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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 567 **7 May 1999**

SCHEDULES UNDER THE SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY ACT, 1998 (ACT NO. 132 OF 1998)

The Minister of Health has, in terms of section 31 read together with section 54 of the South African Medicines and Medical Devices Regulatory Authority Act, 1998 (Act No. 132 of 1998) on the recommendation of the South African Medicines and Medical Devices Regulatory Authority made the schedules in the Schedule

SCHEDULE

SCHEDULE 0

SUBSTANCES AND MEDICINES CONTAINING AN ACTIVE SUBSTANCE OR SUBSTANCES NOT TAKEN UP IN ANY OF THE OTHER SCHEDULES

(a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food, or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) or the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and

(ii) analytical laboratory purposes.

(b) All substances referred to in this Schedule include the following:

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

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

This Schedule includes-

(i) all substances subject to registration in terms of this Act and which are not listed in any of the other Schedules.

(ii) all substances listed in Annexure A below **only** when contained in medicines prepared in a recognised pharmaceutical dosage form which have been exempted from Schedule 1, Schedule 2, Schedule 3, Schedule 4 and Schedule 5, for the express purpose of obtaining registration as an animal health product. Veterinary products are classified as animal health products in terms of the

provisions of Section 48(c) of the Act and according to the guidelines for scheduling.

(iii) all substances listed in Annexure B below **only** when contained in medicines prepared in a recognised pharmaceutical dosage form which have been exempted from Schedule 1, Schedule 2, Schedule 3, Schedule 4 and Schedule 5, for the express purpose of obtaining registration as a veterinary pesticide. Veterinary products are classified as pesticides in terms of the provisions of Section 48(c) of the Act and according to the guidelines for scheduling.

Annexure A
ANIMAL HEALTH PRODUCTS

Albendazole, when intended as an anthelmintic. (S4)
Alphacalcidol. (S4)
Antihistamines. (S1)
Antimicrobial substances as indicated below:
Ampicillin, cloxacillin, dihydrostreptomycin, penethamate hydroiodide and procaine benzylpenicillin; intra-mammary preparations thereof, containing trace dye(s) and intended for the treatment of mastitis in cattle;
Amprolium, decoquinate, dinitolamide, ethopabate, lasalocid, maduramicin, monensin and naracin when intended as anti-coccidial preparations;
Avilamycin, avoparcin, carbadox, flavophospholipol, monensin, nitrovin, olaquindox, virginiamycin and zinc bacitracin when intended to improve production;
Carnidazole, when intended for trichomoniasis in pigeons;
Chlortetracycline, rolitetracycline and tetracycline; injections thereof, intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle;
Chlortetracycline; capsules thereof, for use in pigeons;
Dimetridazole, when intended for trichomoniasis in pigeons, as an anti-bacterial preparation for pigs and to improve production;
Doxycycline;
Furaltadone, when intended as a single oral dosage for gastro-intestinal infections;
Hygromycin, when intended as an anthelmintic for pigs;
Oxytetracycline;
Salinomycin; when intended as an anticoccidial preparation and to promote growth;
Tylosin; when intended for addition to drinking water and feedstuff for administering to poultry and pigs; (S4)
and the following antimicrobial substances when intended for the approved indications:
2-amino-5-nitrothiazole;
Acetyl isovaleryl tylosin tartrate;
Amoxycillin;
Bacquiloprim;
Clopidol;
Fosfomycin;
Kitasamycin;
Metronidazole;
Robenidine;
Ronidazole;
Semduramicin;

Spiramycin. (S4)
Antisera, for veterinary use when intended as an animal health product.(S4)
Arprinocid, when intended as an anticoccidial preparation for poultry. (S4)
Calcium salts; preparations thereof, when intended for injection. (S1)
Clazuril, when intended as an anticoccidial preparation for poultry. (S4)
Closantel, when intended for use as an anthelmintic for sheep and cattle.(S4)
Dichlorophen, when used as a anthelmintic.(S4)
Diclazuril, when intended for use as an anticoccidial preparation for poultry.(S4)
Di-iodohydroxyquinolone, when intended for use as an anticoccidial preparation.(S4)
Diminazene, when intended for use as a antibabesial.(S4)
Disophenol, when intended for use as an anthelmintic for sheep and goats.(S4)
Febantel, when intended for use as an anthelmintic for sheep, goats and cattle.(S4)
Fenbendazole, when used as a anthelmintic.(S1)
Flubendazole when intended as a anthelmintic for pigs.(S1)
Halofuginone, when intended for use as an anticoccidial preparation for poultry.(S4)
Hormones including only zeranol, natural oestrogen, and progesterone, when intended for production improvement in cattle and sheep, and BST (bovine somatotrophin).(S4)
Imidocarb, when intended for use as [babesiacide] antibabesial or for the treatment anaplasmosis. (S4)
Injections registered as animal health products.(S1)
Iron salts, when intended for injection in cattle, sheep and goats.(S3)
Ivermectin, when intended an anthelmintic and/or ectoparasiticide. (S3)
Lactobacillus acidophilus and Lactobacillus bifidus.(S1)
Levamisole, when intended for use as an anthelmintic and as an immunostimulator of clostredial vaccination.(S4)
Lignocaine when contained in antimicrobial preparations as well as ophthalmic preparations.(S4)
Lufenuron, when intended as a systemic preparation against fleas. (S1)
Luxabendazole, when intended as a anthelmintic for sheep, goat and cattle.(S1)
Mebendazole, when intended as a anthelmintic.(S1)
Methenamine (hexamine), intended as an urinary tract antiseptic.(S1)
Morantel citrate, when intended as a anthelmintic for sheep, goat and cattle.(S1)
Nicarbazin, when intended for use as an anticoccidial preparation. (S4)
Nitroxynil, when intended for use as an anthelmintic for sheep, goats and cattle. (S4)
Nux vomica.(S1)
Oxfendazole, when intended as a anthelmintic for sheep, goat and cattle.(S4)
Oxibendazole.(S1)
Oxyclosanide, when intended as a anthelmintic for sheep, goat and cattle.(S4)
Phenamidine, when intended for use as an a antibabesial. (S4)
Praziquantel, when intended for use as an anthelmintic. (S4)
Phenothiazine, when intended as an anthelmintic.(S5)
Phenylmercuric nitrate.(S1)
Pyrantel pamoate, when intended as a anthelmintic.(S1)
Quinoronium sulphate, when intended for use as a antibabesial.(S4)
Rabies vaccine, killed or inactivated, for veterinary use.(S1)
Rafoxanide, when intended for use as an anthelmintic for sheep, goats and cattle. (S4)
Resorantel, when intended for use as an anthelmintic for sheep, goats and cattle. (S4)
Sulphonamides. (S1 S4)
Testosterone, when intended for production improvement in cattle and sheep.(S4)

Tetramisole, when intended for use as an anthelmintic. (S4)
Thiabendazole, when intended for use as an anthelmintic. (S4)
Toltrazuril, when intended for use as an anticoccidial preparation for poultry. (S4)
Trenbolone, when intended for use as a veterinary growth stimulant. (S4)
Triclabendazole, when intended for use as an anthelmintic for sheep, goats and cattle. (S4)
Trimethoprim. (S4)
Vaccines for veterinary use, when intended as an animal health product.(S4)
Vitamin A; preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 I.U. per recommended daily dose. (S3)
Vitamin D; preparations thereof for injection and oral preparations and mixtures thereof containing more than 5 00 I.U. per recommended daily dose. (S3)
Zinc salts for oral ingestion where the daily dose is more than 50 milligrams of elemental zinc.(S3)
The following substances when intended for the approved indications:
Colostrum (immunoglobulins); (S2)
Domperidone; (S2)
Gonodotropin releasing hormone; (S4)
Ketanserin; (S3)
Moxidectin;
Procaine; (S1)
Ractopamine.(S4)

ANNEXURE B
VETERINARY PESTICIDES

Alphamethrin.
Amitraz.
Carbaryl.
Chlorfenvinphos.
Cypermethrin.
Cyromazine.
Cymiazol.
Cyfluthrin.
Dichlorophen.
Deltamethrin.
Diazinon.
Diflubenzuron.
Esfenvalerate.
Fenoxycarb.
Fenitrothion.
Fenthion.
Fipronil.
Flumethrin.
Fluazuron.
Gamma BHC.
Imidoclopid.
Malathion.
Naphthalene.
Permethrin.
Phosmet.
Piperonyl butoxide.
Propetamphos.
Propoxur.
Pyrethrin.
Rotenone.
Triaphos.
Triflumuron.

SCHEDULE 1

MEDICINES WHICH MAY BE SOLD BY AUTHORISED PERSONS WITHOUT A PRESCRIPTION

(*a*) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food, or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) or the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and

(ii) analytical laboratory purposes.

(*b*) All substances referred to in this Schedule include the following:

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

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

(*c*) In terms of Section 31(4)(a)(v) and 33(1)(a), nurses may use, keep, prescribe and supply to patients under their care, the Schedule 1 substances and medicines provided for in Annexure A, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document likewise reflected in Annexure A. Annexure A appears at the end of this Schedule.

Acetanilide and alkyl acetanilides.

Acetarsol, when intended for human vaginal use.

Acetylcysteine.

Acetyldihydrocodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodiene (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Aconite alkaloids; substances, preparations and mixtures containing 0,02 per cent or more thereof.

Acyclovir, when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections.(S4)

Adrenaline (epinephrine), except preparations for injection and except ophthalmic preparations when intended for glaucoma. (S3, S4)

Alkaloids and glycosides; all poisonous alkaloids and glycosides, and the salts of such poisonous alkaloids and glycosides not specifically named in any other Schedule.

Aminopentamide.

Amorolfine.

Anethole trithione.

Anticoagulants, when intended for application to the skin. (S4)

Antihistaminics, irrespective of indication or dosage form, except-

(a) acrivastine, cetirizine, loratidine; (S2)

(b) astemizole and terfenadine; (S4)

(c) in combination with central nervous system depressants (excluding alcohol when present as an excipient); (S2)

(d) when listed seperatey in these Schedules; (S5) and

(e) when intended as an animal health product. (S0)

Antimalarials; preparations containing substances in the 4-aminoquinoline, 8-aminoquinoline,

diguanide and diaminopyrimidine groups of compounds, when intended specifically for malaria prophylaxis. (S4)

Antimicrobial substances, namely bacitracin, gramicidin, polymyxin B and tyrothricin, when intended for application to the skin, nares and external ear, as excluded from the conditions of Schedule 4. (S2, S4)

Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and mixtures containing 1,0 per cent or more thereof.

Antipyrine. (phenazone)

Apomorphine; preparations and mixtures thereof.

Aptocaine.

Arecoline.

Arsenic; substances, preparations and mixtures containing the equivalent of less than 0,01 per cent of arsenic trioxide. (S2)

Atropine; substances, preparations and mixtures thereof, except ophthalmic preparations. (S3)

Azelaic acid.

Barbituric acid and its derivatives, unless listed in another Schedule, excluding amobarbital, cyclobarbital, pentobarbital and secobarbital; preparations and mixtures containing 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 90 milligrams or less phenobarbitone per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S2, S5, S6)

Belladonna alkaloids; substances, preparations and thereof, including belladonna plasters.

Benproperine.

Benzethonium chloride, when intended for human vaginal use.

Benzydamine; preparations and mixtures containing 3 per cent or less of benzydamine, when intended for application to the skin and for use as a mouthrinse. (S3)

Beta-aminopropylbenzene and beta-aminoïsopropylbenzene as excluded from the conditions of Schedule 5. (S5)

Bevonium metilsulfate.

Bifonazole, when intended for application to the skin.

Bioallethrin.

Biologicals, when intended for human use except polyvalent snake antivenom (S2) and except injectable preparations thereof. (S4)

Bitolterol.

Bromhexine.

Bromides; preparations and mixtures thereof containing less than 80 milligrams of bromine as bromide per recommended daily dose. (S5)

Bufexamac, when intended for application to the skin.

Bunamidine.

Butinoline.

Calabar bean alkaloids; substances, preparations and mixtures thereof.

Calcium dobesilate.

Calcium salts; preparations thereof, when intended for injection, except when intended as an animal health product. (S0)

Camylofin.

Cantharidin; substances, preparations and mixtures containing less than 0,01 per cent thereof. (S2)

Canthaxanthin, when intended for medicinal purposes.

Carbocisteine.

Carisoprodol.

Chlorhexedine, when intended for human vaginal use.

Chlorprenaline.

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne; preparations and mixtures containing 5,0 per cent or less of chlorodyne in combination with other active medicinal ingredients. (S6)

Chloroform, except substances, preparations and mixtures containing less than 20 per cent of chloroform.
Chlorzoxazone.
Clanobutin.
Clonidine when intended for treatment of migraine. (S3)
Clotrimazole, when intended for application to the skin. (S2, S4)
Codeine (methylmorphine); preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S6)
Contrast media.
Cyclandelate.
Cyclopentolate, except opthalmic preparations thereof. (S3)
Dapsone and its derivatives, unless listed in another Schedule; preparations and mixtures intended specifically for malaria prophylaxis. (S4)
Dextromethorphan. (S6)
Dialysate preparations.
Diclofenac, when intended for application to the skin. (S2, S3)
Difenoxin (or diphenoxylic acid); mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S6)
Dihydrocodeine; preparations and mixtures when compounded with one or more therapeutically activesubstances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)
Diosmine.
Diphenoxylate; preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S6)
Dithiazanine.
Econazole, when intended for application to the skin. (S2, S4)
Enilconazole.
Ephedra alkaloids, natural or synthetic.
Ergot alkaloids (natural or synthetic), when intended for the treatment of migraine. (S4)
Escin (aescin); medicinal preparations and mixtures thereof intended for application to the skin and containing 1,0 per cent or less of escin. (S3)
Ether (diethyl ether); all substances, preparations and mixtures containing more than 20 per cent of ether.
Ethylmorphine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S6)
Ethylphenylephrine.
Etofenamate, when intended for application to the skin.
Exalamide.
Fedrilate.
Felbinac, when intended for application to the skin.
Fenbendazole, except when registered as an animal health product for use as a anthelmintic.(S0)
Fenticonazole, when intended for application to the skin.
Flavoxate.
Flubendazole, except when registered an animal health product intended as a anthelmintic for pigs.(S0)

Flurbiprofen, when intended for application to the skin, including by transdermal patch, provided that in the case of application by transdermal patch-

(a) each package is accompanied by an approved patient information leaflet;

(b) indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks. (S2,S3, S4)

Flucytosine, when intended for application to the skin. (S4)

Flufenamic acid, when intended for application to the skin. (S3)

Fluorescein, when intended for ophthalmic use.

Fluorides; oral medicinal preparations and mixtures thereof containing 0,25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another Schedule. (S4)

Gadopentetic acid.

Gamma benzene hexachloride; human medicinal preparations and mixtures containing more than 1,0 per cent thereof, when intended for application to the skin.

Gelsemium alkaloids; substances, preparations and mixtures thereof.

Glycopyrronium.

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester) when intended for application to the skin. (S4)

Halogenated hydroxyquinolines, when intended for application to the skin. (S4)

Hexametazine.

Homatropine; preparations and mixtures thereof, except ophthalmic preparations. (S3)

Hormones (Natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, when intended for application to the skin or for human vaginal use. (S2, S3, S4, S5)

Hydrocortisone and hydrocortisone acetate, when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin and hydrocortisone in a maximum concentration of 1,0 per cent used in combination with miconazole for topical application in the treatment of athlete's foot. (S4)

O-(β-hydroxyethyl)rutosides.

Hyoscine; substances, preparations and mixtures thereof, including transdermal preparations when intended for the prevention of the symptoms of motion sickness.

Ibuprofen, when contained in preparations intended for application to the skin and when used in oral medicinal preparations where the recommended daily dose for adults does not exceed 1,2 grams and that for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body mass, except when intended for treatment of inflammatory joint diseases. (S2,S3)

Idoxuridine, when intended for application to the skin. (S4)

Indanazoline.

Indomethacin, when intended for application to the skin. (S2, S3)

Injections, unless listed in another Schedule, except when intended as an animal health product.(S0)

Iopromide.

Ipratropium bromide.

Irrigation fluids.

Isoaminile.

Isoconazole, when intended for application to the skin. (S2, S4)

Isopropamide.

Ketoconazole, when intended for application to the skin, except preparations and mixtures containing not more than 1,0 per cent of ketaconazole, when intended for the prevention and treatment of dandruff. (S0,S4)

Ketoprofen, when intended for application to th skin. (S2, S3)

Ketotifen.

Lactobacillus acidophilus and Lactobacillus bifidus, when intended for therapeutic purposes except when intended as an an animal health product. (S0)

Lithium salts, when intended for application to the skin. (S5)
Lobelia alkaloids; substances, preparations and mixtures thereof.
Local anaesthetics, except when intended for ophthalmic and for parenteral use. (S2, S4)
Lodoxamide.
Loperamide.
Lufenuron, except when registered an animal health product intended as a systemic preparation against fleas.(S0)
Luxabendazole, except when intended as an animal health product for use as a anthelmintic for sheep, goat and cattle. (S0)
Lysozyme, when intended for application to the skin. (S4)
Malathion; except when registered as an animal health product for use as an ectoparasiticide. (S0)
Manganese salts, preparations thereof for injection, when intended for veterinary use.
Mebendazole, except when registered as an animal health product for use as a anthelmintic. (S0)
Mebeverine.
Mepenzolate bromide.
Mercuric ammonium chloride.
Mercuric chloride.
Mercuric iodide.
Mercuric oxides; substances, preparations and mixtures thereof, except those containing less than 3 per cent of mercury.
Mercury organic compounds; substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes and substances, preparations and mixtures containing the equivalent of 0,6 per cent or more of elemental mercury, intended for application to the skin and mucous membranes, except phenylmercuric nitrate when intended as an animal health product.(S0)
Mesna, except preparations intended for injection. (S4)
Methenamine (hexamine), except when intended for application to the skin and except when registered as an animal health product, for use as an urinary tract antiseptic. (S0)
Methionine, when intended for medicinal purposes.
Methocarbamol, when intended for medicinal purposes.
Methoxyphenamine.
Methixene.
Miconazole when intended for application to the skin. (S2, S4)
Microfibrillar collagen hydrochloride.
Morantel citrate, except when registered as an animal health product for use as a anthelmintic for sheep, goat and cattle. (S0)
Morphine; mixtures containing 0,2 per cent or less of morphine, calculated as anhydrous morphine. (S6)
N-acetyl-aspartyl-glutamic acid.
Naphazoline, when intended for nasal use.
Naproxen, when intended for application to the skin and the sodium salt, when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours. (S2, S3)
Nedocromil.
Nicergoline.
Nicotine, when intended for human medicinal use.
Nitrofurantoin, when intended for application to the skin. (S4)
Nitrofurazone, when intended for application to the skin. (S4)
Norcodeine; preparations and mixtures when compounded with one or more therapeutically

active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Noscapine.

Nux vomica; substances, preparations and mixtures thereof, except when intended as an animal health product. (S0)

Octatropine methylbromide.

Oleoresin of aspidium (Filix Mas).

Opium; mixtures containing not more than 0,2 per cent of morphine, calculated as anhydrous morphine. (S6)

Ornidazole, when intended for application to the skin. (S4)

Orthodichlorobenzene, when intended for human medicinal use.

Oxibendazole, except when intended as an animal health product. (S0)

Oxymetazoline, when intended for nasal use.

Oxyphencyclimine.

Oxyphenonium.

Papaverine; substances, preparations and mixtures thereof.

Paracetamol

(1) substances, preparations and mixtures, **except-**

(a) in tablets or capsules each containing 500 milligrams or less of paracetamol, when-

(i) packed in blister strip packaging or in containers with child-resistant closures;

(ii) in a primary pack containing not more that 25 such tablets or capsules;

(iii) the primary pack is labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

CONTAINS PARACETAMOL-READ THE PACKAGE INSERT;

(b) in individually wrapped powders or sachets containing 1000 milligrams or less of paracetamol, when-

(i) in a primary pack containing not more that 12 such powders or sachets;

(ii) the primary pack is labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

CONTAINS PARACETAMOL-READ THE PACKAGE INSERT;

(c) in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres, when-

(i)in a primary pack containing not more than 100 millilitres;

(ii) the primary pack is labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

CONTAINS PARACETAMOL-READ THE PACKAGE INSERT.;

(2) when contained in rectal suppositories.

Paradichlorobenzene, when intended for human medicinal use.

Penciclovir, when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S4)

Pentosan polysulfate sodium, except when intended for the treatment of interstitial cystitis. (S3)

Pentoxifylline.

Phenazopyridine.

Phenylbutazone and its derivatives, when intended for application to the skin, unless listed in another Schedule. (S4)

Phenylephrine, except ophthalmic preparations containing 0,2 per cent or less of phenylephrine.

Phenylpropanolamine; preparations and mixtures where the recommended daily dose for adults does not exceed 150 milligrams and for children 6 to 12 years, 75 milligrams, when

intended for the symptomatic relief of nasal and sinus congestion. (S2)
Pholcodine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit. (S6)
Pholedrine.
Phospholipids, when applied for therapeutic purposes.
Pinaverium.
Pipenzolate.
Pipoxolan.
Pizotifen; preparations and mixtures, when intended forprophylaxis of migraine (S5)
Podophyllum resin; preparations and mixtures containing 20 per cent or less thereof. (S4)
Poldine methylsulphate.
Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1500 milligrams of potassium chloride) per 24 hours and when intended for intravenous infusion or for injection, but except when contained in oral rehydration preparations.
Prifinium bromide.
Procaine hydrochloride, when intended for oral administration.
Procyclidine.
Proglumide.
Proguanil.
Promethazine when intended for application to the skin. (S2, S5)
Propantheline bromide.
Propentofylline, when intended for veterinary use.(S4)
Propyphenazone.
Propylhexedrine, when used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S4)
Proteolytic (fibrinolytic) enzymes for oral use and when intended for application to the skin, unless listed in another Schedule, and except when intended for injection and except when intended for soft contact lens cleaners. (S4)
Pyrantel pamoate, when intended for veterinary use, except when intended as an animal health product intended as a anthelmintic. (S0)
Pyridoxilate.
Pyrodifenium.
Quinine; preparations and mixtures containing more than 1,0 per cent thereof.
Rabies vaccine, killed or inactivated, for veterinary use, except when intended as an animal health product. (S0)
Sabadilla alkaloids; substances, preparations and mixtures containing 1,0 per cent or more thereof.
Siccanin, when intended for application to the skin.
Sodium cromoglycate, except when intended for veterinary use. (S4)
Strychnine; preparations and mixtures containing 0,2 per cent or less thereof, except the substance. (S4)
Sulphonamides, when intended for application to the eyes, nares and vagina, (S4), except when intended as an animal health product. (S0)
Terbinafine, when intended for application to the skin. (S4)
Tetrahydrozoline, when intended for nasal use.
Thiabendazole, when intended for application to the skin. (S0, S4)
Thiram, except when registered as an animal health product for use as a fungiside.(S0)
Ticlatone.
Timepidium.
Tioconazole, when intended for application to the skin. (S2, S4)
Tolmetin, when intended for application to the skin. (S3)

Triamcinolone, when intended for application to oral lesions. (S4)
Trimebutine.
Trospium chloride. (formerley listed as "AS XVII")
L-tryptophan when intended for medicinal use as supplementation for nutritional purposes. (S5)
Tuberculin, when intended for human use. (S4)
Vaccines, when intended for human use. (S4)
Xylometazoline, when intended for nasal use.
Zinc salts, preparations thereof for injection, when intended for veterinary use. (S3)

ANNEXURE A

Substances which nurses may keep, prescribe and supply in terms of Section 31(4)(a)(v) and 33(1)(a) to patients under their care, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document reflected below.

Only those Schedule 1 substances and medicines which appear in the Essential Drug List (EDL).

- END SCHEDULE 1 -

Schedule 2

PHARMACY PRESCRIPTION MEDICINES

(*a*) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food, or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) or the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and

(ii) analytical laboratory purposes.

(*b*) All substances referred to in this Schedule include the following:

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

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

(*c*) In terms of Section 31(4)(a)(v) and 33(1)(a), nurses may use, keep, prescribe and supply to patients under their care, the Schedule 2 substances and medicines provided for in Annexure A of this Schedule, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document likewise reflected in Annexure A. Annexure A appears at the end of this Schedule.

Acrivastine.

Alverin.

Amobarbital, cyclobarbital and pentobarbital; preparations and mixtures thereof containing 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 50 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S5, S6)

Amyl nitrate

Antihistaminics, when in combination with central nervous system depressants (excluding alcohol when present as an excipient) (S0,S1,S4,S5)

Antimicrobial substances, namely griseofulvin, mupirocin, natamycin and nystatin, when intended for application to the skin, nares and external ear, as well as nystatin oral drops and nystatin when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, as excluded from the conditions of Schedule 4. (S1, S4)

Arsenic; substances, preparations and mixtures containing the equivalent of 0,01 per cent or more of arsenic trioxide. (S1)

Azelastin.

Bambuterol.

Beclomethasone dipropionate, when intended for nasal administration (other than by aerosol), in the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to-

(a)a maximum dose of 100 micrograms per nostril;

(b)a maximum daily dose of 200 micrograms per nostril;

(c)a pack size limit of 200 doses. (S3, S4).

Bismuth, when intended for oral use.

Camphorated Opium Tincture BP.

Cantharidin; substances, preparations and mixtures containing 0,01 per cent or more thereof. (S1)

Carbuterol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Cathine ((+)-norpseudoephedrine); preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S6)

Cetirizine.

Chlormezanone; mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S5)

Cholestyramine.

Cimetidine, when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to-

(a)a maximum dose of 200 milligrams;

(b)a maximum daily dose (per 24 hours) of 800 milligrams;

(c)a maximum treatment period of 2 weeks. (S3)

Clidinium bromide.

Clotrimazole, when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1, S4)

Colchicine, in cases of emergency. (S3)

Diclofenac, when supplied by a pharmacist to a patient and intended for -

a) the emergency treatment of acute gout attacks;

b) the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3)

Dicyclomine.

{D-norpseudoephedrine – see cathine}

Domperidone.

Econazole, when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1, S4)

Emepronium.

Etilefrine.

Famotidine, when intended for the short-term symptomatic relief of heartburn caused by excess acid, subject to-

(a) a maximum dose of 10 milligrams;

(b) a maximum daily dose (per 24 hours) of 20 milligrams;

(c) a maximum treatment period of 2 weeks. (S4)

Fenoprofen, when supplied by a pharmacist to a patient and intended for -

a) the emergency treatment of acute gout attacks;

b) the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Fenoterol, except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour. (S4)

Flunisolide, when intended for nasal administration, **other than by aerosol** in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, **subject to-**

(a) a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over the age of 16 years;

(b) a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in the case of children 12 to 16 years of age; and

(c) a pack size containing not more than 240 doses. (S3, S4)

Flurbiprofen, when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3, S4)

Formoterol.

Furazolidone.

Hexoprenaline, except when contained in respirator solutions (S3) and except when intended for

injection or for the prevention or delay of labour. (S4)

Hormones (Natural or synthetic, including recombinant forms), oral contraceptives containing only progestogen. (S0, S1, S3, S4)

Hydroquinone; preparations and mixtures containing 2 per cent or less thereof, when intended for application to the skin. (S3)

Ibuprofen in oral medicinal preparations, when supplied by a pharmacist to a patient and intended for -

a) the emergency treatment of acute gout attacks;

b) the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3)

Indomethacin, when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks. (S1, S3)

Insulin, in cases of emergency. (S3)

Isoconazole, when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1, S4)

Isoprenaline (isoproterenol), except when contained in respirator solutions (S3) and except when intended for injection. (S4).

Isosorbide, in cases of emergency. (S3)

Ketoprofen, where the maximum dose is 100 milligrams, when supplied by a pharmacist to a patient and intended for -

a) the emergency treatment of acute gout attacks;

b) the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3)

Loratadine.

Mefenamic acid, when -

b) intended for the treatment of primary dysmenorrhoea with preparations containing mefenamic acid as the only therapeutically active substance, and where the maximum daily dose is 500 millligrams 3 times a day and the maximum treatment period is 3 days;

a) supplied by a pharmacist to a patient and intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Mephenesin.

Miconazole, when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, and when intended for human use in preparations containing 2 per cent or less of miconazole, for the topical treatment of fungal infections of the mouth (oral candidiasis). (S1, S4)

Minoxidil, when intended for application to the scalp. (S4)

Nabumetone, when when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Naproxen, when supplied by a pharmacist to a patient and intended for -

a) the emergency treatment of acute gout attacks;

b) the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3)

Nefedipine when intended for the emergency treatment of angina (S3)

Nitroglycerine, when intended for medicinal use in cases of emergency. (S3)

Nizatidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to-

(a)a maximum dose of 150 milligrams;

(b)a daily dose of 300 milligrams

(c)a maximum treatment period of two weeks. (S4)

Olopatadine.

Orciprenaline (metaproterenol), except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour (S4)

Orphenadrine.
Otilonium bromide.
Oxybuprocaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4)
Pentaerythritol tetranitrate, in cases of emergency. (S3)
Phenylpropanolamine, except preparations and mixtures where the recommended daily dose for adults does not exceed 150 milligrams and for children 6 to 12 years, does not exceed 75 milligrams, when intended for the symptomatic relief of nasal and sinus congestion. (S1)
Pirbuterol, except when contained in respirator solutions. (S3)
Piroxicam, when supplied by a pharmacist to a patient and intended for -
a) the emergency treatment of acute gout attacks;
b) the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)
Polyvalent snake antivenom.
Procaterol, except when contained in respirator solutions. (S3)
Promethazine; preparations and mixture when intended specifically for the treatment of travel sickness. (S1, S5)
Proxymetacaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4)
Ranitidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to-
(a)a maximum dose of 75 milligrams;
(b)a daily dose of 300 milligrams
(c)a maximum treatment period of two weeks. (S3)
Reproterol, except when contained in respirator solutions. (S3)
Rimiterol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)
Salbutamol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)
Salmefamol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)
Salmeterol.
Silver sulphadiazine, when intended for application to the skin in the short term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams. (S4)
Terbutaline, except when contained in respirator solutions. (S3)
Tetracaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4)
Theophylline and its derivatives, unless listed in another Schedule, except preparations for injection. (S4)
Tiaprofenic acid, when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)
Tioconazole, when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1, S4)
Tulobuterol, except when contained in respirator solutions. (S3)

ANNEXURE A

Substances which nurses may keep, prescribe and supply in terms of Section 31(4)(a)(v) and 33(1)(a) to patients under their care, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document reflected below.

Only those Schedule 2 substances and medicines which appear in the Essential Drug List (EDL).

Schedule 3

FREQUENTLY REPEATED PRESCRIPTION MEDICINES

(*a*) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food, or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) or the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and

(ii) analytical laboratory purposes.

(*b*) All substances referred to in this Schedule include the following:

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

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

(*c*) In terms of Section 31(4)(a)(v) and 33(1)(a), nurses may use, keep, prescribe and supply to patients under their care, the Schedule 3 substances and medicines provided for in Annexure A of this Schedule, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document likewise reflected in Annexure A. Annexure A appears at the end of this Schedule.

Acamprosate.
Acebutolol.
Acetazolamide.
Acetohexamide.
Acetylcholine, when intended for ophthalmic use.
Acipimox.
Adapalene.
Adrenaline (epinephrine); ophthalmic preparations thereof, when intended for glaucoma. (S1, S2, S4)
Alclofenac.
Alendronic acid.
Allopurinol.
Alprenolol.
Amiloride.
Amlodipine.
Ancrod.
Anthiolimine, when intended for injection.
Arsanilic acid.
Atenolol.
Atropine; ophthalmic preparations thereof. (S1, S2)
Azapropazone.
Beclamide.
Benazepril.
Bendazac.
Benfluorex.
Benoxaprofen.

Benzbromarone.
Benzydamine, except preparations and mixtures containing 3 per cent or less of benzydamine, when intended for application to the skin and for use as a mouth rinse. (S1)
Bepridil.
Beta-benzalbutyramide.
Beta-galactosidase, when intended for therapeutic purposes.
Betahistine.
Betaxolol.
Bethanidine.
Bevantolol.
Bezafibrate.
Bisoprolol.
Bopindolol.
Brimonidine.
Buflomedil.
Buformin.
Bumetanide.
Candesartan.
Cadralazine.
Calcipotriol.
Calcium carbimide.
Calcium disodium edetate, when intended for injection.
Captopril.
Carazolol.
Carbachol; ophthalmic preparations thereof when intended for glaucoma. (S4)
Carbamazepine.
Carbenoxolone, except when intended for application to the oral mucosa.
Carbuterol, when contained in respirator solutions. (S2, S4)
Carprofen.
Carteolol.
Carvedilol.
Celiprolol.
Chenodeoxycholic acid.
Chlorazanil.
Chlorexolone.
Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide-1,1-dioxide, whether hydrogenated or not, including hydrochlorothiazide, bendrofluazide, benzthiazide, cyclopenthiazide, hydroflumethiazide, metchlorothiazide and polythiazide.
Chlorpropamide.
Chlorthalidone.
Colestipol.
Chromonar.
Cilazapril.
Cimetidine, except when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, where the maximum dose is 200 milligrams, the maximum daily dose (per 24 hours) is 800 milligrams and the maximum treatment period is 2 weeks. (S2)
Clofibrate.
Clonidine, except when intended for the treatment of migraine. (S1)
Clopidogrel.
Colchicine, except in cases of emergency. (S2)
Copper salts, when intended for injection.
Corticosteroids (natural or synthetic), when contained in preparations intended for inhalation, except-

(a)beclomethasone dipropionate, when intended for nasal administration, other than by aerosol, indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, where the maximum dose per nostril is 100 micrograms, the maximum daily dose per nostril is 200 micrograms and the pack size is limited to 200 doses;

(b)flunisolide, when intended for nasal administration, other than by aerosol, in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, where in the case of adults and children over the age of 16 years, the maximum dose per nostril is 50 micrograms and the maximum daily dose per nostril is 100 micrograms and in the case of children 12 to 16 years, the maximum dose per nostril is 25 micrograms and the maximum daily dose per nostril is 75 micrograms and the pack size is limited to 240 doses. (S2, S4, S5)

Cyclopentolate; ophthalmic preparations thereof. (S2)

Debrisoquine.

Delapril.

Dichlorphenamide.

Diclofenac, except when intended for application to the skin, (S1) and except when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Diflunisal.

Diftalone.

Digitalis; its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams.

Dihydroergocristine.

Dilevalol.

Diltiazem.

Dimercaprol, when intended for injection.

Dipivefrin.

Dipyridamole.

Dipyrocetyl.

Disulfiram.

Dithranol.

Dornase alfa (rh DNase).

Dorzolamide.

Doxazosin.

Enalapril.

Endralazine.

Eprosartan.

Escin (aescin), except preparations and mixtures thereof intended for application to the skin and containing 1,0 per cent or less of escin. (S1)

Esculin, when intended for oral use.

Esmolol.

Ethacrynic acid.

Ethambutol.

Ethionamide, when intended for oral use.

Ethosuximide.

Etisazol.

Etodolac.

Etodolic acid.

Felbamate.

Felodipine.

Fenbufen.

Fenclofenac.
Fendiline.
Fenofibrate.
Fenoprofen, except when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Fenoterol, when contained in respirator solutions. (S2, S4)
Fentiazac.
Floctafenine.
Flufenamic acid, except preparations and mixtures intended for application to the skin. (S1)
Flunixin.
Flurbiprofen, except -

(a) when intended for ophthalmic use; (S4)
(b) when intended for application to the skin, including application by transdermal patch, provided that in the case of application by transdermal patch, each package is accompanied by an approved patient information leaflet and indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks; (S1)
(c) when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Fosinopril.
Furosemide.
Gabapentin.
Gemfibrozil.
Glafenine.
Glibenclamide.
Glibornuride.
Gliclazide.
Glimepiride.
Glimidine.
Glipizide.
Glucosamine, substances, preparations and mixtures when intended for the treatment of primary and secondary osteoarthritis, osteochondrosis and spondylosis.
Guanabenz.
Guanethidine.
Guanfacine.
Guanoxan.
Hexoprenaline, when contained in respirator solutions. (S2, S4)
Homatropine; ophthalmic preparations thereof. (S1, S2)
Hormones (natural or synthetic, including recombinant forms), when intended for oral contraception, except oral contraceptives containing only progestogen. (S0, S1, S2, S4)
Hydralazine.
Hydroquinone; preparations and mixtures thereof containing more than 2,0 per cent hydroquinone. (S2)
Ibuprofen, including ibuprofen when specifically intended for the treatment of inflammatory joint diseases, but excluding ibuprofen -

a) when contained in preparations intended for application to the skin and when used in oral medicinal preparations, not intended for the treatment of inflammatory joint disease, where the recommended daily dose for adults does not exceed 1,2 grams and that for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body mass; (S1)
b) in oral medicinal preparations supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or when intended for the treatment of

post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Indapamide.

Indomethacin, except when intended for application to the skin, (S1) and except when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks.(S2)

Indoprofen.

Indoramin.

Insulin, except in cases of emergency. (S2)

Irbesartan.

Iron salts, when intended for injection, except when intended as an animal heal product for injection in cattle, sheep and goats. (S0)

Isoniazid and its derivatives, unless listed in another Schedule.

Isoprenaline (isoproterenol), when contained in respirator solutions. (S2, S4)

Isosorbide, except in cases of emergency. (S2)

Isoxicam.

Isradipine.

Ivermectin, except when registered as an animal health product for use as an anthelmintic and/or endectocide. (S0)

Ketanserin.

Ketoprofen, except -

a) when intended for application to the skin (S1)

b) where the maximum dose is 100 milligrams and supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Ketorolac trometamol, when intended for ophthalmic use. (S4)

Labetalol.

Lacidipine.

Lamotrigine.

Lercanidipine.

Levobunolol.

Lidoflazine.

Lisinopril.

Lonazolac.

Lornoxicam.

Losartan.

Meclofenamic acid.

Mefenamic acid, except -

a) when intended for the treatment of primary dysmenorrhoea with preparations containing mefenamic acid as the only therapeutically active substance, and where the maximum daily dose is 500 milligrams 3 times a day and the maximum treatment period is 3 days; (S2)

b) when supplied by a pharmacist to a patient and intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Meloxicam.

Mepindolol.

Mesalazine (5-aminosalicylic acid).

Mesulphene.

Metformin.

Methazolamide.

Methimazole.

Methsuximide.

Methyldopa and its esters.
Metipranolol.
Metolazone.
Metoprolol.
Metronidazole, when intended for application to the skin. (S4)
Mibefradil.
Moexipril.
Montelukast.
Moxonidine.
Nabumetone, except when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Nadolol.
Naftidrofuryl.
Naproxen, except -
(a) when intended for application to the skin; (S1)
(b) the sodium salt, when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours; (S1)
(b) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Nicardipine.
Nifedipine.
Niflumic acid.
Nimodipine.
Nisoldipine.
Nitrendipine.
Nitroglycerine, when intended for medicinal use, except in cases of emergency. (S2)
Olsalazine.
Orciprenaline (metaproterenol), when contained in respirator solutions (S2, S4)
Orlistat.
Oxaprozin.
Oxcarbazepine.
Oxitracetam.
Oxovinca.
Oxyprenolol.
Oxybutynin.
Para-aminosalicylic acid and its esters.
Penbutolol.
Penicillinase, when intended for injection.
Pentaerythritol tetranitrate, except in cases of emergency. (S2)
Pentolinium.
Pentosan polysulfate sodium, when intended for the treatment of interstitial cystitis. (S1)
Perindopril.
Phenformin.
Phenoxymethylpenicillin, when intended for the prophylaxis of rheumatic fever. (S4)
Phentolamine.
Phenytoin.
Physostigmine; ophthalmic preparations thereof, when intended for glaucoma. (S4)
Pilocarpine; ophthalmic preparations thereof intended for glaucoma. (S4)

Pindolol.
Piracetam.
Pirbuterol, when contained in respirator solutions. (S2)
Piretanide.
Piroxicam, except when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Pirprofen.
Potassium canrenoate.
Practolol.
Prazosin.
Primidone.
Probenecid.
Probucol.
Procaterol, when contained in respirator solutions. (S2)
Proctofene.
Propacetamol.
Propranolol.
Proquazone.
Proscillaridine.
Prothionamide, when intended for oral use.
Pygeum africanum (lipido-sterolic complex extract thereof).
Pyrazinamide, when intended for oral use.
Pyrithioxin.
Quinapril.
Raloxifene.
Ramipril.
Ranitidine, except where administered orally for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 75 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S2)
Raubasine.
Rauwolfia alkaloids.
Repaglinide.
Reproterol, when contained in respirator solutions. (S2, S4)
Reserpine (natural or synthetic).
Rimiterol, when contained in respirator solutions. (S2, S4)
Roxarzone (3-nitro-4-hydroxyphenylarsonic acid), when intended for veterinary use.
Salbutamol, when contained in respirator solutions. (S2, S4)
Salmefamol, when contained in respirator solutions. (S2, S4)
Solcoseryl; ophthalmic preparations thereof. (S0, S4)
Sotalol.
Spirapril.
Spironolactone.
Strophanthus; its glycosides and their hydrolysis products, and their derivatives, unless listed in another Schedule.
Sulindac.
Suloctidil.
Sulphinpyrazone.
Sulthiame.
Suprofen.
Sylimarin.
Tasosartan.
Tazarotene.

Telmisartan.
Tenidap.
Tenoxicam.
Terazosin.
Terbutaline, when contained in respirator solutions. (S2)
Terizidone.
Terodiline.
Thiacetazone.
Thyroid gland and its active principles and derivatives, unless listed in another Schedule.
Tiaprofenic acid, except when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)
Ticlopidine.
Timolol.
Tolamolol.
Tolazamide.
Tolbutamide.
Tolfenamic acid.
Tolmetin, except when intended for application to the skin. (S1)
Tolterodine.
Topiramate.
Torasemide.
Trandolapril.
Tretinoin.
Triamterene.
Tricaine.
Trimethadione.
Tropicamide.
Tulobuterol, when contained in respirator solutions. (S2)
Ursodeoxycholic acid.
Vedaprofen.
Valproic acid and its derivatives, unless listed in another Schedule.
Valsartan.
Verapamil (iproveratril).
Veratrum alkaloids.
Vigabatrin.
Vincamine.
Vinpocetine.
Vitamin A; preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 I.U. per recommended daily dose, except when intended as an animal health product (S0)
Vitamin D; preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 I.U. per recommended daily dose, except when intended as an animal health product (S0)
Xamoterol.
Xipamide.
Zafirlukast.
Zinc salts for oral ingestion where the daily dose is more than 50 milligrams of elemental zinc (S1), except when intended as an animal health product.(S0)
Zomepirac.

ANNEXURE A

Substances which nurses may keep, prescribe and supply in terms of Section 31(4)(a)(v) and 33(1)(a) to patients under their care, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document reflected below.

Only those Schedule 3 substances and medicines which appear in the Essential Drug List (EDL).

- END SCHEDULE 3 -

Schedule 4

MAIN GROUP MEDICINES

(*a*) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food, or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) or the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and

(ii) analytical laboratory purposes.

(*b*) All substances referred to in this Schedule include the following:

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

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

(*c*) In terms of Section 31(4)(a)(v) and 33(1)(a), nurses may use, keep, prescribe and supply to patients under their care, the Schedule 4 substances and medicines provided for in Annexure A of this Schedule, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document likewise reflected in Annexure A. Annexure A appears at the end of this Schedule.

Acarbose.
Acetarsone diethylamine salt, when intended for injection.
Acitretin
Acyclovir, except when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)
Adenosine.
Adrenaline, when intended for injection. (S1, S2, S3)
Albendazole, except when intended as an animal health product as an anthelmintic. (S0)
Alcuronium.
Alfuzosin.
Alisapride.
Almitrine.
Alphacalcidol, except when intended as an animal health product. (S0)
Alphachymotrypsin, when intended for ophthalmic use.
Alprostadil.
Amantadine.
Amifostine.
Aminoglutethimide.
Aminopyrine (amidopyrine).
Amiodarone.
Amiphenazole.
Amrinone.
Amsacrine.
Anagrelide.
Anastrozole.
Androstanolone.
Androstenediol.

Anticoagulants, except preparations intended for application to the skin. (S1)
Antihemophilic factor.
Antimalarials, excluding the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds and preparations thereof, when these are intended specifically for malaria prophylaxis. (S1)
Antimicrobial substances (chemotherapeutic substances) synthesised in nature or the laboratory, being substances used in the specific treatment of infections, except the following when intended for topical application to the epidermis, nares and external ear:
Bacitracin; (S1)
gramicidin; (S1)
griseofulvin; (S2)
mupirocin; (S2)
natamycin; (S2)
nystatin; (S2)
polymyxin B; (S1)
tyrothricin; (S1)
and except when intended for use as germicides and antiseptics, and except nystatin oral drops (S2) and except nystatin when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S2), and except henoxymethylpenicillin when intended for the prophylaxis of rheumatic fever (S3) and except the antimicrobial substances listed in Annexure A of Schedule 0, when contained in medicines prepared in a recognised pharmaceutical dosage form which are specifically intended and registered as animal health products, for use as indicated in that Schedule. (S0)
Antisera, when intended for veterinary use except when intended as an animal health product.(S0)
Apraclonidine.
Aprotinin.
Arabinosylcytosine.
Arprinocid, except when intended for use as an animal health product for use as an anticoccidial preparation for poultry. (S0)
Arsenamide, when intended for injection.
L-asparaginase.
Astemizole.
Atipamezole.
Atorvastatin.
Atovaquone.
Atracurium besilate.
Auranofin.
Azathioprine.
Baclofen.
Basiliximab.
Bee venom, except preparations intended for application to the skin. (S0)
Bemegride.
Bethanechol.
Biologicals, injectable preparations thereof, when intended for human use, except tuberculin when intended for human use and except vaccines when intended for human use, and except polyvalent snake antivenom. (S1, S2)
Biperiden.
Bleomycin.
Bolandiol.
Bolasterone.
Boldenone.
Bretylium tosylate.

Bromocriptine.
Bufenoide.
Bumadizone.
Buserelin.
Busulphan.
Cabergoline.
Calcitonin.
Calcitriol.
Calcium polystyrene sulphonate, when intended for therapeutic purposes.
Cambendazole.
Capecitabine.
Carbachol, except ophthalmic preparations thereof, when intended for glaucoma. (S3)
Carbidopa.
Carboplatin.
Carbuterol, when intended for injection. (S2, S3)
Carmustine.
Cerivastatin.
Ceruletide.
Chlorambucil.
Chlordantoin, when intended for human vaginal use.
Chloroquine, when intended for antirheumatic use. (S1)
Chymopapain, when intended for injection.
Cisapride.
Cisatracurium.
Cisplatin.
Cladribine.
Clazuril, except when intended as an animal health product for use as an anticoccidial preparation for poultry. (S0)
Clenbuterol.
Clofazimine.
Clomiphene.
Closantel, except when intended as an animal health product for use as an anthelmintic for sheep and cattle. (S0)
Clostebol.
Clotrimazole, except when intended for application to the skin (S1) and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Colfosceril.
Corticosteroids (natural or synthetic), unless listed in another Schedule, except -

a) hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin; (S1)
b) hydrocortisone in a maximum concentration of 1,0 per cent used in combination with miconazole for topical application in the treatment of athlete's foot; (S2)
c) triamcinolone when intended for application to oral lesions; (S1) and
d) when contained in preparations intended for inhalation. (S2, S3)

Cotetroxazine.
Co-trimoxazole.
Cyclofenil.
Cyclophosphamide and its derivatives, unless listed in another Schedule.
Cyclosporin.
Cyprenorphine.
Cyproterone acetate.
Cytarabine.

Dacarbazine.
Dactinomycin (actinomycin D).
Danazol
Dantrolene.
Dapsone and its derivatives, unless listed in another Schedule, except preparations and mixtures intended specifically for malaria prophylaxis. (S1)
Daunomycin (daunorubicin).
Deferoxamine.
Dehydrochloromethyltestosterone
Demecarium.
Desirudin.
Diazoxide.
Dichlorophen, except preparations and mixtures when intended for application to the skin, except when intended as an animal health product. (S0)
Diclazuril, except when intended as an animal health product. (S0)
Diclodronic acid.
Didanosine.
Diethylcarbamazine.
Dihydralazine.
Dihydrotachysterol.
Di-isopropyl fluorophosphate.
Dilazep.
Diloxanide furoate.
Dimethyl sulphoxide.
Diminazene, except when intended as an animal health product for use as a antibabesial. (S0)
Dinitrophenol.
Dinoprostone.
Diphemethoxidine.
Diphenidol.
Diprenorphine.
Disodium pamidronate.
Disophenol, except when intended as an animal health product for use as an anthelmintic for sheep and goats.(S0)
Disopyramide.
Distigmine.
Ditazole.
Dobutamine.
Docetaxol.
Dolasetron.
Dopa.
Dopamine.
Doxapram.
Doxorubicin.
Drostanolone.
Econazole, except when intended for application to the skin (S1) and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Edoxudine.
Edrophonium.
Emetine, except substances, preparations and mixtures containing less than 0,2 per cent of alkaloids, calculated as emetine.
Encainide.
Enoxacin.

Enrofloxacine.
Entacapone.
Epirubicin. (4-epidoxorubicin)
Epitiostanol.
Ergot alkaloids (natural or synthetic), except preparations and mixtures thereof when intended for the treatment of migraine. (S1)
Estramustine.
Etidronate.
Etiproston.
Ethoglucid.
Ethylestrenol.
Etofamide.
Etoposide.
Famciclovir.
Famotidine, except when intended for the symptomatic relief of hearburn caused by excess acid, where the maximum dose is 10 milligrams, the maximum daily dose (per 24 hours) is 20 milligrams and the maximum treatment period is 2 weeks.(S2)
Fazadinium.
Febantel, except when intended as an animal health product.(S0)
Fenchlorphos.
Fenoterol, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)
Fenticonazole.
Fertirelin.
Filgrastim.
Finasteride.
Flecainide.
Flosequinan.
Fluconazole.
Flucytosine, except preparations and mixtures intended for application to the skin. (S1)
Fludarabine.
Flugestone.
Flunisolide.
5-fluorouracil.
Fluoxymesterone.
Flurbiprofen, when intended for ophthalmic use. (S1, S2, S3)
Flutamide.
Fluvastatin.
Formebolone.
Fotemustine.
Ftorafur.
Furazabol.
Gallamine.
Ganciclovir.
Gemcitabine.
Gestrinone.
Glatiramer.
Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester), except when intended for application to the skin. (S1)
Goserelin.
Granisetron.
Halofantrine.
Halofenate.
Halofuginone, except when intended as an animal health product for use as an anticoccidial

preparation for poultry. (S0)
Halogenated hydroxyquinolines, except when intended for application to the skin, (S1) and except di-iodohydroxyquinolone when intended as an animal health product for use as an anticoccidial preparation. (S0)
Hemin.
Heptaminol.
Hexoprenaline, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)
Hormones (natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, unless listed in another Schedule, except-
(a) when intended for application to the skin; (S1)
(b) when intended for human vaginal use; (S1)
(c) when intended for oral contraception; (S2, S3)
(d) insulin; (S2, S3)
(e) epinephrine (adrenaline); (S1, S2, S3 S4)
(f) corticotrophin (adrenocorticotrophic hormone; ACTH); (S5)
(g) human growth hormone (human somatotropin)-all forms; (S5)
(h) zeranol, natural oestrogen, and progesterone, when intended as an animal health product intended for production improvement in cattle and sheep; (S0)
(i) BST, when intended as an animal health product. (S0)
Hyaluronidase.
Hyaluronic acid and its derivatives.
Hylan.
Hycanthone.
Hydroxyurea.
Ibandronic Acid.
Ibutilide.
Idarubicin.
Idoxuridine, except when intended for application to the skin. (S1)
Iloprost.
Imidocarb, except when intended as an animal health product for use as antibabesial or for the treatment anaplasmosis.(S0)
Imiquimod.
Idinavir.
Inosiplex (inosine pranobex).
Interferon alpha.
Interferon beta.
Interferon gamma.
Intra-uterine devices.
Intrifiban.
Irinotecan.
Isepamicin.
Isoconazole, except when intended for application to the skin (S1) and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2)
Isopirin.
Isoprenaline (isoproterenol), when intended for injection. (S2, S3)
Isotretinion.
Isoxsuprine.
Itraconazole.
Ketoconazole, except when intended for application to the skin and except preparations and mixtures containing not more than 1, 0 per cent of ketaconazole, when intended for the prevention and treatment of dandruff. (S0,S1)
Ketorolac trometamol, except when intended for ophthalmic use. (S3)
Lamivudine.

Latanoprost.
Lansoprazole.
Leflunomide.
Letrozole.
Levallorphan.
Levamisole, except when intended as an animal health product for use as an anthelmintic and as an immunostimulator of clostredial vaccination. (S0)
Liarozole.
Local anaesthetics, when intended for ophthalmic and parenteral use, except oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of arc eyes, and except lignocaine when contained in antimicrobial preparations for injection as well as ophthalmic preparations registered as animal health products. (S0)
Lomustine.
Lovastatin.
Lysozyme, except preparations and mixtures when intended for application to the skin. (S1)
Mebolazine
Mecamylamine.
Mefloquin.
Melarsoprol, when intended for injection.
Melphalan and its derivatives, unless listed in another Schedule.
Mephentermine.
Mepirizole.
2-mercaptopropionyl glycine.
6-mercaptopurine and its derivatives, unless listed in another Schedule.
Mercury; preparations and mixtures that contain mercury metal and that are intended for medicinal use.
Mesna, when intended for injection. (S1)
Mesterolone
Metandienone
Metaproterenol (orciprenaline), when intended for the prevention or delay of labour, and preparations thereof for injection. (S2, S3)
Metenolone
Metergoline.
Methacholine.
Methampyrone.
Methandranone.
Methandriol.
Methotrexate.
Methoxsalen.
Mehtyltestosterone.
Methysergide.
Metoclopramide.
Metomidate.
Metronidazole, except where intended for application to the skin. (S3)
Mexiletine.
Mibolerone.
Miconazole, except when intended for application to the skin (S1) and except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, and except when intended for human use in preparations containing 2 per cent or less of miconazole, when intended for the topical treatment of fungal infections of the mouth (oral candidiasis). (S2)
Miglitol.

Milrinone.
Minoxidil, except when intended for application to the scalp. (S2)
Misoprostol.
Mitomycin C.
Mitoxantrone.
Mivacurium.
Mofebutazone.
Molgramostim.
Mometasone.
Moracizine.
Morazone.
Morphazinamide.
Morphethylbutyne.
Mucoglucuronan.
Muromonab.
Mycophenolic acid.
Nalidixic acid.
Nalorphine.
Naloxone.
Naltrexone.
Nandrolone
Naratriptan.
Nefopam.
Nelfinavir.
Neostigmine.
Netobimin.
Nevirapine.
Nicarbazin, except when intended as an animal health product for use as an anticoccidial preparation.(S0)
Nifuratel.
Nikethamide.
Nilutamide.
Nimorazole.
Nimustine.
Niridazole.
Nitrofurantoin, except preparations thereof intended for application to the skin. (S1)
Nitrofurazone, except preparations thereof intended for application to the skin. (S1)
Nitrous oxide gas, alone or in combination with other gasses.
Nitroxoline.
Nitroxynil, except when registered as an animal health product for use as an anthelmintic for sheep, goats and cattle.(S0)
Nizatidine, except where intended for oral administration for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 150 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S2)
Norclostebol.
Norethandronlone.
Obidoxime.
Octreotide.
Omeprazole.
Ondansetron.
Ornidazole, except when intended for application to the skin.(S1)
Oxabolone.
Oxamniquine.

Oxandrolone.
Oxfendazole, except when intended as an animal health product for use as an anthelmintic for sheep, goats and cattle.(S0)
Oxolinic acid.
Oxyclosanide, except when intended as an animal health product for use as an anthelmintic for sheep, goats and cattle. (S0)
Oxymesterone.
Oxymetholone.
Paclitaxel.
Paltitrexid.
Pamidronic acid.
Pancuronium.
Pantoprazole.
Penciclovir, except when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)
Penicillamine.
Pentamidine isethionate.
Pentostatin.
Pergolide.
Perhexiline.
Phenacetin, except preparations and mixtures intended for external use and containing not more than 0,1 per cent phenacetin as stabilizer.
Phenamidine, except when intended as an animal health product for use as an a antibabesial.(S0)
Phenopyrazone.
Phenoxybenzamine.
Phenylbutazone and its derivatives, unless listed in another Schedule, except preparations intended for application to the skin. (S1)
Physostigmine, except ophthalmic preparations thereof when intended for glaucoma. (S3)
Picrotoxin.
Pilocarpine, except ophthalmic preparations thereof intended for glaucoma. (S3)
Pipemidic acid.
Pirenzepine.
Piribedil.
Piromidic acid.
Podophyllum resin; preparations and mixtures containing more than 20 per cent of podophyllum resin. (S1)
Polyglycerylene-dextran.
Potassium dichromate, except preparations and mixtures containing not more than 15 micrograms of potassium dichromate per dosage unit.
Pralidoxime.
Pralidoxime.
Pramipexole.
Prasterone.
Pravastatin.
Praziquantel, except when intended as an animal health product for use as an anthelmintic.(S0)
Procainamide.
Procarbazine.
Propafenone.
Propentofylline, except when intended for veterinary use. (S1)
Propylhexedrine, except when used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S1)
Proteolytic (fibrinolytic) enzymes, when intended for injection. (S1)
Pyridinolcarbamate.

Pyridostigmine.
Quinbolone
Quinoronium sulphate, except when intended as an animal health product for use as a antibabesial (S0)
Rabeprazole.
Ractopamine, when used as an animal health product indented for the improvement of production.
Radio-active compounds, when used for diagnostic purposes.
Rafoxanide, except when intended as an animal health product for use as an anthelmintic for sheep, goats and cattle. (S0)
Recombinant human tissue-type plasminogen activator (rt-PA).
Resorantel, except when intended as an animal health product for use as an anthelmintic for sheep, goats and cattle. (S0)
Riluzole.
Rimiterol, when intended for injection. (S2, S3)
Ritodrine.
Ritonavir.
Rituximab.
Rizatriptan.
Rocuronium bromide.
Ropinirole.
Rosoxacin.
Roxatidine.
Salbutamol, when intended for injection. (S2, S3)
Salmefamol, when intended for injection. (S2, S3)
Saquinavir.
Selegiline.
Selenium salts, preparations thereof for injection, when intended for veterinary use.
Sermorelin.
Sertindole.
Sildenafil.
Simvastatin.
Sodium aurothiomalate.
Sodium cromoglycate, when intended for veterinary use. (S1)
Sodium dihydroazapentacene polysulphonate.
Sodium fluoride; preparations and mixtures thereof containing 40 milligrams or more per daily dose.
Sodium nitroprusside.
Solcoseryl, except ophthalmic preparations thereof and except preparations intended for application to the skin, to the mucous membranes of the mouth and to the lips. (S0, S3).
Stanozolol.
Stavudine.
Stenbolone
Streptokinase
Strychnine, subject thereto that for the control of problem predatory mammals -

a. It shall only be supplied on a written prescription issued by a State Veterinarian, for use in the particular State Veterinarian's area of jurisdiction, in a quantity not exceeding 5 grams; and
b. The State Veterinarian shall obtain prior written approval for such use from the Director of the concerned provincial conservation institution or authority in his area of jurisdiction, a copy of
which shall be attached to the written prescription;

except preparations and mixtures containing 0,2 per cent or less of strychnine when included in Schedule 1.

Schedule 5
SUBSTANCES WITH AN ABUSE POTENTIAL

(a) All substances referred to in this Schedule include the following:
   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

(b) In terms of Section 31(4)(a)(v) and 33(1)(a), nurses may use, keep, prescribe and supply to patients under their care, the Schedule 5 substances and medicines provided for in Annexure A of this Schedule, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document likewise reflected in Annexure A. Annexure A appears at the end of this Schedule.

Amitryptyline and its derivatives, unless listed in another Schedule.
Amoxapine.
Anaesthetic preparations containing pregnanedione derivatives.
Aponal.
Apronalide.
Azacyclonol.
Barbituric acid and its derivatives, unless listed in another Schedule, excluding-
(a) amobarbital, cyclobarbital, and secobarbital; (S2, S6)
(b) pentobarbital in any form other than registered veterinary products; (S6) and
(c) preparations and mixtures containing not more than 30 milligrams per minimum recommended or prescribed dose when intended for continued use in asthma, and not more than 90 milligrams of phenobarbitone per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S1)
Benactyzine and its derivatives, unless listed in another Schedule.
Benfluramate.
Benzoctamine.
Benzodiazepines and their derivatives, unless listed in another Schedule and except flunitrazepam. (S6)
Benzquinamide.
Beta-aminopropylbenzene and beta-aminoisopropylbenzene, any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure) and any salt or substance falling under the above, except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations and except when contained in appliances for inhalation in which the substance is absorbed in solid material and excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof except substances listed in Schedules 7. (S1, S2, S7)
Bromides; preparations and mixtures thereof containing 80 milligrams or more of bromine as bromide per recommended daily dose, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act No. 54 of 1972), and for anaytical laboratory purposes. (S1)
Bromisovalum.
Brotizolam.

Buspirone.
Butriptyline.
Butyrophenones.
Carbamoylatine.
Carbromal.
Chloral derivatives, unless listed in another Schedule.
Chlormezanone, except mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S2)
Chlorprothixene.
Citalopram.
Clomacran.
Clomethiazole (previously listed as heminevrin).
Clomipramine.
Clopenthixol.
Clothiapine.
Clozapine.
Corticotrophin (adrenocorticotrophic hormone; ACTH).
Cyclobenzaprine.
Deanol and its derivatives, unless listed in another Schedule, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act No. 54 of 1972), and for analytical laboratory purposes. (S1)
Desflurane.
Detomidine
Dexfenfluramine.
Dextropropoxyphene; preparations and mixtures for oral use containing not more than 135 milligrams of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 per cent in undivided preparations. (S6)
Diprenorphine.
Donepezil.
Dothiepin.
Doxepin.
Droperidol.
Ecothiopate.
Emylcamate.
Enflurane.
Ethclorvynol.
Ethinamate and its derivatives, unless listed in another Schedule.
Etodroxizine, except preparations and mixtures thereof when used solely as an antihistaminic.(S1)
Etomidate.
Fencamfamine.
Fenfluramine.
Flumazenil.
Fluoxetine.
Flupenthixol.
Fluspirilene.
Fluvoxamine.
Haloperidol.
Halothane.
Hedonal and its esters, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which

have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act No. 54 of 1972), and for anaytical laboratory purposes.

Hydroxyzine.

Human growth hormone (human somatotropin) -all forms.

Imipramine and its derivatives, unless listed in another Schedule.

Iproniazid.

Isoflurane.

Ketamine.

Lithium salts, when intended for medicinal use, except when intended for application to the skin.(S1)

Lofepramine.

Loxapine.

Maprotiline.

Mazindol.

Mechlorethamine and its derivatives, unless listed in another Schedule.

Meclofenoxate.

Medetomidine.

Melitracene.

Mephenoxalone.

Meprobamate.

Methoxyflurane.

Metrifonate.

Mianserin.

Mirtazapine.

Moclobemide.

Molindone.

Nalbuphine.

Nefazodone.

Nomifensine.

Olanzapine.

Oxypertine.

Paraldehyde.

Pargyline.

Paroxetine.

Pemoline and its complexes.

Phenethylhydrazine.

Phenothiazine and its derivatives, unless listed in another Schedule, except preparations and mixtures containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic(S1), and except preparations containing promethazine or its salts when intended specifically for the treatment of travel sickness(S2) or application to the skin, (S1), and except phenothiazines when intended as an animal health product for use as an anthelmintic.

Phentermine.

Pimethixene, except preparations and mixtures thereof when used solely as an antihistaminic. (S2)

Pimozide.

Pipradrol.

Pizotifen, except preparations and mixtures thereof when used solely as an antihistaminic or when intended for the prophylaxis of migraine. (S1)

Prolintane.

Propofol.

Quetiapine.

Quinupramine.

Reboxetine.
Risperidone.
Romifidine.
Sertraline.
Sevoflurane.
Sibutramine.
Sulphonmethane.
Sulpiride.
Thioguanosine.
Thiothixene.
Tiapride.
Tiletamine.
Tizanidine.
Tramadol.
Tranylcypromine.
Trazodone.
Trihexyphenidyl.
L-tryptophan, when intended for medicinal use, except when intended for medicinal use as supplementation for nutritional purposes. (S1)
Venlafaxine.
Viloxazine.
Xylazine.
Zaleplon.
Zimelidine.
Ziprasidone.
Zolazepam.
Zolpidem.
Zopiclone.
Zotepine.
Zuclopenthixol.

ANNEXURE A

Substances which nurses may keep, prescribe and supply in terms of Section 31(4)(a)(v) and 33(1)(a) to patients under their care, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document reflected below.

Only those Schedule 5 substances and medicines which appear in the Essential Drug List (EDL).

- END SCHEDULE 5 -

Schedule 6
SUBSTANCE OF ABUSE

(a) All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):
- (i) The isomers of such substances, where the existence of such isomers is possible within the chemical designation;
- (ii) The esters and ethers of such substances and of the isomers referred to in (a), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;
- (iii) the salts of such substances and of the isomers referred to in (a), as well as the salts of the esters, ethers and isomers referred to in (b), where the existence of such salts is possible;
- (iv) the isomers of any of the salts referred to in (c), where the existence of such isomers is possible;
- (v) all preparations and mixtures of any of the above.

(b) In terms of Section 31(4)(a)(v) and 33(1)(a), nurses may use, keep, prescribe and supply to patients under their care, the Schedule 6 substances and medicines provided for in Annexure A of this Schedule, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document likewise reflected in Annexure A. Annexure A appears at the end of this Schedule.

Acetorphine.

Acetyldihydrocodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S1)

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Amobarbital, except preparations and mixtures thereof containing not more than 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 50 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S2)

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital.

Butorphanol

Cathine ((+)-norpseudoephedrine), except preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S2)

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne; except preparations and mixtures containing 5,0 per cent or less of chlorodyne in combination with other active medicinal substances. (S1)

Chlorphentermine.

Clonitazene.

Coca leaf and any salt, compound, derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except decocainized coca leaf and extractions of coca leaf where such extractions contain no cocaine or ecgonine.

Codeine (methylmorphine); except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S1)

Codoxime.

Cyclobarbital, except preparations and mixtures thereof containing not more than 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 50 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S2, S5)

Desomorphine.

Dextromoramide.

Dextropropoxyphene, except preparations and mixtures for oral use containing 135 milligrams or less of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 per cent in undivided preparations. (S5)

Diampromide.

Diethylpropion (amfepramone).

Diethylthiambutene.

Difenoxin (or diphenoxylic acid), except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S1)

Dihydrocodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and except liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S1)

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphethyl butyrate.

Diphenoxylate, except preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S1)

Dipipanone.

Dronabinol [(-)-transdelta-9-tetrahydrocannabinol], when intended for therapeutic purposes. (S7)

Drotebanol.

Ecgonine, and the esters and derivatives thereof that are convertible to ecgonine and cocaine.

Ethylmethylthiambutene.

Ethylmorphine; except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S1)

Etonitazene.
Etorphine.
Etoxeridine.
Fenproporex.
Fentanyl. (S7)
Flunitazepam.(S5)
Furethidine.
Glutethimide.
Hydrocodone (dihydrocodeinone).
Hydromorphinol (14-hydroxydihydromorphine).
Hydromorphone (dihydromorphinone).
Hydroxypethidine.
Isomethadone.
Ketobemidone.
Levomoramide.
Levophenacylmorphan.
Levorphanol.
Mecloqualone.
Mefenorex.
Meptazinol.
Metazocine.
Methadone.
Methadone-intermediate.
Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan. (S1)
Methyldesorphine.
Methyldihydromorphine.
Methylphenidate and its derivatives, unless listed in another Schedule.
Metopon.
Moramide-intermediate.
Morpheridine.
Morphine, except preparations and mixtures of morphine containing 0,2 per cent or less of morphine, calculated as anhydrous morphine. (S1)
Morphine methobromide and other pentavalent nitrogen morphine derivatives.
Morphine-N-oxide and its derivatives.
Myrophine (myristylbenzylmorphine).
Nicocodine.
Nicodicodine.
Nicomorphine.
Noracymethadol.
Norcodeine; except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S1)
Norlevorphanol.
Normethadone.
Normorphine (demethylmorphine or N-demethylated morphine).
Norpipanone.
Opium and opiates and any salt, compound, derivative or preparation of opium or opiates, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except mixtures containing 0,2 per cent or less of morphine, calculated as anhydrous morphine.(S1)

Opium-poppy and poppy straw, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or whether obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis.
Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).
Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).
Pentazocine.
Pentobarbital, except -

(a) when registered as a veterinary product.(S5);
(b) preparations and mixtures thereof containing not more than 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 50 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S2)

Pethidine, pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S8)
Phenadoxone.
Phenampromide.
Phenazocine.
Phendimetrazine.
Phenomorphan.
Phenoperidine.
Pholcodine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit. (S1)
Piminodine.
Piritramide.
Proheptazine.
Properidine.
Propiram.
Racemoramide.
Racemorphan.
Remifentanil.
Secobarbital.
Sufentanil.
Thebacon.
Thebaine.
Tilidine.
{(-)-transdelta-9-tetrahydrocannabinol - see dronabinol}
Trimeperidine.
Zipeprol.

ANNEXURE A (to Schedule 6)

Substances which nurses may keep, prescribe and supply in terms of Section 31(4)(a)(v) and 33(1)(a) to patients under their care, only within their scope of practice and in accordance with the standard treatment guidelines, set out in the document reflected below.

Only those Schedule 6 substances and medicines which appear in the Essential Drug List (EDL).

- END SCHEDULE 6 -

Schedule 7

PROHIBITED SUBSTANCES

(a) All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

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

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

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

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

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

(Trivial or unofficial names names are marked *)

Aminorex.
Amphetamine.
Brolamfetamine ((±)-4-bromo-2,5-dimethoxy-α-methylphenethylamine)*(DOB).
4-bromo-2,5-dimethoxyphenethylamine (2C-B) *(Nexus).
Bufotenine (N,N-dimethylserotonin).
Cannabis (dagga), the whole plant or any portion or product thereof, except dronabinol ((-)transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes. (S6)
Cathinone ((-)-(S)-2-aminopropiophenone).
Dexamphetamine.
Diethyltryptamine [3-(2-(diethylamino) ethyl) indole] *(DET).
(±)-2,5-dimethoxy-α-methylphenethylamine *(DMA).
2,5-dimethoxy-α-4-dimethylphenethylamine *(DOM, STP).
3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-ol *(DMHP).
(±)-N,α-dimethyl-3, 4-(methylenedioxy)phenethylamine * (MDMA).
Dimethyltryptamine [3-(2-(dimethylamino) ethyl) indole] *(DMT).
(±)-4-ethyl-2,5-dimethoxy-α-phenethylamine *(DOET).
Etilamfetamine (N-ethylamphetamine).
Etryptamine.
Fenetylline.
Fentanyl-analogues (unless listed in another Schedule):
- acetyl-alpha-methylfentanyl;
- alpha-methylfentanyl;
- alpha-methylfentanyl-acetanilide;
- alpha-methylthiofentanyl;
- benzyl-fentanyl;
- beta-hydroxyfentanyl;
- beta-hydroxy-3-methylfentanyl;
- 3-methylfentanyl and its two isomeric forms:
  - cis-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide; and
  - trans-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide;
- 3-methylthiofentanyl;
- para-fluorofentanyl; and
- thiofentanyl. (S6)

Harmaline (3,4-dihydroharmine).
Harmine [7-methoxy-1-methyl-9H-pyrido (3,4-b)-indole].

Heroin (diacetylmorphine).
3-hexyl-7,8,9,10-tetrahydro-6,6,0-trimethyl-6H-dibenzo [b,d]-pyran-1-o1* (parahexyl).
Lefetamine *(SPA).
Lysergide (Lysergic acid diethylamide)*(LSD).
Mescaline (3,4,5-trimethoxyphenethylamine).
Mesocarb.
Methamphetamine and methamphetamine racemate.
Methaqualone and any preparation containing methaqualone.
Methcathinone.
2-methoxy-α-methyl-4,5-(methylenedioxy)phenethylamine *(MMDA).
p-methoxy-α-methylphenethylamine *(PMA).
4 methylaminorex.
(Methylenedioxyamphetamine *(MDA) and its analogues - see tenamphetamine)
Methyprylon.
Nabilone.
Pethidine-analogues:
1-methyl-4-phenyl-4-propionoxy-piperidine *(MPPP);
1-methyl-4 phenyl-1,2,5,6-tetrahydropiperidine *(MPTP); and
1-phenylethyl-4-phenyl-4-acetyloxy-piperidine *(PEPAP).
Phencyclidine *(PCP) and its congeners:
eticyclidine (N-ethyl-1-phenylcyclohexylamine *(PCE));
rolycyclidine (1-(1-phenylcyclohexyl) pyrrolidine *(PHP or PCPY)); and
tenocyclidine (1-[1-(2-thienyl) cyclohexyl] piperidine *(TCP).
Phenmetrazine.
Psilocin (4-hydroxy-NN-dimethyltryptamine).
Psilocybine (4-phosphoryloxy-NN-dimethyltryptamine).
Pyrovalerone (4'-methyl-2-(1-pyrrolidinyl) valerophenone).
Tenamfetamine (methylenedioxyamphetamine *(MDA)) and its analogues:
(±)-N-ethyl-α-methyl-3,4-(methylenedioxy) phenethylamine *(N-ethyl MDA):
(±)-N-[α-methyl-3,4-(methylenedioxy) phenethyl] hydroxylamine *(N-hydroxy MDA).
Tetrahydrocannabinol, except dronabinol, when intended for therapeutic purposes. (S6)
(+)-3, 4, 5-trimethoxy-α-methylphenethylamine *(TMA).

- END SCHEDULE 7 -

Repeal

The Schedules to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) are hereby repealed.

N C Dlamini-Zuma
Minister of Health


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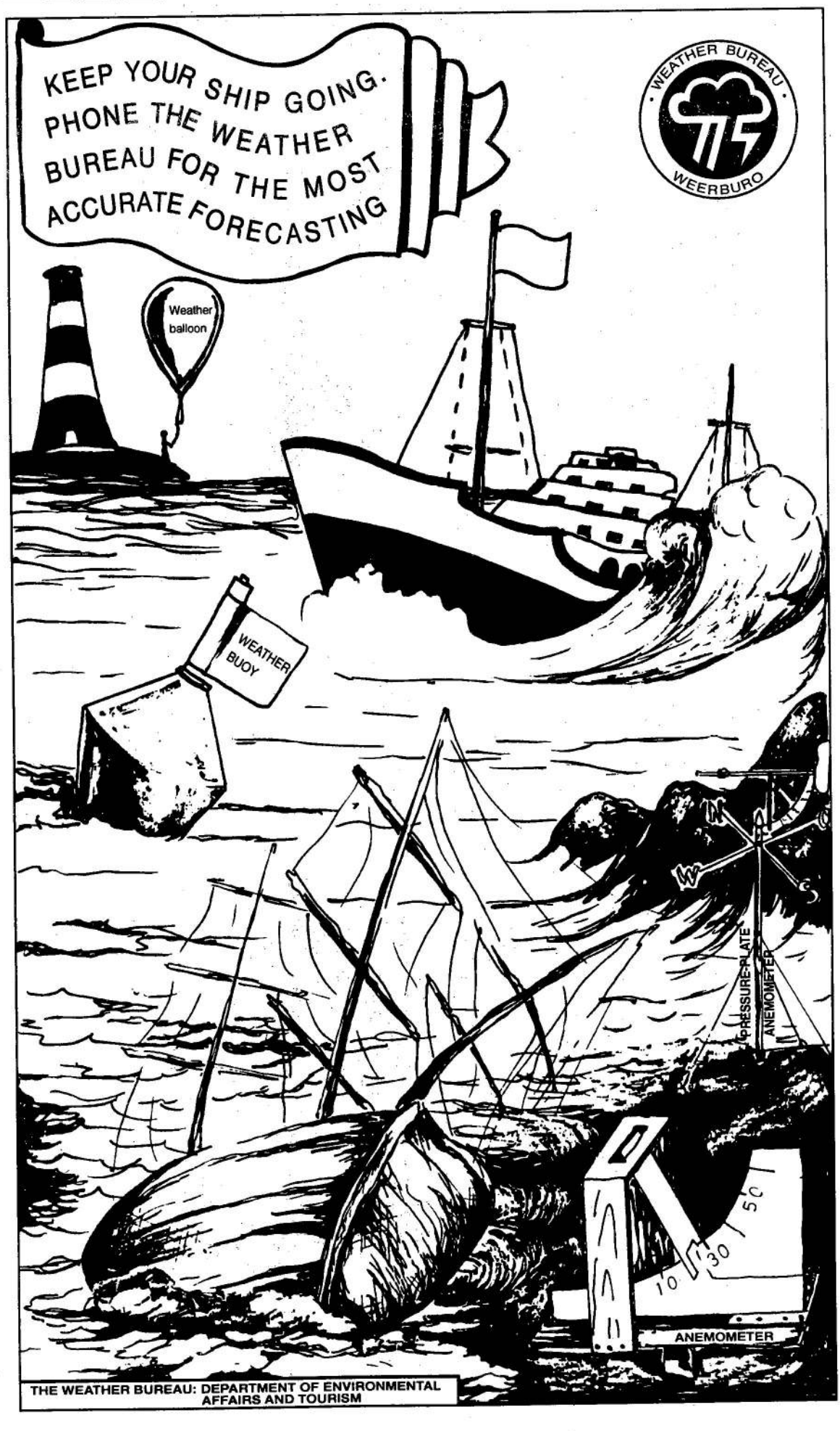
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