Pharmacology for Health Sciences

Fourth Edition

A Dreyer, R Kharwa, S Moch and Y Thandar

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Foreword

I would like congratulate professor Anton Dreyer (whom I have known since the mid-1970s when I was an undergraduate student in Pharmacy filled with admiration, an admiration I still hold today, for his wealth of knowledge in Pharmacology) and his competent co-authors with this fourth edition of *Pharmacology for Health Sciences*. I have been involved in Pharmacology for three decades at national and international levels as an educator, researcher and practitioner. I therefore appreciate the major advances included in this new edition, which focus on students and their learning experiences in Pharmacology. The well-designed additions to the fourth edition enable students not only to understand fully the actions of the drugs they will encounter as healthcare professionals, but also to apply pharmacotherapeutic principles. This updated edition is indeed a culmination of outstanding work by a group of dedicated pharmacologists who have strived to present the most recent developments in drug therapy for health professionals.

Pharmacology for Health Sciences displays an array of recent enablers in layout and in digital technology. Examples of these innovations for enhancing students' learning experiences include:

- additional supportive illustrations
- key information boxes that summarise critical information
- pop-up glossary definitions that provide immediate access to the meaning of key terms
- infographics that summarise major themes in each chapter in graphic format
- QR codes that provide access to additional online information
- Study-on-the-Go, a smart mobile integration between text and online content.

These innovations are supported by the 'Review your understanding' tool at the end of each chapter. Together, they provide opportunities that will assist students to learn, revise and complete practice exercises designed to enable them to achieve a level of competency in Pharmacology that will allow them to fulfil their role in the healthcare team.

Pharmacology for Health Sciences begins with four introductory chapters. These are followed by thirteen medicine-focused chapters that address medicines for specific biological systems, medicines in infections and infestations, medicines in oncology, and finally, medicines and poisoning.

The introductory chapters include key principles of medicines within the context of public health, medicine control and safety of medicines. Firstly, this section provides content to understand the importance of a regulatory framework for medicines and how the supply to patients is controlled through a scheduling system for all medicines in South Africa. Secondly, it addresses both basic and clinical aspects of pharmacology in order to equip students with the understanding of the two main areas of pharmacology, namely pharmacodynamics and pharmacokinetics of medicines. Thirdly, the content on the pharmaceutical

dosage forms, as a means to administering medicine to patients through different routes, i.e. topical, parental, and oral as examples, give students insight into the applications of these routes of administration and their advantages. Lastly, it covers the principles of adverse effects of medicine and drug interactions. These principles provide students with in-depth information on the dangers of medicines and how they can affect patients, as well as guidelines on their safe administration.

The medicine-focused chapters provide students with content to integrate the pharmacodynamics, i.e. mechanism of action, and the pharmacokinetics; absorption, distribution, metabolism and excretion of pharmacological active molecules, with the pathophysiology of organ systems (e.g. the brain, heart, gastrointestinal tract and lungs). Pharmacotherapeutic treatment for cancers, infections and infestations are also covered. The aim of all the medicine-focused chapters is to realise successful pharmacotherapeutic outcomes that take into consideration the safety aspect of each pharmacological agent.

Students are reminded that pharmacology is experienced by all patients with every dose of medicine they take. Mastering pharmacology is thus critical in ensuring that those in the care of health practitioners benefit fully from their medicines.

I am confident that mastering *Pharmacology for Health Sciences* will contribute to a fulfilling career in health sciences and will encourage you, in view of the continuing advancement of knowledge, to become a lifelong learner of pharmacology.

'Many of the things you can count, do not count.
Many of the things you can not count, really count.'
Albert Einstein

Douglas W. Oliver
Professor and past-chair of Pharmacology: North-West University,
Potchefstroom Campus
Chair and Co-Founder: Pharmacology for Africa
Past-President: South African Society of Basic and Clinical Pharmacology
Past-Councillor: International Union of Basic and Clinical Pharmacology
douglas.oliver@nwu.ac.za

About the authors

Professor AC (Anton) Dreyer graduated as a pharmacist at North-West University and received his doctorate in Pharmacology from the same institution. He lectured in Pharmacology for almost 30 years and was appointed Head of the Department of Pharmacy Practice at North-West University. Professor Dreyer has been a member of a number of national and international professional organisations, and has received a variety of awards. He served as a member of the Medicines Control Council for 14 years and is author of many scientific publications and co-author of a number of textbooks. Professor Dreyer retired from active academia in 1995 and continues to write from his home in Pretoria.

Dr Yasmeen Thandar is a full time academic at the Durban University of Technology (DUT) in the Department of Basic Medical Sciences. She holds a Doctorate degree in Pharmacology from the University of KwaZulu-Natal where she graduated with a Bachelor of Pharmacy and a Masters in Medical Science with a speciality in Clinical Pharmacology. After spending a number of years in clinical practice in both academic hospital and the private sector, she joined DUT as a senior lecturer in Pharmacology. Since then, she has accumulated over 17 years of teaching experience at many reputable universities including the Universities of Witwatersrand, Johannesburg and KwaZulu-Natal where she has lectured to students of pharmacy, medicine, dentistry, nursing, podiatry, homeopathy and chiropractic. She is currently the principal co-ordinator for Pharmacology across all allied health disciplines at DUT. Dr Thandar is involved in pharmacology curriculum development, research supervision and lecturing to postgraduate and undergraduate nursing students as well as students of emergency medical care and rescue, homoeopathy, chiropractic and dental assisting. Her passion lies in delivering the subject of pharmacology in a manner that is easy to understand using a variety of resources to reach as many students as possible. Training health students and working with many professionals in the allied healthcare sector has steered her interest in complementary and alternative medicines (CAM) and their evidence-based role in treating diseases. Dr Thandar has published and presented much of her research both locally and internationally.

Ms Razia Kharwa is a pharmacist who holds a Bachelor of Pharmacy degree and a Master in Medical Sciences (Clinical Pharmacology) from the University of KwaZulu-Natal. She is a member of the Pharmaceutical Society of South Africa, and has 14 years of clinical experience in both the private and public hospital sectors, where she worked in a managerial capacity. Razia has spent the past 22 years as a full time academic, 10 of which were as a Head of Department of Basic Medical Sciences, at the Durban University of Technology (DUT). She is currently a senior lecturer of pharmacology and teaches students of various allied health professions in the Faculty of Health Sciences, including Nursing, Clinical Technology, Medical Orthotics and Prosthetics and Somatology, amongst others.

She was also part of a pilot project involving the development and implementation of e-learning modules at the university.

Ms Shirra Moch holds a Bachelor of Pharmacy degree and a Masters in Medicine in the field of Pharmacology from the University of the Witwatersrand (Wits). She has been a lecturer in pharmacology at Wits since 1993 and has taught a wide range of disciplines: nurses, physiotherapists, dentists, pharmacists and medical students. Shirra also holds a Masters in Education from Wits in the field of University Teaching and has participated in pharmacology curriculum development for the Faculty of Health Sciences.

Shirra's enthusiasm for the subject is apparent, as is her expertise. She was awarded the Pharmacology Educator award from the Society for Basic and Clinical Pharmacology (2013) and was the recipient of the Wits University Vice-Chancellor's Teaching Award (2014). She is currently the vice-chair of IUPHAR-Ed, the education section of the International Union of Basic and Clinical Pharmacology.

Abbreviations and acronyms

ACE	Angiotensin-converting enzyme
ACTH	Adrenocorticotropic hormone
ADH	Antidiuretic hormone
ADHD	Attention Deficit Hyperactivity Disorder
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral treatment
ARV	Antiretroviral
AV	Atrio ventricular
BA-MDI	Breath-actuated MDI
BBB	Blood–brain barrier
CCF	Congestive cardiac failure
CCMT	Comprehensive care, management and treatment
CNS	Central nervous system
COC	Combined oral contraceptives
COPD	chronic obstructive pulmonary disease
COX	Cyclo-oxygenase
COXIBS	Selective COX 2 inhibitors
CRH	Corticotropin-releasing hormone
CTZ	Chemoemetic trigger zone
DMARD	Disease-modifying anti-rheumatic drug
DNA	Deoxyribonucleic acid
DoH	Department of Health
DPI	Dry powder inhaler
DVT	Deep vein thrombosis
ECG	Electrocardiogram
EDL	Essential Drug list
EPS	Extrapyramidal side effects
FSH	Follicle-stimulating hormone
GH	Growth hormone
GIT	Gastro-intestinal tract
GORD	Gastro-oesophageal reflux disease
HDL	High-density lipoproteins
HIV	Human immunodeficiency virus
HRT	Hormone replacement therapy
IBS	Irritable bowel syndrome
ICSH	Interstitial cell-stimulating hormone
IDDM	Insulin-dependent diabetes mellitus
INR	International normalised ratio
LDL	Low-density lipoproteins
LH	Luteinising hormone
MAOB	Monoamine oxidase Type B

MAOI	Monoamine oxidase inhibitor
MCC	Medicines Control Council
MDI	Metered-dose inhaler
MDR-TB	Multidrug-resistant tuberculosis
MI	Myocardial infarction
NAPQI	N-acetyl-para-benzoquinoneimine
NARI	Selective noradrenaline re-uptake inhibitor
NIDDM	Non-insulin-dependent diabetes mellitus
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NSAID	Non-steroidal anti-inflammatory drug
ORS	Oral rehydration solutions
PABA	Para-aminobenzoic acid
PEP	Post-exposure prophylaxis
PG	Prostaglandin
PI	Protease inhibitor
PMS	Premenstrual syndrome
PNS	Peripheral nervous system
POP	Progesterone-only pills
PT	Prothrombin time
PTT	Partial thromboplastin time
RAS	Reticular activating system
RNA	Ribonucleic acid
SA	Sino-atrial
SNRI	Serotonin and noradrenaline re-uptake inhibitors
SNS	Sympathetic nervous system
SSRI	Selective serotonin re-uptake inhibitor
SSS	Solution of salt and sugar
STI	Sexually transmitted infections
TB	Tuberculosis
TCA	Tricyclic antidepressant
TDM	Therapeutic drug monitoring
TI	Therapeutic index
TRH	Thyrotropin-releasing hormone
TSH	Thyroid-stimulating hormone
VLDL	Very-low-density lipoproteins
WHO	World Health Organisation
XDR-TB	Extensively-drug resistant tuberculosis

Chapter 1

General aspects of drug therapy

Introduction

Chapter 1 outlines the legal aspects pertaining to the sale and supply of medicine in South Africa. This is essential information for the practice of pharmacotherapy by nurses and other health practitioners in the private or public sectors.

- *Pharmacology* embraces the knowledge of the source, physical and chemical properties, physiological effects, absorption, distribution, biotransformation, excretion and therapeutic use of drugs.
- A *drug* is any chemical substance that influences life processes and which is used to prevent, diagnose and treat disease.
- *Medicines* are the dosage forms in which drugs are administered, for instance capsules, tablets and mixtures. A medicine may therefore contain more than one drug, as well as inactive substances necessary for its manufacture.

1.1 Drug names

Drugs that are important in drug therapy have two types of names: their generic names and their trade names.

The *generic name* is the name given to a specific chemical compound when it is registered for official use as a drug. This name is generally accepted internationally. There are, however, a few exceptions. For example, in some countries, *paracetamol* is referred to as *acetaminophen* and *adrenaline* is referred to as *epinephrine*.

The *trade name* is the name under which a particular manufacturer registers and markets a specific medicine. A chemical compound therefore has one generic name, but may be marketed under different trade names, as long as there is no question of patent rights. A well-known example is the **antibiotic** with the generic name of *ampicillin*, which is currently marketed under trade names such as Ranamp® and Be-Ampicil®.

Antibiotic A medicine, such as penicillin, which slows down or prevents the growth of microorganisms, or destroys them

A note on generic drugs

A generic drug (also known as a 'generic') is defined as a drug product that contains the same active ingredients as the reference product and is equivalent in dosage form, strength, route of administration, intended use and quality. Generic drugs are usually sold at significantly lower prices than the original branded product. This is because the generic manufacturers do not bear the burden of providing safety and

Reasons generic drugs are cheaper than original drugs

Generic drugs are cheaper than the original drugs because:

- no clinical trials are required and so research and development costs are minimal
- raw materials for manufacture may readily be available
- marketing costs are substantially reduced
- competition between companies to manufacture a generic once the original patent has expired drives prices down.

efficacy characteristics through clinical trials for their products, since the trials have already been conducted by the brand name company.

The time it takes for the original drug to appear on the market varies. Pharmaceutical companies spend billions of rands on research and development of a new drug, and it is estimated that it takes between 7 and 15 years after patent rights have been gained to final approval to market that particular drug. Drug patents usually give their owners 20 years of protection. For as long as the product patent lasts, a brand name company enjoys a period of market monopoly. A well-known example is the anti-inflammatory drug, *diclofenac*, which was originally introduced to the market under the trade name Voltaren®. Now that the patent rights have expired, generics are marketed in South Africa under various trade names such as Adco-diclofenac® and Panamor®.

Some medicines consist of a combination of two or more drugs. A medicine like this, marketed under a particular trade name, contains two or more active ingredients, each of which has a generic name. An example is Atacand Plus® which contains *candesartan* and *hydrochlorothiazide*.

1.2 Sources of drugs

Most drugs are synthetically prepared, but a number are derived from natural products that have animal or other biological origins, or are derived from sources of mineral origin.

1.2.1 Natural products as a source of drugs

Natural products as a source of drugs can be of plant, animal or biological origin. They are all organic compounds.

- **Plant origin.** Alkaloids, such as *atropine* from the plant *Atropa belladonna*, or glycosides, such as *digoxin* from the plant *Digitalis lanata*, are of plant origin.
- **Animal origin.** Hormones, such as the thyroid hormone obtained from the thyroid of edible animals or sera and vaccines obtained from animal fluids, are of animal origin.
- **Biological origin.** Antibiotics obtained from microorganisms, such as penicillin-G from *Penicillium chrysogenum* or streptomycin from *Streptomyces griseus*, are of biological origin.

1.2.2 Mineral products as a source of drugs

- **Mineral origin.** These are metals such as iron, or non-metals such as iodine, which are used as drugs. These products are inorganic compounds.

1.2.3 Synthetic products

- **Synthetic products.** These are products that are synthesised in a laboratory. They may be organic, such as *aspirin*, or they may be inorganic, for example magnesium oxide. Some natural products may be modified semi-synthetically

in the laboratory, such as acid-labile *penicillin-G*, which is processed to acid-stable *phenoxymethylpenicillin* so that it can be administered orally.

1.3 Legal aspects pertaining to the sale and supply of medicine

In 1965 the Medicines and Related Substances Control Act 101 of 1965 was passed. In terms of this act, all medicines sold in South Africa must be registered and must comply with certain standards of quality, safety and effectiveness. The statutory body that decides on the registration and scheduling of medicines is the Medicines Control Council (MCC). It consists of a group of experts from various health professions appointed by the Minister of Health. The MCC divides medicines into a number of schedules according to the degree of safety with which they can be used.

1.3.1 Scheduling of medicines

In terms of the Medicines and Related Substances Control Act, all medicines sold in South Africa are grouped into one of nine schedules.

Table 1.1 Medicine schedules

Schedule	Medicines
0	These medicines have a relatively favourable safety profile and require little professional control. This group, which includes aspirin, vitamins and disinfectants, may be sold in pharmacies and many other retail outlets, such as cafés and supermarkets.
1	These medicines justify some degree of professional control and are therefore sold only in pharmacies. A large number of patent medicines, such as certain cough remedies, nose drops and ear drops, belong to this group.
2	These medicines may be sold only by pharmacists and include substances such as certain appetite suppressants and antihistamine combinations.
3	This schedule is reserved for medicines used for the treatment of chronic conditions and includes antihypertensives, contraceptive pills and insulin. Schedule 3 medicines may be supplied only on the prescription of a doctor, dentist or veterinarian.
4	This schedule contains medicines used for acute disorders that require a differential diagnosis and strict clinical judgement and control. It includes oral and **parenteral** antibiotics and corticosteroids. They may be supplied only on the prescription of a doctor, dentist or veterinarian.
5	This schedule is the classification for psychotropic drugs such as the hypnotics, antidepressants and tranquillisers. These medicines may be supplied only on the prescription of a doctor, dentist or veterinarian.

continued

Parenteral Administered elsewhere in the body, other than the mouth or alimentary canal, e.g. intravenous, subcutaneous and intramuscular

i Drugs that are scheduled as 5, 6 and 7 are often dependence-producing.

Schedule	Medicines
6	This is the so-called 'narcotics' group for which strict national and international control measures are required. It includes substances such as *morphine* and *flunitrazepam* (Rohypnol®). Careful records of supply are demanded by law.
7 & 8	These medicines are banned substances that may not be manufactured, kept or supplied without a permit issued by the Director-General of Health. Banned substances include *cannabis* ('dagga'), *methaqualone* (Mandrax®) and amphetamine.

1.3.2 Package or container labelling of medicines

Section 18 (and the general regulations) of the Medicines and Related Substances Control Act requires that all medicines marketed in South Africa must have legible labels on their packages or containers that include the following information:

- registration number
- batch number
- scheduling status
- trade names and generic names of the medicine
- active ingredients and their quantities
- any preservatives used
- form of dosage, expiry date, storage instructions, and, where possible, dosage and indications.

Figure 1.1 An example of a medicine label

1.3.3 Package inserts of medicines

In terms of Section 24 of the Medicines and Related Substances Control Act, every container of medicine that is manufactured must contain a special information brochure known as the package insert.

The package insert is a scientific document that includes the following information:

- registration number
- scheduling status
- generic names and trade names
- composition of medicine
- pharmacological classification and action
- indications
- contraindications
- warnings
- dosage and directions for use
- **side effects** and special precautions.

Side effects Unpredictable adverse reactions encountered with therapeutic dosages

This important document is compiled mainly for the information of the therapist. Certain medicines contain a patient information leaflet for the patient or layperson to consult. It is more user-friendly than the package insert.

XX PHARMACEUTICALS (PTY) LTD
SCHEDULING STATUS: S0
PROPRIETARY NAME (and dosage form): *TURBOLAX* Tablets
COMPOSITION:
Each tablet contains:
Aloe Ferox Extract 300 mg
Bisacodyl 10 mg
Sennosides B 10 mg
PHARMACOLOGICAL CLASSIFICATION:
12.6 Laxatives
PHARMACOLOGICAL ACTION:
Turbolax is a laxative that produces effective peristalsis and evacuation of the bowel
INDICATIONS:
Constipation
CONTRA-INDICATIONS:
Hypersensitivity to any of the ingredients. Intestinal obstruction or undiagnosed abdominal pain
WARNINGS:
Misuse of laxatives may result in excessive water and electrolyte loss
DOSAGE AND DIRECTIONS FOR USE:
Adults and children 12 years & over: 1–2 tablets usually at bedtime
SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Abdominal cramps. Not to be given in pregnancy or during breastfeeding
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Abdominal cramps and vomiting. Stomach lavage is indicated
IDENTIFICATION:
Brown tablets
PRESENTATION:
Turbolax comes in boxes of 30 tablets
STORAGE INSTRUCTIONS:
Store below 25 °C. Keep out of reach of children
REGISTRATION NUMBER:
45/12.6/0166
NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
XXX Pharmaceuticals (Pty) Ltd., Aloe Street, Johannesburg
DATE OF PUBLICATION OF THIS PACKAGE INSERT:
21 March 2015

Figure 1.2 An example of a medicine package insert

www.quickto.mobi/PEA-INSERT

More about package inserts

i The absence of a proper registration number on the label, carton, package insert and advertising material of all medicine sold in South Africa is an indication that the particular medicine has not yet been evaluated and approved for safety, efficacy and quality as required by Act 101 of 1965.

1.3.4 Registration numbers of medicines

The registration number allocated to a medicine is an important piece of information about that particular product. By law, the registration number must appear on the container label and package insert, and on all advertising material for that particular product. The registration number is usually followed by the words 'Act 101/1965'.

Let us use the registration number 35/7.5/0277 as an example to see what the numbers represent.

- The first two numbers indicate when the application for registration was first submitted to the MCC. When products were first submitted for registration in 1965, the letter 'A' was allocated for that particular year. After 26 years all the letters of the alphabet had been used and it was decided that numbers, instead of letters, be used from then on. It was also decided to start with '27' (following the 26 letters of the alphabet). Applications submitted in 2000, 35 years later, received the number '35' (as in the example above).
- The numbers between the two slashes indicate the pharmacological classification of the product. According to Regulation 25 of the Act, all products with the number '7.5' belong to the group of 'Serum cholesterol reducers'.
- The last numbers in the above example show that this was the 277th application received by the MCC for that particular year.

Complementary and alternative medicines

Complementary and alternative medicines are defined as: *any substance or mixture of substances that –*

a) originates from plants, minerals or animals;

b) is used or intended to be used for, or manufactured or sold for assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and

c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982).

Examples of complementary and alternative medicines are:

- homeopathic medicines
- naturopathic medicines
- ayuverdic medicines
- osteopathic medicines
- chinese herbal medicines
- phytotheraputic herbal remedies
- aromatherapy plant extracts and oils.

However, almost all of the complementary medicines currently sold in South Africa (as well as many of the dietary supplements, herbal remedies, and the numerous so-called products of 'natural origin' recommended for various afflictions) have not yet been evaluated or approved for registration in terms of the Medicines and Related Substances Act 101. Ammendments to (Act 101 of 1965) have recently set new boundaries for the sale of complementary and alternative medicines in South Africa.

www.quickto.mobi/PEA-ACT

The Medicines Control Act

This new legal requirement (published on 15 November 2013) requires more than 150 000 of these medicines to go through a registration process to prove that they are safe, effective and meet the required standards for quality applied to mainstream medicines. This new amendment to the Act is currently, as at January 2015, being opposed in court by the complementary medicines industry.

1.3.5 Drugs that may be prescribed and supplied by nurses under specific circumstances

In hospitals, the pharmacy is responsible for supplying medicines that doctors have prescribed to specific patients. Although nurses in hospitals do handle many medicines of all schedules, and administer them to patients daily, they normally do this on the instruction of a doctor.

Nurses may, however, under certain circumstances, obtain authorisation to acquire, prescribe and administer certain medicines to patients under their care. This is usually done in terms of Section 56(1) of the Nursing Act 33 of 2005 or via a special permit issued in terms of Section 22A(15) of the Medicines and Related Substances Control Act 101 of 1965. Where appropriate, it can also be done under a licence to dispense medicine in terms of Section 22C of the same Act.

1.4 Prerequisites for the administration of drugs to patients

Drugs are powerful chemical substances in the hands of health-care givers. For patients to attain maximum benefits of drug therapy and in order to minimise any undesirable effects on them, the therapist must ensure the following:

- The correct drug must be given to the right patient.
- The correct dosage must be given to the patient at the correct dosage interval.
- The required route of administration must be followed.
- The drug must be within the expiry date printed on the original container.

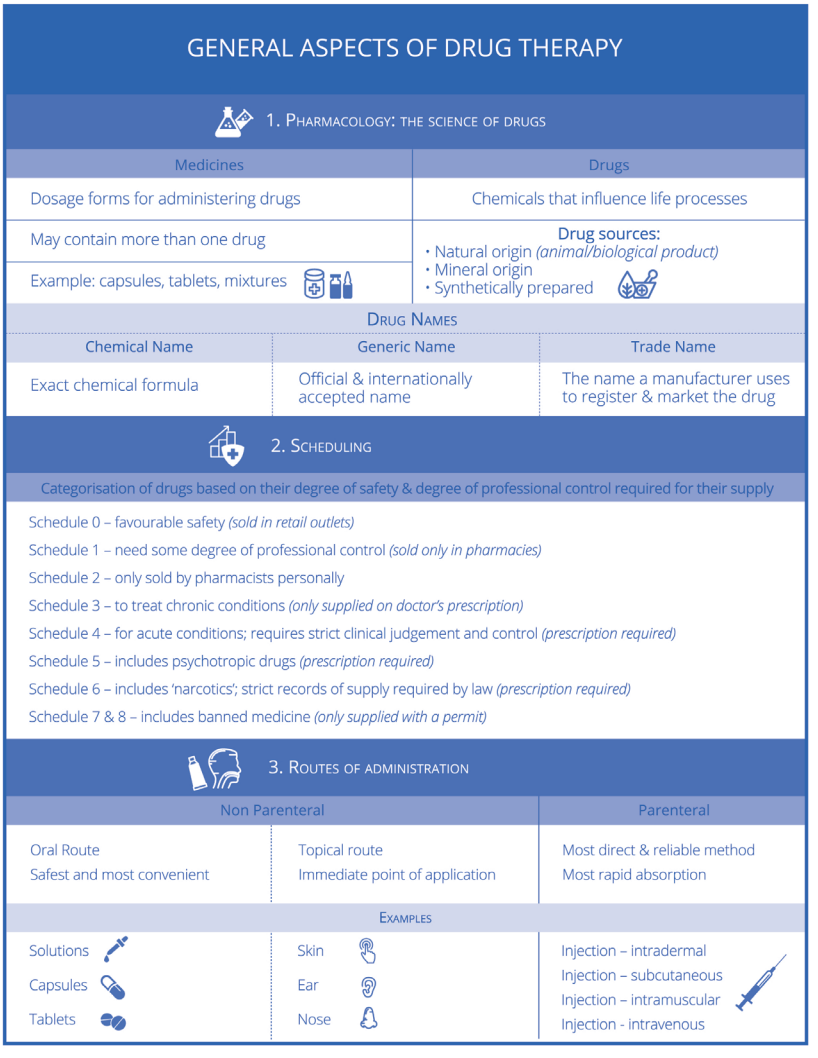

Figure 1.3 A summary of the general aspects of drug therapy

Review your understanding

Having worked through the contents of this chapter, you should now be able to:

- Explain what is meant by a drug and a medicine.
- Describe the difference between the generic name and the trade name of a medicine.
- Explain the difference between an original drug and a generic drug.
- Give an overview of the origin of drugs.
- Outline the purpose of scheduling of medicines and how this affects the availability of certain medicines to the public.
- Explain the type of information that can be obtained from the package insert that is provided with every container of medicine.
- List the important information reflected in the registration number of a medicine.
- Describe the legalities pertaining to the prescribing and dispensing of medicine by nurses in South Africa.