GOVERNMENT GAZETTE

OF THE

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 240 2004

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965:
REGISTRATION OF CERTAIN MEDICINES

In terms of section 17 of the Medicines and Related Subtances Control Act, 1965 (Act No. 101 of 1965), the registrar gives notice that the medicines set out in the Schedule have been registered in terms of that Act.

SCHEDULE

Registration Number	Name of Medicine	Form of Preparation	Active Component(s)	Quantity	Applicant
04/5.7.1/1709	Xyzal	Tablets	Cetirizine Dihydrochloride	5,0mg/ Tablet	Nampharm (Pty) Ltd, Windhoek Namibia
04/5.7.1/0453	Verlix	Tablets	Cetirizine Dihydrochloride	10,0mg/ Tablet	Nampharm (Pty) Ltd, Windhoek Namibia
04/5.7.1/0451	Verlix	Oral Drops	Cetirizine Dihydrochloride	10,0mg/ml	Nampharm (Pty) Ltd, Windhoek Namibia
04/5.7.1/0452	Verlix	Oral Solution	Cetirizine Dihydrochloride	1,0mg/ml	Nampharm (Pty) Ltd, Windhoek Namibia

04/2.5/1714	Keppra	Tablets	Levetiracetam	1000,0mg/ Tablet	Nampharm (Pty) Ltd, Windhoek Namibia
04/2.5/1713	Keppra	Tablets	Levetiracetam	500,0mg/ Tablet	Nampharm (Pty) Ltd, Windhoek Namibia
04/2.5/1712	Keppra	Tablets	Levetiracetam	250,0mg/ Tablet	Nampharm (Pty) Ltd, Windhoek Namibia
04/20.2.8/ 0230	Norvir Sec	Capsules	Ritonavir	100,0mg	Abbott Laboratories South Africa (Pty) Ltd
04/20.2.8/ 0231	Norvir	Solution	Ritonavir	80,0mg	Abbott Laboratories South Africa (Pty) Ltd
04/16.4/0943	Zofran Zydis	Tablets	Ondansentron	8.0mg	GlaxoSmith-Kline (S.A.)(Pty) Ltd, H/House, Midrand
04/16.4/0942	Zofran Zydis	Tablets	Ondansentron	4,0mg	GlaxoSmith-Kline (S.A.)(Pty) Ltd, H/House, Midrand
04/15.4/1152	Boxinate	Eye Drops	Benoxinate Hydrochloride	2%	Drug Holding Company, Cairo Egypt
04/15.4/1151	Ocucarpine	Eye Drops	Pilocarpine Hydrochloride	2%	Drug Holding Company, Cairo Egypt
04/3.3/1149	Colmediten	Tablets	Colchicine	0.5mg	Drug Holding Company, Cairo Egypt
04/15.4/1145	Cidamex	Tablets	Acetazolamide	250.0mg	Drug Holding Company, Cairo Egypt
04/21.3/1146	Carbimazole	Tablets	Carbimazole	4,0mg	Drug Holding Company, Cairo Egypt
04/15.1/1150	Ocuphenicol	Eye Drops	Chloramphenicol	0,5%	Drug Holding Company, Cairo Egypt
04/20.1.7/ 1147	Ultragriseo fulvin	Tablets	Griseofulvin	125,0mg	Drug Holding Company, Cairo Egypt
04/5.7/1148	Anallerge-4	Tablets	Chlorpheniramine	4,0mg	Drug Holding Company, Cairo Egypt

Note:

The above medicines are registered subject to the following conditions:

(a) the manufacture of medicine and the control of medicine must be done in accordance with current good manufacturing practices as required by the World Health Organisation;

(b) in order to assess compliance with paragraph (a), investigations and inspections may be carried out by inspectors at such reasonable times as the council may consider necessary;

(c) every manufacturer of medicine must, with the approval of the council, ensure that the information contained in the medicine package insert is regularly updated and varied so as to provide accurate information to the user of the medicine;

(d) the provisions of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), apply to every manufacturer of medicine;

(e) the quality, safety and therapeutic efficacy of the registered medicine will be reviewed on a regular basis;

(f) the first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration;

(g) a validation report must be submitted within one month from the date of completion of the validation process referred to in paragraph (f);

(h) the council may review the registration dossier at such intervals as may be determined by the council; and

(i) the council may, as it considers necessary, vary the conditions of registration.

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 241 2004

PROPOSED REGULATIONS RELATING TO
MEDICINES AND RELATED SUBSTANCES

In terms of section 44(2) of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), the Minister of Health and Social Services hereby -

(a) publishes the text of the proposed regulations relating to medicines and related substances as set out in the Schedule;

(b) declares the intention to make the regulations contemplated in paragraph (a); and

(c) invites any interested person who wishes to make any comments on those proposed regulations or who wishes to make any representations with regard to those proposed regulations to furnish, in writing, any comments or representations that such person wishes to make on or with regard to those proposed regulations to that Minister at: The Ministry of Health and Social Services, Ground Floor, Room GW 5, Harvey Street, Windhoek or Private Bag 13198, Windhoek, not later than 15 February 2005.

SCHEDULE

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Definitions

1. In these regulations, unless the context otherwise indicates, any word or expression to which a meaning has been assigned in the Act has 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, biodiversity 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 the 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 Professions Act, 1993 (Act No. 30 of 1993);

"scheduling status", in relation to a medicine, means the status of the medicine concerned according to the Schedule that it is classified 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 for the same purpose referred to therein on the basis of their principal pharmacological purpose or therapeutic effect, further subdivided into the pharmacological classes set out in Annexure I.

(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 products 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) Applicants referred to in subregulation (1)(b) and (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 applicants referred to in subregulation (1)(b) and (d) and (d), the Council may make such investigations or cause such investigations to be made, as it deems necessary to establish any fact contemplated in subregulation (2).

(4) Every applicant referred to in subregulation (1) must mention in the application 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 communication with the Council.

(5) Every applicant referred to in subregulation (1) who is not resident in Namibia must appoint a local representative (who 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 authorisation 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 of the medicine concerned.

Application form and other requirements in respect of application for registration of a medicine

4. Subject to regulation 5, every application for the registration of a medicine must be submitted to the Registrar in the form set out in Annexure II, 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

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

(a) three samples of the final product 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 product 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 every 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 of Annexure III;

(b) veterinary medicines register relating to veterinary medicines must be kept in the form of Annexure IV;

(c) complementary medicines register relating to complementary medicines must be kept in the form of Annexure V,

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 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 deems necessary to establish whether or not the amendment concerned should be approved.

(3) No amendment contemplated in this regulation may 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 set out in Annexure VII.

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 set out in Annexure VIII 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 on which the following particulars pertaining to the contents of such package must appear in clearly legible indelible letters in the official language, namely -

(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;

(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; and

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

(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 (a), (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), (m), (n) and (o) of subregulation (1), repeated as frequently as is practicable.

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

(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 licensed 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; or

(c) any medicine sold by a pharmacist or by a hospital 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 name of the patient;

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

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

(v) the dispensing date; and

(vi) 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, 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, 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) 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)";

(w) 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;

(x) the date of publication of the package insert;

but the Council may, on application to it by an applicant, authorise -

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

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

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

(2) Subject to subregulation (3), 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 by a pharmacist or by a hospital in accordance with a prescription issued by a medical practitioner or dentist or veterinarian for the treatment of a particular patient.

(3) Nothing contained in subregulation (2) 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 with other medicines or food that the patient may take;

(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, e.g. bottle, blister pack etc.;

(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 authorise a deviation from subregulation (1) if it deems fit.

(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) 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 only the following particulars pertaining to the contents of such package must appear in clearly legible indelible lettering in the official language, namely -

(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 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.

(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 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), (b), 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), (m), (n) and (o) of subregulation (1) repeated as frequently as is practicable.

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

(i) the name of the medicine or the name of each active ingredient or constituent medicine unless the relevant prescription issued by the veterinarian concerned has been clearly marked with the words "*non nomen propium*";

(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 use of the medicine;

(iv) the name of 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 25(1)(f), 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, 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 authorise 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 substance appearing in Schedule 1,

may be advertised to the public.

(2) Medicines which contain a substance appearing in Schedule 2, Schedule 3 or Schedule 4 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) A written advertisement for 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) Any advertisement to the public which advertises a medicine must be approved by the Council.

Informing Council of adverse reaction

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 set out in Annexure IX of any adverse reaction which occur during the use of any medicine.

Notice of particulars of applications received for registration of medicine

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 a 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 of 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 medicine or scheduled substance concerned wants to carry out a parallel analysis the sample must include the extra quantity required thereof;

(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 the taking of 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 any witness.

(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 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 scheduled substances

21. (1) An inspector may seize any 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 scheduled substance concerned -

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

(ii) is suspected to be a counterfeit;

(iii) is misbranded;

(iv) has expired;

(v) is suspected 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 scheduled substance concerned be made available to the public.

(2) An inspector who has seized any scheduled substance as contemplated in subregulation (1) must as soon as possible and at the scene of seizure make a written inventory of all 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 scheduled substances concerned were seized;

(c) the name and quantity of every 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 any scheduled substance as contemplated in subregulation (1) may dispose thereof as contemplated in regulation 33.

(4) For the purposes of subregulation (1), "counterfeit" in relation to a scheduled substance, means 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 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 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 in the case of a Schedule 4 substance 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 electronically transmitted 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 if the patient consents thereto, must indicate the diagnosis on the prescription.

(4) An authorised prescriber may only write a 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; and

(f) the period of validity of the prescription.

(2) A prescription book or other permanent record referred to in subregulation (1) must be retained at the business address of the seller for a period of at least three years after 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 name of the scheduled substance;

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

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

(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 scheduled substance was sold;

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

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

(2) Any pharmacist, intern pharmacist or pharmacist's 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) Any prescription book or other permanent record kept in terms of subregulation (1) must be retained at the business address of the seller for a period of not less than three years after the date of the last entry therein.

Records in respect of Schedule 3 and Schedule 4 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) Any record kept in terms of subregulation (1) must be retained at the business address of the seller for a period of not less than three years after the date of the last entry therein.

Register and prescription book or other permanent record 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 set out in Annexure XII, 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) subject to subregulation (2), the balance of such substance on hand noted after each transaction; and

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

(2) The register referred to in subregulation (1) must in addition to the requirement contemplated in paragraph (h) thereof -

(a) reflect the physical quantity of each Schedule 4 substance remaining in stock as on the last day of March, June, September and December of every year; and

(b) be retained at the business address of the person required by the Act to keep the said register for a period of not less than 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)(b) 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.

Importation permits for Schedule 3 or Schedule 4 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 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 set out in Annexure XIII.

(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 (29)(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 set out in Annexure XIV.

(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.

Exportation permits for Schedule 3 or Schedule 4 substances

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

(a) section 29(15)(b) of the Act for the exportation of a 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 set out in Annexure XV.

(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 3 or Schedule 4 substance -

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

(b) must be in the form set out in Annexure XIV.

(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 3 or Schedule 4 substances

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

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

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

must apply therefore to the Permanent Secretary in the form set out in Annexure XVI.

(2) A permit issued in terms of section 29(15)(a) or (23)(a) of the Act in respect of the manufacturing 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 set out in Annexure XVII.

(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 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.

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

31. (1) Any 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 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 set out in Annexure XVIII.

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

(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 (e.g. 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 prescribed in Annexure I; 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 3, 4 and 5 substance may only be destroyed in the presence of an inspector, a member of the Namibian Police Force Service or any other person authorised by the Permanent Secretary, and the inspector, member of the Namibian Police Force Service or other person concerned, as the case may be, must issue a certificate in the form set out in Annexure XX confirming the destruction of the scheduled substance concerned;

(b) a Schedule 1 and 2 substance may be destroyed by a pharmacist or an authorised person referred to in paragraph (a) 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 (a) 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 substance 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) Any 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) Any -

(a) person lawfully performing a health service and who intends to apply in terms of section 31(1) of the Act for a licence referred to therein 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 referred to therein 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 as the Council may from time to time specify for that purpose;

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

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

(2) An application form referred to in subregulation (1) -

(a) must be accompanied by a copy of a notice in the official language for publication by the applicant in at least one newspaper circulating in Namibia of the intention of the applicant to perform the acts permitted by the licence concerned, and the notice must not be smaller than 100mm x 100mm; and

(b) must contain the following information -

(i) the name of the applicant;

(ii) the physical and postal addresses of the residential and business addresses of the applicant;

(iii) 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;

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

(v) proof of registration with the relevant professional board;

(vi) motivation as to the need for a licence in a particular area;

(vii) proof of ability to supply a patient information leaflet; and

(viii) 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) Any person may support or oppose an application referred to in subregulation (1) by making a written representation to the Council within 30 days of the publication of the notice referred to in subregulation (2)(a)(ii).

(5) Any person, pharmacist, medical practitioner, dentist or veterinarian referred to in subregulation (1) who has been issued with a licence -

(a) must keep sales records either in a hard copy or in an electronic format relating to the scheduled substances possessed, prescribed, used, sold or dispensed, as the case may be, for a period of 3 years from the date of sale;

(b) must ensure that the dispensary and any 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;

(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 substances 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) 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;

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

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

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

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

(7) A licence issued in terms of section -

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

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

(c) 31(3) of the Act must be in the form set out in Annexure XXIV,

respectively.

(8) 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, or the Veterinary and Para-veterinary Professions Proclamation, 1984.

(9) Any 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 set out in Annexure XXV.

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

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

(b) must be in the form set out in Annexure XXVI.

(11) 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 set out in Annexure XXVII.

(12) A licence referred to in subregulation (11) must be issued in the form set out in Annexure XXVIII.

(13) Prior to commencing business a person referred to in subregulation (11) -

(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 person who resides in Namibia who is responsible to the Council for compliance with the Act.

(14) 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.

(15) Subject to subregulation (16) -

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

(b) the Minister may revoke a permit referred to in subregulation (9);

(c) the Council may revoke a licence referred to in subregulation (11),

if the Council or the Minister, as the case may be, is of the opinion that subregulation (14) in respect of the licence or permit concerned have not been complied with.

(16) No licence or permit referred to in subregulation (15) 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.

(17) The holder of a licence referred to in subregulation (1) and the holder of a permit referred to in subregulation (9) -

(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.

(18) 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 a person duly authorised thereto by the Permanent Secretary -

(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.

(19) If a licence holder referred to in subregulation (18) 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 any person duly authorised thereto by the Permanent Secretary may collect the items concerned from the licence holder.

(20) The Permanent Secretary or any person duly authorised thereto by the Permanent Secretary must make a written inventory of all items collected as provided in subregulation (19) 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 in pharmaceutical business

35. (1) Any application for the registration of the premises of -

(a) a retail pharmacy;

(b) wholesale pharmacy;

(c) a licence holder referred to in section 31(1);

(d) a licence holder referred to in section 31(3); or

(e) a pharmaceutical manufacturer,

must be submitted to the Registrar in the form of Annexure XXIX.

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

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

36. (1) Any person registered as a nurse or a midwife in terms of the Nursing Professions Act, 1993, who intends to purchase, acquire or keep for administration in a midwifery case the scheduled substances set out in Annexure XXX, must apply in writing in the form of Annexure XXXI 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 Board referred to in section 2(1) of the Nursing Professions Act, 1993;

(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 set out in Annexure XXXII; 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 set out in Annexure XXXIII in which must be recorded in Part A 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 maximum stock on hand;

(b) the pharmacist supplying the scheduled substances must with each supply record the following particulars in Part B 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 Board 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 scheduled substances

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

(a) the Hosea Kutako International Airport near Windhoek;

(b) the Walvis Bay harbour;

(c) the Ariamsvlei border post near Ariamsvlei;

(d) the Noordoewer border post;

(e) the Buitepos border post;

(f) the Oshikango border post ;

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

(h) 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 authorized by the Council to import such unregistered medicine.

(3) A person who imports any scheduled substance must on arrival thereof in Namibia take a sample of each batch of that substance and analyse that sample or cause it to be analysed against the specifications of that 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 3 or 4 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 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) must while in Namibia, 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 the warehouse concerned, unless authorized 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) if the pharmacist concerned is absent, a pharmacist intern, a medical practitioner, a dentist, a pharmacist's assistant, a pharmaceutical technician, a registered nurse or a practitioner in the hospital concerned,

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

(2) Medicines and scheduled substances in hospitals and health facilities 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.

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 Profession Act, 1993 (Act No. 23 of 1993).

(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 (WHO).

(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 WHO 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 WHO guidelines on current good manufacturing practices; and

(b) that conditions mentioned in the WHO 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 authorise, 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 drugs which is accompanied by a declaration by the applicant that such a medicine is listed in the prevailing Namibian Essential Drugs List published by the Ministry responsible for health;

(b) subject to subregulation (3), of any medicine containing new chemical entities that are 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 Drugs List referred to in paragraph (a);

(c) of any medicine tendered internationally by 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 WHO; 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 unregistered medicine

46. Every application for the sale of an unregistered medicine must be submitted to the Registrar in the form set out in Annexure XXXIV and must contain the information required therein.

Fees

47. (1) The fees set out in Annexure XXXV 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. Any person who contravenes or fails to comply with regulations 12, 16(1), (2), (4), (5) and (6), 17, 20, 22(b), 23, 24, 25, 26, 32, 34(1), (8), (9), (11), (17) and (18), 36(1), (4), (5) and (7), 37 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 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 deem 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 an adjourned meeting.

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

(5) Any member of the Council who intends to bring any matter before the Council must forward in writing to the Registrar at least 30 days before the date for which a meeting of the Council is to be convened, a written notice of his or her motion, and the notice must -

(a) appear in the notice convening the meeting; and

(b) be dealt with the other business to be considered by the Council 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 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 do proceed 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 do now adjourn".

(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 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 any meeting may be convened at shorter notice.

(2) Only business specified in the notice relating thereto 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 an adjourned meeting.

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

(5) Any member of the executive committee who intends to bring any matter before the committee must forward in writing to the chairperson of the Council at least 30 days before the date for which a meeting of the committee is to be convened, a written notice of his or her motion, and the notice must -

(a) appear in the notice convening the meeting; and

(b) be dealt with the other business to 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 every 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) Any member of the veterinary medicines committee who intends to bring any matter before the committee must forward in writing 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, a written notice of his or her motion, and the notice must -

(a) appear in the notice convening the meeting; and

(b) be dealt with the other business to 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) Any 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, 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 47 of 15 March 2001 are hereby repealed.

ANNEXURE I

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

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 uUinary 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; and

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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR REGISTRATION OF A MEDICINE
(Regulation 4)

A. PARTICULARS OF PROSPECTIVE HOLDER OF THE CERTIFICATE OF REGISTRATION

Name: .....
Business address: .....
Postal address: .....
Telephone No: ..... Fax No: .....
E-mail address: .....
Site master file reference number: .....
Pharmacist/Other person with appropriate knowledge of all aspects of the medicine, who is responsible for communication with the Council:
Name: .....
Business address: .....
……..
Telephone no: ..... Fax No: .....
E-mail: .....
(Attach letter of authorisation signed by the Managing Director)

B. PARTICULARS OF MEDICINE TO BE REGISTERED

Proprietary name: .....
Pharmacological classification: .....
Dosage form: .....
Dosage unit: .....
Active pharmaceutical ingredient(s) and strength(s) per dosage unit: .....

.....

.....

Descriptive name of biological medicine: .....
Route of administration: .....
Pharmacological classification: .....
Manufacturer: .....
Business address: .....
Site master file reference number: .....
Packer: .....
Business address: .....
Site master file reference number: .....
Final product release control (FPRC): .....
Business address: .....
Site master file reference number: .....
Final product release responsibility (FPRR): .....
Business address: .....
Site master file number:.....

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

.....
Signature of Managing Director/Authorised person

....
Name in block letters Date of application

....
Designation Date of current amendment
(Post-registration only)

C. POST REGISTRATION AMENDMENTS

DATE OF APPLICATION FOR AMENDMENT	SUMMARISED DETAILS OF AMENDMENT	DATE OF APPROVAL BY COUNCIL

Guideline references:

.....

TECHNICAL DATA

PART 1 A(i): SCIENTIFIC PACKAGE INSERT (HUMAN MEDICINES)

The information below with regard to this medicine must appear on the scientific package insert in the format stipulated, but the Council may authorise any deviation from such information or such format, as contemplated in regulation 12(1)(w)(i):

1. The scheduling status.

2. The proprietary name and dosage form.

3. The composition.

4. The pharmacological classification.

5. The pharmacological action, including pharmacokinetics, pharmacodynamics and summary of clinical studies, if applicable.

6. The indications.

7. The contra-indications.

8. Any warnings.

9. The interactions.

10. The effect during pregnancy and lactation.

11. The dosage and directions for use.

12. The side effects and special precautions to be taken.

13. The known symptoms of over-dosage and particulars of its treatment.

14. The identification.

15. The presentation.

16. The storage instructions.

17. The registration number.

18. The name and business address of the holder of the certificate of registration.

19. The date of publication of the package insert.

PART 1 A(ii): SCIENTIFIC PACKAGE INSERT (VETERINARY MEDICINES)

The information below with regard to this medicine must appear on the scientific package insert in the format stipulated, but the Council may authorise any deviation from such information or such format as contemplated in regulation 15(2).

1. The words "**Veterinary Medicine**".

1. The scheduling status.

3. The proprietary name and dosage form.

4. The scheduling status.

5. The dosage form.

6. The composition.

7. The pharmacological classification.

8. The pharmacological action, including pharmacokinetics and pharmacodynamics.

9. The indications.

10. The contra-indications.

11. Any warnings or the withdrawal period in the case of food-producing animals.

12. The dosage and directions for use including age and species dosage.

13. The side effects and special precautions for use per species.

14. The known signs of over-dosage and particulars of its treatment per species.

15. The conditions of registration.

16 The identification.

17. The presentation.

18. The storage instructions.

19. The registration number.

20. The name and business address of the holder of the certificate of registration.

21. The date of publication of the package insert.

PART 1 B: PATIENT INFORMATION LEAFLET

The information below with regard to this medicine must appear on the patient information leaflet in the format stipulated, but the Council may authorise any deviation from such information or such format as contemplated in regulation 13(2).

1. The scheduling status.

2. The proprietary name and dosage form.

3. The composition.

4. The approved indication and use.

5. The instructions before taking the medicine (refer to the Guidelines).

6. The instructions on how to take the medicine (refer to the Guidelines).

7. The side effects (refer to the Guidelines).

8. The storage and disposal information (refer to the Guidelines).

9. The presentation.

10. The identification.

11. The registration number.

12. The name and business address of the holder of the certificate of registration.

13. The date of publication of the patient information leaflet..

PART 1 C: SPECIMEN OF THE LABEL

A specimen of the immediate container label and, if applicable, the outer label must be included here, as contemplated in regulation 11 in the case of medicines for human use, and regulation 14 in the case of a veterinary medicine.

PART 1 D: REGISTRATION IN COUNTRIES OUTSIDE NAMIBIA

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

2..1 If the medicine has been registered in a country outside Namibia, the conditions of registration and proof thereof must be submitted.

2.2 If the medicine has been registered in the European Union, Australia, United Kingdom, United States of America, Canada, The Netherlands, Sweden and Japan, the approved package insert (data sheet) must also be submitted. (All documents must be submitted in English).

3. The name and business address of the manufacturer, the packer and the testing laboratory, if applicable, must be submitted.

4. Details of any negative decision by any medicines regulatory authority must be submitted.

PART 2A(i): ACTIVE PHARMACEUTICAL INGREDIENT (DEVELOPMENT CHEMISTRY AND CHARACTERISATION)

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

International Nonproprietary Name (INN) or approved name and chemical name	Structural formula, empirical formula, molecular mass	Solubility	Storage requirements	Shelf-life (and re-test period)

(b) The active pharmaceutical ingredients may be obtained from (name and business address of the manufacturer(s)): .....
.....
.....

(c) Please submit -

(i) the Active Pharmaceutical Ingredient File (APIF), DMF (open part) or certificate of suitability (CEP);

(ii) a certificate of analysis of two batches;

(iii) proof of physical and chemical equivalence (more than one manufacturer); and

(iv) the stability data and shelf-life of the active pharmaceutical ingredient.

PART 2A(ii): PRIMARY PRODUCTION LOT/BATCH (BIOLOGICAL MEDICINES)

1. DESCRIPTION OF THE PREPARATION AND PRODUCTION OF THE PRIMARY PRODUCTION LOT

Please submit -

(a) the name and address of the manufacturing facility in which production of the primary production lot takes place; and

(b) 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.

2. SPECIFICATIONS OF RAW MATERIALS USED IN THE PRIMARY PRODUCTION LOT

Please submit the specifications that apply to the raw materials used in the primary production or bulk lot of a biological medicine, including the titles of the tests and the limits and criteria of acceptance of each parameter contained in the specification. (If the test mentioned corresponds to a recognised pharmacopoeia, the source must be mentioned).

3. TESTS CARRIED OUT ON RAW MATERIALS IN THE PRIMARY PRODUCTION LOT AND THE LABORATORIES

Please submit a complete description of the tests carried out on all the raw materials used in the primary production or bulk lot, specifying the name(s) and address(es) of the laboratory or laboratories in which such tests were carried out.

PART 2 B(i): FORMULATION

FORMULATION OF THE FINAL DOSAGE FORM FOR PHARMACEUTICAL MEDICINES AND FORMULATION OF THE FINAL FILLING LOT/BATCH FOR BIOLOGICAL MEDICINES

(a) Please -

(i) submit below a schedule of the names and quantities of each active and inactive ingredient contained in a dosage unit; and if no dosage unit exists, any other suitable unit of mass or volume of the medicine may be used and these must conform to the relevant particulars in the package insert and on the label with regard to the active pharmaceutical ingredients; and

(ii) specify below the purpose(s) of each inactive ingredient in the formulation, including that of raw materials used in manufacturing, but which are not present in the final product.

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

*mg per tab/cap/loz/supp or mg or ml per specified volume or mass of product

(b) Please -

(i) submit, with regard to potency calculations, a statement to the effect that the actual quantity of the active pharmaceutical ingredient will depend on the potency;

(ii) submit the composition of inactive ingredients in combination and mixtures;

(iii) submit any overages and the justification for their inclusion; and

(iv) indicate the toxicity level per dosage unit for all solvents and for other ingredients if required by the Council, and the levels must be indicated as per "USP DI", "Martindale", "The Complete Drug Reference" or other specified reference.

PART 2 B (ii): FORMULATION OF THE RECONSTITUTING LIQUID FOR THE FINAL FILLING LOT FOR BIOLOGICAL MEDICINES

Please -

(a) submit below a schedule of the names and quantities of each ingredient contained in the diluent; and

(b) specify below the purpose of each ingredient in the formulation, including that of raw materials used in the composition, but which are not present in the diluent.

Approved name or chemical name of constituent	Quantity	Purpose

PART 2C: SPECIFICATIONS AND CONTROL PROCEDURES FOR RAW MATERIALS

(a) Pharmacopoeial ingredients:

Raw Material		Specifications and Pharmacopoeial reference*	Limits	Additional Tests (e.g. particle size)
Active				
Inactive				

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

(b) Non-pharmacopoeial ingredients:

Raw Material		Specifications	Limits	In-house control procedures
Active				
Inactive				

(c) The applicant must comply with and confirm the following requirements in the application -

(i) the identification and assay of the active raw material, irrespective of the possession of a certificate of analysis from the supplier;

(ii) the identification of the inactive raw material, irrespective of the possession of a certificate of analysis from the supplier; and

(iii) the performing of any other tests not included in a valid certificate of analysis.

(d) The frequency of testing of water, if applicable, must be included.

PART 2D: CONTAINER AND PACKAGING MATERIAL

1. DESCRIPTION OF CONTAINERS

This description must refer to -

(a) the immediate container, including any patient-ready packs, closure, wadding, desiccant (type of material and dimensions, including sketches);

(b) the outer container (type of material of container);

(c) the bulk container (type of material of container); and

(d) the application and administrative sets (type of material and dimensions including sketches).

2. SPECIFICATIONS AND LIMITS FOR PACKAGING MATERIALS

Specification	Limit	Name of manufacturer/packer of the final product

(Indicate the tests performed by the supplier of the packaging material.)

3. DESCRIPTION OF CONTROL PROCEDURES PERFORMED BY MANUFACTURER OR PACKER OF FINAL PRODUCT

Describe the control procedures performed by the manufacturer or the packer of the final product.

4. PACK SIZES

(Please state the pack sizes for the medicine concerned):

.....
.....
.....
.....

PART 2E: MANUFACTURING PROCEDURES

MANUFACTURING PROCEDURES OF FINAL PRODUCT (PHARMACEUTICAL MEDICINES) AND FINAL FILLING LOT AND DILUENT (BIOLOGICAL MEDICINES)

1. INSPECTION FLOW DIAGRAM

Please submit the inspection flow diagram.

2. MANUFACTURING PROCEDURES

Please -

(a) submit the batch manufacturing formula(s) and the batch size(s);

(b) submit a copy of the batch or master manufacturing document for a real batch;

(c) submit a comprehensive flow diagram or a description of the manufacturing procedures detailing the various stages of manufacturing;

(d) indicate the type of equipment, sieve sizes (μm), duration of treatment, temperature, light and humidity conditions, machine settings (e.g. rotation speed or rpm); and

(e) show the frequency of all in-process control tests (analytical, microbiological, and physical) in the flow diagram or specified in the description.

3. PACKAGING PROCEDURES

Please -

(a) submit a copy of the batch/master packaging document, a comprehensive flow diagram or a description of the packaging procedures detailing the various stages of packaging and labelling;

(b) indicate the type of equipment used in the packaging process; and

(c) include the in-process tests, the frequency of testing and control procedures carried out during the packaging process.

4. MANUFACTURING PROCESS VALIDATION PROTOCOL

Please submit the process validation protocol.

PART 2F: FINISHED PRODUCT (PHARMACEUTICAL) FINAL FILLING LOT AND DILUENT (BIOLOGICAL)

1. SPECIFICATIONS AND LIMITS

If applicable, list specifications and limits for -

(a) the in-process control;

(b) the final product control;

(c) the stability tests; and

(d) the manipulated final product.

Specifications	Limits

(See guideline on **Stability** for specifications to be considered for each dosage form).

2. TABLE OF TESTS TO BE PERFORMED

	TITLE OF SPECIFICATION
FPRC	
FPRC responsible for tests after importation	**Identification** Assay
FPRR	Appearance of dosage form Container Package insert Label Batch No. Expiry date. Certificate of Analysis Batch release documents

3. CONTROL PROCEDURES

Please include the control procedures for all the specifications in paragraph 1.

4. CERTIFICATE OF ANALYSIS OF THE FINAL PRODUCT

Please submit the certificate of analysis of the final product.

5. VALIDATION

Please include the validation data for all quantitative assay methods.

PART 2G: STABILITY DATA FOR THE FINISHED PRODUCT

1. STABILITY PROGRAMME

Describe the stability programme to be followed, including -

(a) the conditions (temperature and humidity);

(b) the time points of determination, e.g. 0, 3, 6, 9 months;

(c) the specifications to be determined;

(d) the frequency of stability testing on future batches according to the WHO and good manufacturing practices stability testing guidelines; and

(e) the stability test control procedures.

2. PRESENTATION OF STABILITY DATA

Product Name: Batch No.: Batch Size: Date of Manufacture:				Packaging (material and pack sizes): Storage conditions: Name of manufacturer: Source of active pharmaceutical ingredient:			
Date of commencement of stability study:							
		Time intervals (Months)					
Specification	Limit	0	3	6	9	12	24

3. DISCUSSION AND CONCLUSION OF SHELF-LIFE FOR EACH TYPE OF CONTAINER

Discuss and conclude the effect of different stress conditions and different container material and sizes used on the derived data. Please submit proof that the shelf life as shown on the package insert or the label has been determined correctly.

PART 2 H: PHARMACEUTICAL DEVELOPMENT

1. Highlight and motivate any differences in the formulation or method of manufacturing of the different batches used in stability, bioequivalence and clinical studies.

2. Please state in the pharmaceutical expert report -

(a) the active pharmaceutical ingredient(s);

(b) the formulation;

(c) the production and manufacture;

(d) the stability;

(e) the conclusion of the expert report;

(f) the name, signature and date of the responsible person; and

(g) the reference list used in the compilation of the report.

PART 2I: EXPERTISE AND PREMISES USED FOR MANUFACTURING OF BIOLOGICAL MEDICINES

1. DETAILS RELATING TO THE PREMISES WHERE PRIMARY PRODUCTION IS UNDERTAKEN AND THE STAFF INVOLVED IN THE PRODUCTION AND TESTING OF BIOLOGICAL MEDICINES.

Please -

(a) give a description of the premises where all procedures involved in the preparation of the primary production or bulk batch is carried out, and also includes a floor plan;

(b) give details of other purposes for which the premises are used; and

(c) give the names, qualifications and field and duration of experience of the persons responsible for the manufacture, testing and release of the biological medicine, in the form of the primary production or bulk lot and the final containers ready for sale.

2. NAME AND ADDRESS OF FACILITY WHERE THE IMPORTED FINAL FILLING LOT IS STORED

Please submit the name and address of the facility where the imported final filling lot is stored.

PART 3: BIOEQUIVALENCE STUDIES FOR PROOF OF EFFICACY

1. THE PURPOSE OF THE STUDY

Please state the purpose of the study -

(a) as comparison of the formulation to be marketed versus formulation used in clinical trials, or

(b) as proof of efficacy for a generic application, or

(c) as proof of efficacy of a new formulation (a formulation change).

2. REFERENCE PRODUCT USED

Please state -

(a) the clinical trial formulation;

(b) the innovator product; and

(c) the 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 API		

3. METHOD USED

Please describe the method used in full, e.g. bioavailability and dissolution.

4. VALIDATION

Please include the validation data for all quantitative assay methods.

5. DATA

Please list any derived and tabulated data for scrutiny.

6. DISCUSSION AND CONCLUSION

If applicable, attach documents containing the discussion and conclusion.

PART 4: PRE-CLINICAL STUDIES

1. Please submit the pre-clinical expert report.

2. Please describe the following parts 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 -

   (a) acute toxicity,

   (b) subacute toxicity studies;

   (c) chronic toxicity studies;

   (d) reproduction toxicity and teratogenicity studies;

   (e) carcinogenicity studies;

   (f) mutagenicity studies; or

   (g) other tests to substantiate the safety of the medicine; and

   (h) pharmacokinetics studies.

3. Please state 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.

In cases where well-known active pharmaceutical ingredients are concerned, the Council may grant exemption from the submission of some or all of the above information.

PART 5:CLINICAL STUDIES

Please submit -

(a) the clinical expert report;

(b) the clinical trials performed on human volunteers and patients (target species for veterinary medicines) with regard to the safety of the use of the medicine, with special reference to the particular dosage, routes of administration used and the side-effects observed;

(c) the particulars of clinical trials conducted to establish the efficacy of the use of the medicine;

(d) the 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;

(e) the periodic safety update report for medicines for human use; and

(f) in the case of veterinary medicines, the residue studies and withdrawal period.

In cases where well-known active pharmaceutical ingredients are concerned, the Council may grant exemption from the submission of some or all of the above information.

ANNEXURE III

MEDICINES REGISTER FOR MEDICINES WHICH ARE NOT VETERINARY MEDICINES OR COMPLEMENTARY MEDICINES

(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

VETERINARY MEDICINES REGISTER

(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

COMPLEMENTARY MEDICINES REGISTER

(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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR AMENDMENT OF ENTRY IN REGISTER
(Regulation 8(1))

TO:
The Registrar of Medicines
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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

CERTIFICATE OF REGISTRATION
(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, if any, set out below.

Issued at ..... on.....

.....
Registrar of Medicines

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: .....
Conditions of registration of medicine: .....
.....
.....
.....
.....

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: .....
.....
.....

ANNEXURE VIII

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR APPROVAL OF TRANSFER OF CERTIFICATE OF REGISTRATION
(Regulation 10)

TO:
The Registrar of Medicines
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 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)* / .....
.....
(name of body corporate) of .....
.....
(postal and physical business address).*

....
Signature of applicant Date

* Delete whichever is not applicable.

Note: Please attached 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

REPORT OF ADVERSE DRUG REACTION
(Regulation 17(5))

TO:
The Registrar of Medicines
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 of administration	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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

CERTIFICATE BY INSPECTOR
(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):
.....
.....

3. 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

CERTIFICATE BY ANALYST
(Regulation 22)

I, (full names and surname), ...
duly authorised 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

SCHEDULE 4 SUBSTANCES REGISTER AND PRESCRIPTION BOOK

(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	Reference No	Prescriber's Name and address	Units received	Units issued	Balance	Signature

ANNEXURE XIII

THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR PERMIT TO IMPORT A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE
(Regulation 28(1))

TO:
The Permanent Secretary
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 import a Schedule 3 / a Schedule 4 *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, harbour or post office.)

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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

IMPORT/EXPORT PERMIT* FOR A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE

(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 3/Schedule 4* 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, harbour or post office).

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

THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR PERMIT TO EXPORT A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE
(Regulation 29(1))

TO:
The Permanent Secretary
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 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 3/Schedule 4* 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR PERMIT TO MANUFACTURE A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE
(Regulation 30(1))

TO:
The Registrar of Medicines
Ministry of Health and Social Services
Private Bag 13366
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 3/Schedule 4* 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

PERMIT TO MANUFACTURE A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE

(Regulation 30(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* business at ..... (physical address) to manufacture the following Schedule 3/Schedule 4* substance, subject to the conditions set out herein:

(a) the name of the Schedule 3/Schedule 4* 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR PERMIT TO CULTIVATE OR COLLECT PLANTS OR A PORTION OF A PLANT FROM WHICH A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE CAN BE EXTRACTED, DERIVED, PRODUCED OR MANUFACTURED

(Regulation 31(1))

TO:
The Registrar of Medicines
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 cultivate or collect plants or portions of plants from which a Schedule 3/Schedule 4* 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 3/Schedule 4* 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.

ANNEXUREX XIX

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

PERMIT TO CULTIVATE OR COLLECT PLANTS OR A PORTION OF A PLANT FROM WHICH A SCHEDULE 3 OR A SCHEDULE 4 SUBSTANCE CAN BE EXTRACTED, DERIVED, PRODUCED OR MANUFACTURED
(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 3/Schedule 4* 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003
(ACT NO. 13 OF 2003)

CERTIFICATE OF DESTRUCTION AND DISPOSAL OF SCHEDULED SUBSTANCES AND MEDICINES
(Regulation 33(1))

1. Details of premises where the scheduled substances were found:

Name: .....

Postal address: .....

Physical address: .....

Name of person in charge: .....

2. Items destroyed:

Name of scheduled substance	Quantity	Reason for destruction

3. Method of destruction and disposal:.....
.....
.....
.....
.....

4. Name of inspector: .....

....
Signature of Inspector Date

....
Signature of person in charge of premises Date

ANNEXURE XXI

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR LICENCE IN TERMS OF SECTION 31(1), (2) OR (3)
(Regulation 34(1))

TO:
The Registrar of Medicines
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: .....
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 for the licence concerned, -

   (a) demographic considerations;

   (b) disease patterns; and

   (c) the health status of users to be served.

4. A notice in the official language for publication in at least one newspaper circulating in Namibia of the intention of the applicant to perform the acts permitted by 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 served by the applicant: .....
   .....
3. Estimated population in the geographical area: .....

4. What is the estimated number of consultations per month the applicant will conduct?: .....

5 Name of medical aid scheme to which members of the general public belong, if known?: .....
.....

6. Estimated percentage of members of the general public in the geographical area who do not belong to any medical aid scheme or auxiliary scheme: .....
.....

7. Supply below the names of other health service providers within a radius of 20 kilometres from the premises where the applicant intends to provide his or her services (specify the distance in each case from such premises). If there are more than three such provider of a specific type mentioned in paragraphs (a), (b,) (c) and (d) below, mention only the closest three):

(a) Pharmacies:

(i) .....

(ii) .....

(iii) .....

(b) Medical Practitioners:

(i) .....

(ii) .....

(iii) .....

(c) Dentists:

(i) .....

(ii) .....

(iii) .....

(d) Veterinarians:

(i) .....

(ii) .....

(iii) .....

(e) Persons other than pharmacists, medical practitioners, dentists or veterinarians contemplated in section 31(1):

(i) .....

(ii) .....

(iii) .....

(f) Hospitals:

(i) .....

(ii) .....

(iii) .....

(g) Primary health care clinics and other health facilities:

(i) .....

(ii) .....

(iii) .....

8. From which distributor or pharmacy will the scheduled substances concerned be purchased? .....
.....
.....

....
Signature of applicant Date

ANNEXURE XXII

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

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 .....

(postal business 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
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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 XXIII

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

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 .....
(postal business 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
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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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

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 .....
(postal business 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR PERMIT IN TERMS OF SECTION 31(4)
(Regulation 34(9))

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 apply 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

PERMIT ISSUED IN TERMS OF SECTION 31(4)
(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	Scheduled substances, medicine, strength and dosage form	Quantity

Conditions :.....
.....
.....
.....

Period of validity of licence: .....

....
Minister responsible for health Date

ANNEXURE XXVII

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR LICENCE IN TERMS OF SECTION 31(5)
(Regulation 34(11))

TO:
The Permanent Secretary
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 apply 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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

LICENCE ISSUED IN TERMS OF SECTION 31(5)
(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

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR REGISTRATION OF PREMISES USED IN PHARMACEUTICAL BUSINESS
(Regulation 35)

TO:
The Registrar of Medicines
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

1. Name of applicant: .....
2. Postal address of applicant: .....
3. Telephone No.: ..... Fax No: .....
4. Residential address of applicant: .....
   .....

5. State whether application is made for the registration of the premises of -

   (a) a retail pharmacy;*

   (b) a wholesale pharmacy;*

   (c) a licence holder referred to in section 31(1);*

   (d) a licence holder referred to in section 31(3); or *

   (e) a pharmaceutical manufacturer.*

6. Physical address of premises: .....
.....
.....

....
Signature of applicant Date

* Delete whichever is not applicable.

ANNEXURE XXX

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

SCHEDULED SUBSTANCES FOR USE BY REGISTERED NURSE OR MIDWIFE

(Regulation 36(1))

Schedule	Medicine	Strength	Dosage	Maximum Stock on Hand
S1	Soluble aspirin tablets and codeine phosphate 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 /ml	0,5 mg IM	50 x 1 ml ampoules
S2	Naloxonehydrochloride injection (neo-Natal)	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%	15-20ml 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 XXXI

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003
(ACT NO. 13 OF 2003)

APPLICATION BY REGISTERED NURSE*/MIDWIFE *TO PURCHASE, ACQUIRE OR KEEP FOR ADMINISTRATION IN A MIDWIFERY CASE THE SCHEDULED SUBSTANCES SET OUT IN ANNEXURE XXX.
(Regulation 36(1))

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 of the Nursing Professions Act, 1993 (Act No. 30 of 1993) hereby apply to acquire the scheduled substances mentioned in the column below, being scheduled substances set out in Annexure XXX:

The other required particulars are as follows:
Postal business 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).

Name of Scheduled medicine /substance	Strength and dosage form	Maximum quantity

....
Signature of Applicant Date

ANNEXURE XXXII

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

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 Professions Act, 1993 (Act No. 30 of 1993), to purchase, acquire or keep for administration the following scheduled substances:

Schedule	Medicine	Strength	Dosage	Maximum Stock permitted
S1	Soluble aspirin tablets and codeine phosphate 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 /ml	0,5 mg IM	50 x 1 ml ampoules
S2	Naloxonehydrochloride injection (neo-Natal)	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%	15-20ml 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)

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

ANNEXURE XXXIII

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

REGISTER OF SCHEDULED SUBSTANCES TO BE KEPT BY REGISTERED NURSE OR MIDWIFE
(Regulation 36(4))

PART A
RECEIPT
(To be completed by permit holder)

Schedule	Name of substance or medicine	Strength	Maximum stock on hand

PART B
(To be completed by pharmacist supplying the scheduled substances concerned)

Date	Number of permit	Quantity	Name and address of pharmacy	Issued by	Received by
Brought forward					
New stocks acquired					

Full names and surname of pharmacist: .....

....
Signature of pharmacist Date

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 Adminis-tered	Administered by		Reason for administration	Balance on hand
				Signature	Qualification		

ANNEXURE XXXIV

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

APPLICATION FOR SALE OF UNREGISTERED MEDICINE
(Regulation 46)

TO:
The Registrar of Medicines
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

PART A
PARTICULARS OF APPLICANT

Name: .....
Business address: .....
Postal address: .....
Telephone No: ..... Fax No: .....
E-mail address: .....
File reference number: .....
Pharmacist/Other person with appropriate knowledge of all aspects of the medicine, who is responsible for communication with the Council:
Name: .....
Business address: .....
.....
Telephone no: ..... Fax No: .....
E-mail: .....
(Attach letter of authorisation signed by the Managing Director)

PART B
PARTICULARS OF MEDICINE TO BE SOLD

Proprietary name: .....
Pharmacological classification: .....
Dosage form: .....
Dosage unit: .....
Active pharmaceutical ingredient(s) and strength(s) per dosage unit:
.....
.....
.....
.....
Descriptive name of biological medicine: .....
Route of administration: .....
Pharmacological classification: .....
Manufacturer: .....
Business address: .....
File reference number: .....
Packer: .....
Business address: .....
File reference number: .....
Final product release control (FPRC): .....
Business address: .....
File reference number: .....
Final product release responsibility (FPRR): .....
Business address: .....
Master file number: .....

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

.....
Signature of applicant

....
Name in block letters Date of application

PART C

State whether application is made for authorisation for the sale of a medicine -

(a) registered outside Namibia but not registered in Namibia;*

(b) not registered at all;*

(c) not registered at all, but forming part of a clinical trial;*

(d) registered in Namibia, but forming part of a clinical trial for purposes of other indications;* or

(e) prescribed for a specific patient. *

* Delete whichever is not applicable.

ANNEXURE XXXV

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

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: US$ 500-00;

(bb) for registration: US$ 150-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: US$ 250-00;

(bb) for registration: US$ 100-00

(iii) for a line extension of a medicine -

(aa) per application: US$ 250-00;

(bb) for registration: US$ 100-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: US$ 250-00;

(bb) for registration: US$ 100-00;

(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:* US$ 150-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): US$ 150-00;

(bb) transfer of a certificate of registration (whether approved or not): US$ 100-00.

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: US$ 300-00;

(bb) for registration: US$ 100-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: US$ 125-00;

(bb) for registration: US$ 50-00

(iii) for a line extension of a medicine -

(aa) per application: US$ 125-00;

(bb) for registration: US$ 50-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: US$ 125-00;

(bb) for registration: US$ 50-00;

(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:* US$ 75-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): US$ 75-00;

(bb) transfer of a certificate of registration (whether approved or not): US$ 50-00.

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 the premises of a retail pharmacy, a wholesale pharmacy, a licence holder referred to in section 31(1) or (3) and a pharmaceutical manufacturer: 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 retail pharmacy N$160-00 per hour;

(b) in respect of the premises of a wholesale pharmacy N$800-00 per site;

(c) in respect of the premises of a licence holder referred to in section 31(1) N$160-00 per hour;

(d) in respect of the premises of a licence holder referred to in section 31(3) N$160-00 per hour;

(e)	in respect of the premises of a pharmaceutical manufacturer	N$400-00 per hour.

* 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.

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(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.
