrinolytic) enzymes for oral use and if intended for application to the skin, unless listed in another Schedule, but not if intended for injection and if intended for soft contact lens cleaners. (S2)
Proxymetacaine, if contained in eye drops intended for emergency treatment of arc eyes. (S2)
Pyrantel pamoate, except if registered as an antherlmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remidies Act, 1947.
Pyridoxilate.
Quinine, preparations and mixtures containing more than 1,0% thereof.
Ranitidine, if administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to - (a) a maximum dose of 75 milligrams; (b) a daily dose of 300 milligrams; (c) maximum treatment period of two weeks. (S2)
Reproterol, if not contained in respirator solutions. (S2)
Rimiterol, if not contained in respirator solutions and if not intended for injection. (S2)
Sabadilla alkaloids; substances, preparations and mixtures containing 1.0 per cent or more thereof.
Salbutamol, if not contained in respirator solutions and if not intended for injection. (S2)
Salmefamol, if not contained in respirator solutions and if not intended for injection. (S2)
Salmeterol.
Sertaconazole, if intended for application to the skin. (S2)
Siccanin, if intended for application to the skin.
Silver sulphadiazine, if intended for application to the skin in the short-term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams. (S2)
Sodium cromoglycate, if not intended for veterinary use. (S2)

Sodium fluoride; preparations and mixtures thereof containing 40 milligrams or more per daily dose. (S2)
Sodium pentosan polysulphate.
Solcoseryl, preparations thereof intended for application to the skin, to the mucous membranes of the mouth and to the lips. (S2)
Strychnine, preparations and mixtures containing 0.2 per cent or less thereof except the substance. (S2)
Sulphonamides, if intended for application to the eyes, nares, and vagina. (S2), except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947 (Act No 36 of 1947).
Terbinafine, if intended for application to the skin. (S2)
Terbutaline, if not contained in respirator solutions. (S2)
Tetracaine, if contained in eye drops intended for emergency treatment of arc eyes. (S2)
Tetrahydrozoline, including preparations intended for nasal use.
Theophylline and its derivatives, unless listed in another Schedule, if not intended for injection. (S2)
Thiabendazole, if intended for application to the skin. (S2)
Thiram, if not intended and registered as a fungicide under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.
Tiaprofenic acid, if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Ticlatone; if intended for application to the skin.
Timepidium.
Tioconazole, if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Tiotropium
Tolmetin, if intended for application to the skin. (S2)
Triamcinolone, if intended for application to oral lesions. (S2)
Trimebutine.
Trospium.
L-tryptophan if intended for medicinal use as supplementation for nutritional purposes. (S3)
Tuberculin, if intended for human use. (S2)
Tulobuterol, if not contained in respirator solutions. (S2)
Vaccines, if intended for human use. (S2)
Xylometazoline including preparations intended for nasal use.
Zinc salts, preparations thereof for injection, if intended for veterinary use. (S2)

SCHEDULE 2

4-aminosalicylic acid (para-aminosalicylic acid) and its esters.
Abacavir.
Acamprosate.
Acarbose.
Acebutolol.
Aceclofenac.
Acertarsone diethylamine salt, including preparations intended for injection.
Acetazolamide.
Acetohexamide.
Acetylcholine, including preparations intended for ophthalmic use.
Acipimox.
Acyclovir, if not intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)
Adapalene.
Adenosine.
Adrenaline (epinephrine), preparations intended for injection and ophthalmic preparations thereof intended for glaucoma. (S1)
Albendazole.
Alclofenac.
Alcuronium.
Aldesleukin.
Alfuzosin.
Alendronic acid.
Alisapride.
Allopurinol.
Almitrine.
Alosetron
Alpha-chymotrypsin, including preparations intended for ophthalmic use.
Alphacalcidol, except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Alprenolol.
Alprostadil.
Amantadine.
Amifostine
Amiloride.
Aminoglutethimide.
Aminopyrine (amidopyrine).
Amiodarone.

Amiphenazole.
Amlodipine
Amprenavir.
Amrinone.
Amsacrine.
Anagrelide.
Anastrozole.
Ancrod.
Anthiolimine, including preparations intended for injection.
Anticoagulants, preparations not intended for application to the skin. (S1)
Antihaemophilic factor.
Anti-malarials, excluding the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds and preparations thereof intended specifically for malaria prophylaxis. (S1)
Antimicrobial substances (chemotherapeutic substances) synthesised in nature or the laboratory, being substances used in the specific treatment of infections, but not (a) the following if intended for topical application to the skin, nares and external ear - (i) bacitracin (S1); (ii) gramicidin (S1); (iii) griseofulvin (S1); (iv)mupirocin (S1); (v) natamycin (S1); (vi) nystatin (S1); (vii) polymyxin B (S1); (viii) tyrothricin (S1) (b) if intended for use as germicides and antiseptics, (c) nystatin oral drops (S1); (d) nystatin if intended for human vaginal use, specifically for the treatment of recurent vaginal candidiasis (S1), except if intended for use as indicated below and registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies Act, 1947: ampicillin, cloxacillin, dihydrostreptomycin, penethamate hydriodide and procaine benzylpenicillin; intra-mammary preparations thereof, containing tracer dye(s) and intended for the tratment of mastitis in cattle; amprolium, decoquinate, dinitolmide, ethopabate, lasalocid, maduramicin, monensin and narasin if intended as anti-coccidial preparations; avilomycin, avoparcin, carbadox, flavophospholipol, monensin, nitrovin, olaquindox, virginiamycin and zinc bacitracin if intended to promote growth as a feed additive; carnidazole, if intended for trichomonas in pigeons; chlortetracycline, rolitetracycline and tetracycline; injections thereof, intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle; chlortetracycline; capsules thereof, for use in pigeons; chlortetracycline and tetracycline derivatives if intended for topical use in the management of wounds in animals; dimetridazole, if intended for trichomonas in pigeons, as an anti-bacterial preparation for pigs and to promote growth; doxycycline and oxytetracycline; preparations thereof, except preparations intended to be used as an additive to feed; furaltadone, if intended as a single oral dosage for gastro-intestinal infections; hygromycin, if intended as an anthelmintic for pigs; oxytetracycline; salinomycin, if intended as an anti-coccidial preparation and to promote growth; tylosin, if intended for addition to drinking water and feedstuff for administering to poultry and pigs.
Antisera for veterinary use.
Apomorhine, if indicated for the treatment of erectile dysfunction. (S1)
Apraclonidine.
Aprotinin.

Arabinosylcytosine.
Arprinocid, except if intended and registered as an anticoccidial preparation for poultry in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Arsanilic acid.
Arsenamide, including preparations intended for injection.
Artemether and its derivatives.
Artemotil.
L-asparaginase.
Astemizole.
Atenolol.
Atipamezole.
Atorvastatin.
Atosiban.
Atovaquone.
Atracurium besilate.
Atropine, ophthalmic preparations thereof. (S1).
Auranofin.
Azapropazone.
Azathioprine.
Baclofen.
Balsalazide.
Barnidipine.
Basiliximab.
Beclamide.
Bee venom, preparations not intended for application to the skin.(S1)
Bemegride.
Benazepril.
Bendazac.
Benfluorex.
Benoxaprofen.
Benzbromarone.
Benzydamine, but not preparations and mixtures containing - (a) 3% or less of benzydamine, if intended for application to the skin and (b) 0.5 per cent or less of benzydamine if intended for use as a mouth-rinse or for topical application in the mouth and throat: Provided that the total dose does not exceed 36mg of benzydamine per day. (S1)
Bepridil.
Beta-benzalbutyramide.
Beta-galactosidase, if intended for therapeutic purposes.
Betahistine.

Betaxolol.
Bethanechol.
Bethanidine.
Bevantolol.
Bezafibrate.
Bimatoprost.
Biologicals, injectable preparations thereof, if intended for human use, but not tuberculin if intended for human use and vaccines if intended for human use and not polyvalent snake antivenom. (S1)
Biperiden.
Bisoprolol.
Bleomycin.
Bopindolol.
Bretylium tosylate.
Brimonidine.
Brinzolamide.
Bromocriptine.
Bufenoide.
Buflomedil.
Buformin.
Bumadizone.
Bumetanide.
Buserelin.
Busulphan.
Cabergoline.
Cadralazine.
Calcipotriol
Calcitonin.
Calcitriol.
Calcium carbimide.
Calcium disodium edetate, if intended for injection.
Calcium dobesilate.
Calcium polystyrene sulphonate, if intended for therapeutic purposes.
Cambendazole.
Candesartan.
Capecitabine.
Captopril.
Carazolol.

Carbachol.
Carbamazepine.
Carbenoxolone.
Carbidopa.
Carboplatin.
Carbuterol, if contained in respirator solutions and if intended for injection. (S1)
Carmustine.
Carprofen.
Carteolol.
Carvedilol.
Celecoxib.
Celiprolol.
Cerivastatin.
Ceruletide.
Chenodeoxycholic acid.
Chlorambucil.
Chlorazanil.
Chlordantoin, including preparations intended for human vaginal use.
Chlorexolone.
Chloroquine, if intended for anti-rheumatic use. (S1).
Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide-1,1-dioxide, whether hydrogenated or not, including hydrochlorothiazide, bendrofluazide, benzthiazide, cyclopenthiazide, hydroflumethiazide, metchlorothiazide and polythiazide.
Chlorpropamide.
Chlorthalidone.
Cholestyramine resin.
Chromonar.
Chymopapain, including preparations intended for injection.
Cilazapril.
Cimetidine, but not if intended for the short-term symptomatic relief of heart-burn, dyspepsia and hyperacidity, subject to - (a) a maximum dose of 200 milligrams; (b) a maximum daily dose (per 24 hours) of 800 milligrams; and (c) a maximum treatment period of 2 weeks. (S1)
Cisapride.
Cisatracurium.
Cisplatin.
Cladribine.
Clanobutin.

Clazuril, except if intended and registered as an anticoccidial preparation for poultry in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Clenbuterol.
Clofazimine.
Clofibrate.
Clomiphene.
Clonidine, if intended for any other treatment than migraine. (S1)
Clopidogrel.
Closantel, except if intended and registered as an anthelmintic for sheep and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Clotrimazole, if not intended for application to the skin and not intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis. (S1)
Co-trimoxazole.
Colchicine, not in cases of emergency. (S1)
Colestipol.
Colfosceril.
Copper salts, if intended for injection.
Corticosteroids (natural or synthetic), unless listed in another Schedule, but not hydrocortisone and hydrocortisone acetate if used as a single active ingredient in a maximum concentration of 1,0per cent in preparations intended for application to the skin, (S1) and not triamcinolone, if intended for application to oral lesions (S1) and if contained in preparations intended for inhalation. (S1).
Cotetroxazine.
Cyclandalate.
Cyclofenil.
Cyclopentolate, ophthalmic preparations thereof. (S1)
Cyclophosphamide and its derivatives, unless listed in another Schedule.
Cyclosporin.
Cyprenorphine.
Cyproterone acetate.
Cytarabine.
Dacarbazine.
Dacliximab.
Dactinomycin (actinomycin D).
Dantrolene.
Dapsone and its derivatives.
Daunomycin (daunorubicin).
Debrisoquine.
Deferoxamine.
Delapril.
Demecarium.

Desirudin.
Di-isopropyl fluorophosphate.
Diazoxide.
Dichlorophen, but not preparations and mixtures intended for application to the skin (S1) and not if intended for use and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947 (Act No 36 of 1947).
Diclazuril, except if intended and registered as an anticoccidial preparation for poultry in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act,1947 (Act No 36 of 1947).
Diclodronic acid.
Diclofenac, if not intended for application to the skin, not intended for emergency treatment of acute gout attacks and not intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1)
Dichlorphenamide.
Didanosine.
Diethylcarbamazine.
Diflunisal.
Diftalone.
Digitalis, its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams.
Dihydralazine.
Dihydroergocristine.
Dihydrotachysterol.
Dilazep.
Dilevalol.
Diloxanide furoate.
Diltiazem.
Dimercaprol, including preparations intended for injection.
N,N-Dimethylformamide (DMF)
Dimethyl sulphoxide.
Diminazene, except if intended and registered as a babesiacide in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Dinitrophenol.
Dinoprostone.
Diphemethoxidine.
Diphenidol.
Dipivefrin.
Diprenorphine.
Dipyridamole.
Dipyrocetyl.
Disodium pamidronate.
Disophenol, except if intended and registered as an anthelmintic for sheep and goats in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.

Disopyramide.
Distigmine.
Disulfiram.
Ditazole.
Dithranol.
Dobutamine.
Docetaxol.
Dolasetron.
Dopa.
Dopamine.
Dornase alfa (rhDNase).
Dorzolamide.
Doxapram.
Doxazosin.
Doxepin, if intended for application to the skin (S3)
Doxorubicin.
Drotrecogin
Econazole, if not intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis.(S1)
Edoxudine.
Edrophonium.
Efavirenz.
Eletriptan.
Eltenac.
Emetine, but not substances, preparations and mixtures containing less than 0,2% of alkaloids, calculated as emetine. (See ipecacuanha S1).
Enalapril.
Encainide.
Endralazine.
Enilconazole, except if intended for application to the skin. (S1)
Enoxacin.
Enrofloxacine.
Entacapone.
Epirubicin (4-epidoxorubicin).
Eprosartan.
Ergot alkaloids (natural or synthetic), preparations and mixtures thereof not intended for the treatment of migraine. (S1)
Escin (aescin), but not preparations and mixtures thereof intended for application to the skin and containing 1,0% or less of escin. (S1)

Esculin, including preparations intended for oral use.
Esmolol.
Esomeprazole.
Estramustine.
Ethacrynic acid.
Ethambutol.
Ethionamide, including preparations intended for oral use.
Ethoglucid.
Ethosuximide.
Etidronate.
Etiproston.
Etisazol.
Etodolac.
Etodolic acid.
Etofamide.
Etofenamate, except if intended for application to the skin. (S1)
Etoposide.
Famciclovir.
Famotidine, but not if intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to - (a) a maximum dose of 10 milligrams; (b) a maximum daily dose (per 24 hours) of 20 milligrams; and (c) a maximum treatment period of 2 weeks. (S1)
Fazadinium.
Febantel, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Felbamate.
Felodipine.
Fenbufen.
Fenchlorphos.
Fenclofenac.
Fendiline.
Fenofibrate.
Fenoprofen, if not intended for emergency treatment of acute gout attacks and not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1).
Fenoterol, if contained in respirator solutions and if intended for the prevention or delay of labour and preparations thereof for injection. (S1)
Fentiazac.
Fenticonazole.
Fertirelin.

Filgrastim.
Finasteride.
Flecainide.
Floctafenine.
Flosequinan.
Fluconazole.
Flucytosine, preparations and mixtures not intended for application to the skin. (S1) (See corticosteroids)
Fludarabine.
Flufenamic acid, preparations and mixtures not intended for application to the skin. (S1)
Flugestone.
5-Fluorouracil.
Flunisolide.
Flunixin.
Fluorescein, except if intended for ophthalmic use. (S1)
Fluorides; except oral medicinal preparations and mixtures thereof containing 0.25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another schedule (S1).
Flurbiprofen, if intended for ophthalmic use, except - (a) if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1) (b) if intended for application to the skin, including application by transdermal patch, and the indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks. (S1)
Flutamide.
Fluvastatin.
Fondaparinux.
Fosinopril.
Fotemustine.
Ftorafur.
Furazolidone.
Furosemide.
Gabapentin.
Galantamine.
Gallamine.
Ganciclovir.
Ganirelix.
Gemcitabine.
Gemfibrozil.
Gemtuzumab.
Gestrinone.
Glafenine.

Glatiramer.
Glibenclamide.
Glibornuride.
Gliclazide.
Glimepiride.
Glimidine.
Glipizide.
Gliquidone.
Glucosamine, substances, preparations and mixtures if intended for the treatment of primary and secondary osteoarthritis, osteochondrosis and spondylosis.
Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester), if not intended for application to the skin. (S1)
Goserelin.
Granisetron.
Guanabenz.
Guanethidine.
Guanfacine.
Guanoxan.
Halofantrine.
Halofenate.
Halofunginone, but not if intended and registered as an anti-coccidial preparation for poultry in terms of the Fertilizers, Farm Feeds, Agricultural Remedies Act, 1947.
Halogenated hydroxyquinolines, if not intended for application to the skin (S1).and except di iodohydroxyquinoline if intended and registered as an anticoccidial preparation in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947 (Act No 36 or 1947).
Hemin.
Heptaminol.
Hexoprenaline, if contained in respirator solutions and if intended for the prevention or delay of labour and preparations thereof for injection. (S1)
Homatropine, ophthalmic preparations thereof. (S1)
Hormones (natural or synthetic, including recombinant forms), with either hormonal or antihormonal action, unless listed in another Schedule, but not - (a) if intended for human vaginal use (S1); (b) if intended for oral contraception (S1), (c) insulin (S1), (d) epinephrine (adrenaline) (S1), (e) corticotrophin (adrenocorticotrophic hormone, ACTH) (S3). (f) human growth hormone (human somatotropin) - all forms (S3); (g) zeranol, natural estrogen, and progesterorone, if intended and registered in terms of the Act as a veterinary production improver (S1); (h) BST (Bovine somatotropin) if intended and registered in terms of the Act for veterinary use. (S1)
Hyaluronidase.
Hyaluronic acid and derivatives.
Hycanthone.
Hydralazine.

Hydroquinone; preparations and mixtures thereof containing more than 2.0 per cent hydroquinone. (S2).
Hydroxyurea.
Hylan.
Ibandronic acid.
Ibuprofen, if specifically intended for the treatment of inflammatory joint diseases. (S1)
Ibutilide.
Idarubicin.
Idoxuridine, if not intended for application to the skin. (S1)
Iloprost.
Imatinib.
Imidocarb, except if intended and registered as an antibabesial for the treatment of babesiosis in terms of the the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Imiglucerase.
Imiquimod.
Indapamide.
Indinavir.
Indomethacin, if not intended for application to the skin and if not intended for the emergency treatment of acute gout attacks. (S1)
Indoprofen.
Indoramin.
Infliximab.
Inosiplex (inosine pranobex).
Insulin, but not in cases of emergency. (S1)
Interferon alpha.
Interferon beta.
Interferon gamma.
Intra-uterine devices.
Intrifiban.
Irbesartan.
Irinotecan
Iron salts, if intended for injection, except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Isepamicin.
Isoconazole, if not intended for application to the skin and not intended for human vaginal use, specifically for the treatment of recurrent vaginal candidasis. (S1)
Isoniazid and its derivatives, unless listed in another Schedule.
Isopirin.
Isoprenaline (isoproterenol), if contained in respirator solutions and if intended for injection. (S1)
Isosorbide, but not in cases of emergency. (S1)

Isoxicam.
Isoxsurprine.
Isradipine.
Itraconazole.
Ivermectin, except if intended and registered as an anthelmintic and or ectoparasiticide in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Ketanserin.
Ketoconazole, if not intended for application to the skin and if not preparations and mixtures containing not more than 1.0 per cent of ketoconazole if intended for the prevention and treatment of dandruff. (S1)
Ketoprofen, if not - (a) intended for application to the skin (S1); (b) intended for the short-term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains asspociated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours. (S1); (c) intended for the emergency treatment of acute gout attacks and if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 75 milligrams, for a maximum period of 5 days. (S1)
Ketorolac trometamol, including preparations intended for ophthalmic use.
L-Asparaginase.
L-tryptophan, if intended for medicinal use, but not if intended for medicinal use as supplementation for nutritional purposes. (S1)
Labetalol.
Lacidipine.
Lamivudine.
Lamotrigine.
Lansoprazole, except if intended for the temporary short-term relief of heartburn and hyperacidity, subject to - (a) a maximum daily dose of 15 mg; (b) a maximum treatment period of 14 days.(S1)
Latanoprost.
Leflunomide.
Lercanidipine.
Letrozole.
Levetiracetam.
Levallorphan.
Levamisole, except if intended and registered as an anthelmintic and an immunomodulator in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Levobunolol.
Levobupivacaine.
Levosemindan.
Liarozole.
Lidoflazine.
Lisinopril.

Local anaesthetics, if intended for ophthalmic and parenteral use, but not oxybuprocaine, proxymetacaine and tetracaine, if contained in eye drops intended for emergency treatment of arc eyes, and not lignocaine if contained in antimicrobial preparations for injection as well as in ophthalmic preparations registered for veterinary use. (S1)
Lomustine.
Lonazolac.
Lopinavir.
Lornoxicam.
Losartan.
Loxapine.
Lovastatin.
Lumefantrine.
Lysozyme, preparations and mixtures thereof not intended for application to the skin. (S1)
Mecamylamine.
Meclofenamic acid.
Mefenamic acid, if not intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days, but not preparations containing mefenamic acid as the only therapeutically active substance if intended for the treatment of primary dysmenorrhoea, if the maximum daily dose is 500 milligrams of mefenamic acid 3 times a day and the maximum treatment period is 3 days. (S1)
Mefloquine.
Melarsoprol
Melitracene.
Meloxicam.
Melphalan, and its derivatives, unless listed in another Schedule.
Mephentermine.
Mepindolol.
Mepirizole.
2-mercaptopurine glycine.
6-mercaptopurine, and its derivatives, unless listed in another Schedule.
Mercury, preparations and mixtures that contain mercury metal and that are intended for medicinal use.
Mesalazine (5-aminosalicylic acid).
Mesna, if intended for injection. (S1)
Mesulphene.
Metaproterenol (orciprenaline), if contained in respirator solutions and if intended for injection or for the prevention or delay of labour. (S1)
Metergoline.
Methacholine.
Metformin.
Methampyrone.
Methazolamide.

Methimazole.
Methotrexate.
Methoxsalen.
Methsuximide.
Methyldopa and its esters.
Methysergide.
Metipranolol.
Metoclopramide.
Metolazone.
Metomidate.
Metoprolol.
Metronidazole.
Mexiletine.
Mibefradil.
Miconazole, if not intended for application to the skin, if not intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis and if not intended for human use in preparations containing 2% or less of miconazole, if intended for the topical treatment of fungal infections of the mouth (oral candidiasis). (S1)
Mifepristone.
Miglitol.
Milrinone.
Miltefosine.
Minoxidil, if not intended for application to the scalp. (S1)
Misoprostol.
Mitomycin C.
Mitoxantrone.
Mivacurium.
Mizolastine.
Moexipril
Mofebutazone.
Molgramostim.
Mometasone.
Montelukast.
Moracizine.
Morazone.
Morphazinamide.
Morphethylbutyne.
Moxonidine.

Mucoglucuronan.
Muromonab.
Mycophenolic acid.
Nabumetone, if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1)
Nadolol.
Naftidrofuryl.
Nalidixic acid.
Nalorphine.
Naloxone.
Naltrexone.
Naproxen, except - (a) if intended for application to the skin. (S1); (b) the Sodium salt if intended for short-term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 600 milligrams naproxen (660milligrams naproxen sodium) in 24 hours (S1); and (c) if intended for emergency treatment of acute gout attacks, and if not intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1)
Naratriptan.
Nateglinide.
Nebivolol.
Nefopam.
Nelfinavir.
Neostigmine.
Netobimin.
Nevirapine.
Nicarbizin, except if intended and registered as an anticoccidial preparation in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Nicardipine.
Nifedipine.
Niflumic acid.
Nifuratel.
Nikethamide.
Nilutamide.
Nimesulide.
Nimodipine.
Nimorazole.
Nimustine.
Niridazole.
Nisoldipine.

Nitrendipine.
Nitrofurantoin, preparations thereof not intended for application to the skin. (S1)
Nitrofurazone, preparations thereof not intended for applications to the skin. (S1)
Nitroglycerine, if intended for medicinal use but not in cases of emergency. (S1)
Nitrous Oxide Gas, alone or in combination with other gases.
Nitroxoline.
Nitroxynil, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Nizatidine; except if intended for oral administration for short-term symptomatic relief of heartburn and hyperacidity, if the maximum dose is 150 milligrams, the maximum daily dose is 300 milligrams and the treatment period is two weeks.(S1)
Obidoxime.
Octreotide.
Olsalazine.
Omeprazole.
Ondansetron.
Oprelvekin.
Orlistat.
Ornidazole, if not intended for application to the skin. (S1)
Oseltamivir.
Oxamniquine.
Oxaprozin.
Oxcarbazepine.
Oxfendazole, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Oxiracetam.
Oxolinic acid.
Oxovinca.
Oxprenolol.
Oxybuprocaine, except if contained in eye drops intended for emergency treatment of arc eyes (S1)
Oxybutynin.
Oxyclosanide, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Paclitaxel.
Palivizumab.
Paltitrexid.
Pamidronic acid.
Pancuronium.
Pantoprazole.

Parecoxib.
Paricalcitrol
Penbutolol.
Penciclovir, except if intended for application to the lips in the early treatment of recurrent Herpes simplex virus. (S1)
Penicillamine.
Penicillinase, including preparations intended for injection.
Pentaerythritol tetranitrate, but not in cases of emergency. (S1)
Pentamidine isethionate.
Pentolinium.
Pentosan polysulfate if intended for the treatment of intersititial cystitis.
Pentostatin.
Pergolide.
Perhexiline.
Perindopril.
Phenacetin, but not preparations and mixtures intended for external use and containing not more than 0,1% phenacetin as stabiliser.
Phenamidine, except if intended and registered as a babesiacide in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Phenformin.
Phenobarbital, preparations and mixtures containing not more than 90 milligrams of Phenobarbital per minimum recommended or prescribed dose if intended for continued use in epilepsy (S3)
Phenopyrazone.
Phenoxybenzamine.
Phenoxymethylpenicillin, if intended for the prophylaxis of rheumatic fever. (S2)
Phentolamine.
Phenylephrine, ophthalmic preparations containing more than 0,2 per cent of phenylephrine.
Phenylbutazone and its dertivatives
Phenytoin.
Physostigmine
Picrotoxin.
Pilocarpine
Pimecrolimus.
Pindolol.
Pioglitazone.
Pipemidic acid.
Piracetam.
Pirbuterol, if contained in respirator solutions. (S1)
Pirenzepine.

Piretanide.
Piribedil.
Piromidic acid.
Piroxicam, if not intended for the emergency treatment of acute gout attacks and if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1)
Pirprofen.
Podophyllum resin, preparations and mixtures containing more than 20% thereof. (S1)
Polyglycerylene-dextran.
Poractant alpha.
Potassium canrenoate.
Potassium dichromate, but not preparations and mixtures containing not more than 15 micrograms of potassium dichromate per dosage unit.
Practolol.
Pralidoxime.
Pramipexole.
Pravastatin.
Praziquantel, except if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Prazosin.
Primidone.
Probenecid.
Probucol.
Procainamide.
Procarbazine.
Procaterol, if contained in respirator solutions. (S1)
Proctofene.
Propacetamol.
Propafenone.
Propentofylline, except ifntended for veterinary use (S1)
Propiverine.
Propylhexedrine, if not used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S1)
Propranolol.
Proquazone.
Proscillaridine.
Proteolytic (fibrinolytic) enzymes, if intended for injection. (S1)
Prothionamide, including preparations intended for oral use.
Proxymetacaine, except if contained in eye drops intended for emergency treatment of arc eyes (S1)
Pygeum africanum (lipido-sterolic complex extract thereof).

Pyrazinamide, including preparations intended for oral use.
Pyridinolcarbamate.
Pyridostigmine.
Pyrimethamine.
Pyrithioxin.
Quinapril.
Quinoronium sulphate, except if intended and registered as a babesiacide in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Rabeprazole.
Racecadotril.
Ractopamine, including if used as a veterinary production improver.
Radio-active compounds, if used for diagnostic purposes.
Rafoxanide, except if intended and registered as an anthelmintic for sheep and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Raloxifene.
Ramipril.
Ranitidine, except if administered orally for short-term relief of symptoms of heartburn and hyperacidity, if the maximum dose is 75 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S1).
Rapacuronium.
Rasburicase.
Raubasine.
Rauwolfia alkaloids.
Recombinant human tissue-type plasminogen activator (re-PA).
Repaglinide.
Reproterol, if contained in respirator solutions. (S1)
Reserpine (natural or synthetic).
Resorantel. except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Riluzole.
Rimiterol, if contained in respirator solutions and if intended for injection. (S1)
Risedronate
Ritodrine.
Ritonavir.
Rituximab.
Rizatriptan.
Rocuronium bromide.
Rofecoxib.
Ropinirole.

Rosiglitazone.
Rosoxacin.
Rosuvastatin.
Roxarzone (3-nitro-4-hydroxyphenylarsonic acid), including if intended for veterinary use.
Roxatidine.
Salbutamol, if contained in respirator solutions and if intended for injection. (S1)
Salmefamol, if contained in respirator solutions and if intended for injection (S1)
Saquinavir.
Selegiline.
Selenium salts, including preparations thereof for injection, if intended for veterinary use.
Sermorelin.
Sertaconazole, except if intended for application to the skin. (S1)
Sertindole.
Sildenafil.
Simvastatin.
Sirolimus.
Sodium aurothiomalate.
Sodium cromoglycate, if not intended for veterinary use. (S1)
Sodium dihydroazapentacene polysulphonate.
Sodium fluoride, except oral medicinal preparations and mixtures thereof containing 40 milligrams or more per daily dose.(S1)
Sodium nitroprusside.
Solcoseryl, ophthalmic preparations, except preparations thereof intended for application to the skin, to the mucous membranes of the mouth and to the lips. (S1)
Sotalol.
Spirapril.
Spironolactone.
Stavudine.
Streptokinase.
Strophanthus, its glycosides and their hydrolysis products and their derivatives, unless listed in another Schedule.
Strychnine, subject thereto that for the control of problem predatory mammals - (a) it shall be supplied on a written prescription issued by a state veterinarian for use in the particular area where the veterinarian has jurisdiction in a quantity not exceeding 5 grams; and (b) the state veterinarian must obtain prior written approval for such use from the Minister responsible for environment and wildlife, a copy of which shall be attached to the written prescription, but not preparations and mixtures containing 0.2 per cent thereof. (S1)
Styramate.
Sulindac.
Suloctidil.
Sulphinpyrazone.

Sulphonamides, except - (a) substances, preparations and mixtures intended for application to the eyes, nares and vagina (S1); (b) silver sulphadiazine if intended for application to the skin in the short-term treatment of minor burns, provided that the pack size in limited to a maximum of 50 grams; (S1); (c) if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Sulthiame.
Sumatriptan.
Suprofen.
Suramin.
Suxamethonium.
Suxethonium.
Sylimarin.
Tacrine
Tacrolimus.
Tadalafil.
Tamoxifen.
Tasosartan.
Tamsulosin.
Tasonermin.
Tazarotene.
Tegafur.
Tegaserod.
Telmisartan.
Temozolomide.
Tenecteplase.
Tenidap.
Teniposide.
Tenoxicam.
Terazosin.
Terbinafine, if not intended for application to the skin. (S1)
Terbutaline, if contained in respirator solutions. (S1)
Terfenadine,
Terconazole.
Teriparatide.
Terizidone.
Terodiline.
Tetramisole, except if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Theophylline and its derivatives, unless listed in another Schedule, preparations intended for injection. (S1)

Thiabendazole, if not intended for application to the skin. (S1) and except if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947 (Act No 36 of 1947).
Thiacetazone.
Thioguanine.
Thymopentin.
Thyroid gland and its active principles and derivatives, unless listed in another Schedule.
Tiagabine
Tiaprofenic acid, if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1)
Tibolone.
Ticlopidine.
Tiludronic acid.
Timolol.
Tin fluoride, including preparations intended for injection.
Tinidazole.
Tioconazole, if not intended for application to the skin and not intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)
Tirilazad.
Tocainide.
Tolamolol.
Tolazamide.
Tolbutamide.
Tolcapone.
Tolfenamic acid.
Tolmetin, if not intended for application to the skin. (S1)
Tolrestat.
Tolterodine.
Toltrazuril, except if intended and registered as an anticoccidial preparation for poultry in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Topiramate.
Topotecan.
Torasemide.
Toremifene.
Trandolapril.
Tranexamic acid.
Trastuzumab.
Travoprost.
Treosulfan.
Tretinoin.

Triamterene.
Tricaine.
Triclabendazole, except if intended and registered as an anthelmintic for sheep, goats and cattle in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Triethylene thiophosphoramide.
Trifluorothymidine.
Trimetaphane.
Trimethadione.
Trimethoprim, except if specifically intended and registered in terms of the Act for the treatment of gastro enteritis and pneumonia in animals.
Trimetrexate.
Trioxsalen.
Triptorelin.
Tromantadine.
Trometamol.
Tropicamide.
Tropisetron.
Tuberculin, if intended for veterinary use. (S1)
Tubocurarine.
Tulobuterol, if contained in respirator solutions. (S1)
Unoprostone.
Urapidil.
Urethane.
Urokinase.
Ursodeoxycholic acid.
Vaccines for veterinary use.
Valaciclovir.
Valdecoxib,
Valproic acid and its derivatives, unless listed in another Schedule.
Valsartan.
Vanillic acid diethylamide.
Vardenafil.
Vasoactive intestinal polypeptide.
Vecuronium bromide.
Vedaprofen.
Verteporfin.
Verapamil (iproveratril).
Veratrum alkaloids.

Vidarabine.
Vigabatrin.
Vinblastine.
Vincamine.
Vincristine.
Vindesine.
Vinorelbine
Vinpocetine.
Vitamin A, preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 I.U. per recommended daily dose, except if registered in terms of the Act for veterinary use.
Vitamin D, preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 I.U. per recommended daily dose, except if registered in terms of the Act for veterinary use.
Voriconazole.
Vorozole.
Xamoterol.
Xipamide.
Zafirlukast.
Zalcitabine.
Zanamivir.
Zidovudine. (AZT).
Zinc salts, for oral ingestion if the daily dose is more than 50 milligrams of elemental zinc, except if registered in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Zolmitriptan.
Zoledronic acid.
Zomepirac.

SCHEDULE 3

Acitretin.
Amisulpride.
Amitryptyline and its derivatives, unless listed in another Schedule.
Amoxapine.
Anaesthetic preparations containing pregnanedione derivatives.
Androstanolone.
Androstenediol.
Aponal.
Apronalide.
Azacyclonol.
Barbituric acid and its derivatives, unless listed in another Schedule, but not amobarbital, cyclobarbital, pentobarbital and Secobarbital (S4) and not preparations and mixtures containing more than 90 milligrams of phenobarbital per minimum recommended or prescribed dose if intended for continued use in epilepsy. (S2,)

Benactyzine and its derivatives, unless listed in another Schedule.
Benfluramate.
Benzoctamine.
Benzodiazepines and their derivatives, unless listed in another Schedule and except flunitrazepam. (S4).
Benzquinamide.
Beta-aminopropylbenzene and beta-aminoisopropylbenzene, any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both substitution and ring closure), and any salt or substances falling under the above, but not preparations and mixtures of the above if used as vasoconstrictors and decongestants in antihistamine nose and eye preparation and not if contained in appliances for inhalant in which the substance is absorbed in solid material and excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedine, phenylpropanolamine, prenylamine and preparations and mixtures thereof, but not substances listed in Schedule 5. (S1)
Bolandiol.
Bolasterone.
Boldenone.
Bromides, preparations and mixtures thereof containing 80 milligrams or more of bromine as bromide per recommended daily dose, but not if specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectant Act, 1972. (S1)
Bromisovalum.
Brotizolam.
Bupropion.
Buspirone.
Butriptyline.
Butyrophenones.
Carbromal.
Chloral derivatives, unless listed in another Schedule.
Chloroform, preparations and mixtures containing more than 20 per cent of chloroform. (S1)
Chlormezanone, except mixtures thereof if the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone.(S1)
Chlorprothixene.
Citalopram.
Clomacran.
Clomethiazole (previously listed as ‘heminevrin’).
Clomipramine.
Clopenthixol.
Clostebol.
Clothiapine.
Clozapine.
Corticotrophin (Adrenocortocotrophic hormone: ACTH).
Cyclobenzaprine.

Danazol.
Deanol and its derivatives, unless listed in another Schedule, but not if specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 172.
Dehydrochloromethyltestosterone.
Desflurane.
Detomidine.
Dexfenfluramine.
Dexmedetomidine.
Dextropropoxyphene, preparations and mixtures for oral use containing not more than 135 milligrams of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5% in undivided preparations. (S4)
Diprenorphine.
Donepezil.
Dothiepin.
Doxepin, except if intended for application to the skin. (S2)
Droperidol.
Drostanolone.
Ecothiopate.
Emylcamate.
Enflurane.
Ephedrine (natural or synthetic) except if contained in products registered in terms of the Act. (S1)
Epitiostanol.
Escitalopram.
Ethchorvynol.
Ether(diethyl ether); except substances, preparations and mixtures containing more than 20 per cent of ether.(S1)
Ethinamate and its derivatives, unless listed in another Schedule.
Ethylestrenol.
Etodroxizine, but not preparations and mixtures thereof if used solely as an antihistamine. (S1)
Etomidate.
Etretinate.
Fencamfamine.
Fenfluramine.
Flumazenil.
Fluoxetine.
Fluoxymesterone.
Flupenthixol.

Fluspirilene.
Fluvoxamine.
Formebolone.
Furazabol.
Haloperidol.
Halothane.
Hedonal and its esters, but not if specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 .
Human growth hormone (all forms of human somatotropin).
Hydroxyzine.
Imipramine, and its derivatives, unless listed in another Schedule.
Iproniazid.
Isoflurane.
Isotretinion.
Ketamine.
Lithium salts, if intended for medicinal use, except if intended for application to the skin. (S1)
Lofepramine.
Loxapine.
Maprotiline.
Mazindol.
Mebolazine.
Mechlorethamine, and its derivatives, unless listed in another Schedule.
Meclofenoxate.
Medetomidine.
Melitracene.
Mephenoxalone.
Meprobamate.
Mesterolone.
Metandienone.
Metenolone.
Methandranone.
Methandriol.
Methoxyflurane.
Methyltestosterone.
Metrifonate.
Mianserin.

Mibolerone.
Milnacipran.
Mirtazapine.
Moclobemide.
Molindone.
Nalbuphine.
Nandrolone.
Nefazodone.
Nomifensine.
Norclostebol.
Norethandrolone.
Olanzapine.
Oxabolone.
Oxandrolone.
Oxymesterone.
Oxymetholone.
Oxypertine.
Paraldehyde.
Pargyline.
Paroxetine.
Pemoline, and its complexes.
Phenethylhydrazine.
Phenothiazine and its derivatives, unless listed in another Schedule, except preparations and mixtures containing promethazine or dimethothiazine or their salts if used solely as an antihistamine (S1) and except preparations containing promethazine or its salts if intended specifically for the treatment of travel sickness or application to the skin (S1), and except phenothiazine if intended and registered as an anthelmintic in terms of the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.
Phentermine.
Pimethixene, except preparations and mixtures thereof of used solely as an antihistamine. (S1)
Pimozide.
Piperazine (BZP)
Pipradrol.
Pizotifen, except preparations and mixtures thereof if used solely as an antihistamine or if intended for the prophylaxis of migraine. (S1)
Prasterone (Dehydroepiandrosterone, DHEA).
Prolintane.
Propofol.
Quetiapine.
Quinbolone.

Quinupramine.
Reboxetine.
Risperidone.
Rivastigmine.
Romifidine.
Sertraline.
Sevoflurane.
Sibutramine.
Stanozolol.
Stenbolone.
Sulphonmethane.
Sulpiride.
Testolactone.
Testosterone, except subcutaneous implants thereof if specifically intended and registered as veterinary production improver.
Thioguanosine.
Thiothixene.
Tiapride.
Tiletamine.
Tizanidine.
Tramadol.
Tranylcypromine.
Trazodone.
Trenbolone. except subcutaneous implants thereof if specifically intended and registered as a veterinary production improver
Trihexyphenidyl.
L-tryptophan, if intended for medicinal use, except if intended for medicinal use as supplementation for nutritional purposes (S1)
Venlafaxine.
Viloxazine.
Xylazine.
Zaleplon.
Zimelidine.
Ziprasidone.
Zolazepam.
Zolpidem.
Zopiclone.
Zotepine.
Zuclopenthixol.

SCHEDULE 4

Acetorphine.
Acetyldihydrocodeine, but not preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and not liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrochodeine (calculated as base) per 5 millilitre dosage unit. (S1)
Acetylmethadol.
Alfentanil.
Allylprodine.
Alphacetylmethadol.
Alphameprodine.
Alphamethadol.
Alphaprodine.
Amobarbital.
Anileridine.
Benzethidine.
Benzphetamine.
Benzylmorphine.
Betacetylmethadol.
Betameprodine.
Betamethadol.
Betaprodine.
Bezitramide.
Buprenorphine.
Butalbital
Butorphanol
Cathine ((+)-norpseudoephedrine), preparations and mixtures containing more than 50 milligrams of cathine per dosage unit. (S1)
Chlorodyne (Chloroform and morphine Tincture BP1980) or any preparation or mixture thereof described as chlorodyne, except preparations and mixtures containing 5 per cent or less of chlorodyne in combination with other active medicinal substances. (S1)
Chlorphentermine.
Clonitazene.
Coca leaf and any salt, compound derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, but not decocainised coca leaf and extractions of coca leaf if such extractions contain no cocaine or ecgonine.
Codeine (methylmorphine), except preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit.(S1).
Codoxime.
Cyclobarbital.

Desomorphine.
Dextromoramide.
Dextropropoxyphene, but not preparations and mixtures for oral use containing not more than 135 milligrams of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2.5 per cent in undivided preparations. (S3)
Diampromide.
Diethylpropion (amfepramone).
Diethylthiambutene.
Difenoxin (or diphenoxylic acid), except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to more than 5,0per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S1)
Dihydrocodeine, except preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and except liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millitre dosage unit. (S1)
Dihydroetorphine.
Dihydromorphine.
Dimenoxadol.
Dimepheptanol.
Dimethylthiambutene.
Dioxaphethyl butyrate.
Diphenoxylate, but not preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base and not less than 25 micrograms of atropine sulphate per dosage unit. (S1)
Dipipanone.
Dronabinol [(-)-transdelta-9-tetrahydrocannabinol], if intended for therapeutic purposes. (S5)
Drotebanol.
Ecgonine, and the esters and derivatives thereof that are convertible to ecgonine or cocaine.
Ethylmethylthiambutene.
Ethylmorphine, except preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S1)
Etonitazene.
Etorphine and analogues.
Etoxeridine.
Fenproporex.
Fentanyl if intended for therapeutic purposes. (S5)
Flunitrazepam.
Furethidine.
Glutethimide.
Hydrocodone(dihydrocodeinone).
Hydromorphinol (14-hydroxydihydromorphine).
Hydromorphone (dihydromorphinone).

Hydroxypethidine.
Isomethadone.
Ketobemidone.
Levomoramide.
Levophenacylmorphan.
Levorphanol.
Mecloqualone.
Mefenorex.
Meptazinol.
Metazocine.
Methadone-intermediate.
Methadone.
Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan. (S1)
Methyldesorphine.
Methyldihydromorphine.
Methylphenidate and its derivatives, unless listed in another Schedule.
Metopon.
Moramide-intermediate.
Morpheridine.
Morphine methobromide and other pentavalent nitrogen morphine derivatives.
Morphine, preparations and mixtures of morphine containing more than 0,2% of morphine, calculated as anhydrous morphine. (S1)
Morphine-N-oxide and its derivatives.
Myrophine (myristylbenzylmorphine).
Nicocodine.
Nicodicodine.
Nicomorphine.
Noracymethadol.
Norcodeine, except preparations and mixtures if compounded with one or more therapeutical active substances and containing 20 milligrams or less of of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S1)
Norlevorphanol.
Normethadone.
Normorphine (demethylmorphine or N-demethylated morphine).
Norpipanone.
Opium and opiates and any salt, compound, derivative or preparation of opium or opiates whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, but not mixtures containing 0,2% or less of morphine, calculated as anhydrous morphine. (S1)

Opium-poppy and poppy straw, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or whether obtained independently by chemical synthesis or by a combination of extraction and chemical synthesis.
Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).
Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).
Pentazocine.
Pentobarbital.
Pethidine, pethidine-intermediate A, pethidine-intermediate B, and pethidine-intermediate C. (S5)
Phenadoxone.
Phenampromide.
Phenazocine.
Phendimetrazine.
Phenomorphan.
Phenoperidine.
Pholcodine, except preparations and mixtures if compounded with one or more therapeutically active substances containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit.(S1).
Piminodine.
Piritramide.
Proheptazine.
Properidine.
Propiram.
Racemoramide.
Racemorphan.
Remifentanil.
Secobarbital.
Sufentanil.
Thebacon.
Thebaine.
Tilidine.
Trimeperidine.
Zipeprol.

SCHEDULE 5

(±)-2,5 –dimethoxy-α-methylphenethylamine (DMA).
(±)-3,4,5,-trimethoxy-α-methylphenethylamine (TMA).
(±)-4-ethyl-2,5-dimethoxy-α-phenethylamine (DOET).
(±)-N,α-dimethyl-3,4-(methylenedioxy) phenethylamine (MDMA).
(±)-N-(α-methyl-3,4-(methylenedioxy) phenethyl) hydroxylamine (N-hydroxy MDA).
(±)-N-ethyl-α-methyl-3,4-(methylenedioxy)phenethylamine (N-ethyl MDA):
2-methoxy-α-methyl-4,5-(methylenedioxy)phenethylamine (MMDA).
3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo [b,d] pyran-1-ol (DMHP).
3-hexyl-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-o1(parahexyl).
4-bromo-2,5-dimethoxyphenethylamine (2C-B), (Nexus).
4-methyl-2,5-dimethoxyamphetamine (DOM) and its derivatives.
4-methylaminorex.
Amphetamine and its salts, preparations thereof.
Brolamfetamine ((±)-4-bromo-2,5-dimethyoxy-a—methylphenethylamine).
Bufotenine (N,N-dimethylserotonin).
Cannabis (dagga), the whole plant or any portion or product thereof, but not - (a) if separately specified in the Schedules; (b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre, provided that the product does not contain whole cannabis seeds and in a form not suitable for ingestion, smoking or inhaling purposes; or (c) processed product made from cannabis seeds containing not more than 10mg/kg (0.001 per cent) of tetrahydrocannabinol and does not contain whole cannabis seeds; (d) dronabinol [(-)-transdelta-9-tetrahydrocannabinol], if intended for therapeutic purposes. (S4)
Cathinone ((-)-(S)-2-aminopropiophenone.
Dexamphetamine and its salts; preparations thereof.
Diethyltryptamine [3-(2-(diethylamino)-ethyl)-indole].
Dimethyltryptamine [3-(2-(dimethylamino)-ethyl)-indole].
Etilamfetamine (N-ethylamphetamine).
Etryptamine.
Fenetylline.
Fentanyl-analogues (unless listed in another Schedule), including - (a) acetyl-alpha-methyl-fentanyl; (b) alpha-methyl-fentanyl; (c) alpha-methyl-fentanyl-acetanilide; (d) alpha-methyl-thio-fentanyl; (e) benzyl-fentanyl; (f) beta-hydroxy-fentanyl; (g) beta-hydroxy-3-methyl-fentanyl; (h) 3 methylthiofentanyl; (i) 3-methyl-fentanyl and its two isomeric forms: (j) cis-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide; (k) trans-N-(3-methyl-1-(2-phenethyl)-4-piperidyl)propionanilide; (l) para-fluoro-fentanyl; and (m) thiofentanyl (S4).
Gamma-hydroxybutyrate (GHB).
Harmaline (3,4-dihydroharmine).

Harmine (7-methoxy-1-methyl-9H-pyrido (3,4-b)-indole).
Heroin (diacetylmorphine).
Lefetamine (SPA).
Lysergide (Lysergic acid diethylamide).
Mescaline (3,4,5-trimethoxyphenethylamine).
Mesocarb.
Methamphetamine and methamphetamine racemate.
Methaqualone and any preparation containing methaqualone.
Methcathinone.
Methyprylon.
Nabilone.
ρ-methoxy-α-methylphenethylamine (PMA).
Pethidine-analogues, including - (a) 1-methyl-4-phenyl-4 propionoxy-piperidine (MPPP); (b) 1-methyl-4-phenyl-1,2,5,6-tetrahydropiperidine (MPTP); and (c) 1-phenylethyl-4-phenyl-4-acetyloxy-piperidine (PEPAP).
Phencyclidine and its congeners, including - (a) Eticyclidine (N-ethyl-1-phenylcyclohexylamine (PCE); (b) Rolycyclidine (1-1-phenylcyclohexyl) pyrrolidine (PHP or PCPY)); and (c) Tenocyclidine (1-(1-(2-thienyl) cyclohexyl) piperidine (TCP).
Phenmetrazine.
Psilocin (4-hydroxy-NN-dimethyltryptamine).
Psilocybine (4—phosphoryloxy-NN-dimethyltryptamine).
Pyrovalerone (4-methyl-2-(1-pyrrolidinyl) valerophenone).
Tenamfetamine (methylenedioxyamphetamine (MDA)) and its analogues:
Tetrahydrocannabinol, but not - (a) dronabinol, if intended for therapeutic purposes (S4); (b) in hemp seed oil containing 10mg/kg or less or tetrahydrocannabinols, if labelled “Not to be taken”; or (c) in products for purposes other than internal human use containing 10mg/kg or less of tetrahydrocannabinols.