Reference document

Patient counselling and medicine information... does one size fit all?

Ref 1

Rules relating to Code of Conduct

1.1 WELLBEING OF THE PATIENT

Principle: A pharmacist's prime concern in the performance of his/her professional duties must be for the wellbeing of both the patient and other members of the public**.**

Ref 2

Patients Rights Charter

2. Participation in decision-making

Every citizen has the right to participate in the development of health policies and everyone has the right to participate in decision making on matters affecting one's health.

3. Access to health care

Everyone has the right of access to health care services that include:

i. **receiving timely emergency care** at any health care facility that is open regardless of one's ability to pay;
ii. **treatment and rehabilitation** that must be made known to the patient to enable the patient to understand such treatment or rehabilitation and the consequences thereof;
iii. **provision for special needs** in the case of newborn infants, children, pregnant women, the aged, disabled persons, patients in pain, persons living with HIV or AIDS patients;
iv. **counseling without discrimination**, coercion or violence on matters such as reproductive health, cancer or HIV/AIDS;
v. **palliative care** that is affordable and effective in cases of incurable or terminal illness;

8. Informed consent

Everyone has the right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and the costs involved for one to make a decision that affects any one of these elements.

Responsibilities of the patient

Every patient or client has the following responsibilities:

6. To provide health workers with relevant and accurate information for diagnostic, treatment, rehabilitation or counselling purposes.

Ref 3

NATIONAL HEALTH ACT NO. 61 OF 2003

CHAPTER 2
RIGHTS AND DUTIES OF USERS AND HEALTH CARE PERSONNEL

6. User to have full knowledge.—(1) Every health care provider must inform a user of—

(*a*) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;

(*b*) the range of diagnostic procedures and treatment options generally available to the user;

(*c*) the benefits, risks, costs and consequences generally associated with each option; and

(*d*) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

(2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

7. Consent of user.—(1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless—

(*a*) the user is unable to give informed consent and such consent is given by a person—

(i) mandated by the user in writing to grant consent on his or her behalf; or

(ii) authorised to give such consent in terms of any law or court order;

(*b*) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;

(*c*) the provision of a health service without informed consent is authorised in terms of any law or a court order;

(*d*) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or

(*e*) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.

(3) For the purposes of this section **"informed consent"** means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

8. Participation in decisions.—(1) A user has the right to participate in any decision affecting his or her personal health and treatment.

(2) (*a*) If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.

(*b*) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7.

(3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest.

Ref 4

The Consumer Protection Act (CPA) interpretation Rene Doms Forensic Corner

The CPA is a watershed advance in the field of consumer protection. It will have a material impact on the relationship between consumers and industry under the banner of “consumer interest”, the overarching theme of the CPA.

The CPA must be interpreted in a manner that gives effect to its purposes which are to promote and advance the social and economic welfare of consumers in South Africa. The provisions of the Medicines and Consumer Protection Acts are to be read conjointly (together as one) and in the light of the values enshrined in the Constitution and, unless it does not prove possible to do so, interpreted in a manner which respects those values. To the extent that this method cannot apply, the provision that extends the greater protection to a consumer prevails over the alternative provision.

Medicines are not a commodity of trade

Medicines differ from ordinary commodities in four crucial ways:

a) Prescribed medicines have a four-tiered demand structure - the patient, the prescribing doctor, the dispensing pharmacist and the payer (medical aid);

b) Medicines technical qualities are difficult to assess;

c) Medicines information is hard to interpret objectively; competitive bias may be present;

d) Medicines are inherently unsafe.

The CPA’s sting – strict liability

The law has changed from caveat emptor ("let the buyer beware") to strict liability for manufacturing defects that make a product unreasonably dangerous or unsafe for its intended use.

Strict liability involves extending the responsibility of the vendor or manufacturer to all individuals who might be injured by the product, even in the absence of fault. An injured party must prove that the item was defective, the defect proximately caused the injury, and the defect rendered the product unsafe for its intended use.

The principle

A manufacturer and those in the distribution chain are strictly liable in law when an article they place on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a person.

Although in these cases strict liability has usually been based on the theory of an express or implied warranty running from the manufacturer to the plaintiff, the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but now imposed by law (CPA) and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products make clear that the liability is not one governed by the law of contract but by statutory strict liability law (CPA).

The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers or vendors that put such products on the market rather than by the injured persons who are powerless to protect themselves.

The remedies of injured consumers ought not to be made to depend upon the intricacies of the law of sales. To establish the manufacturer's liability, it is sufficient that plaintiff proves that she was injured while

using the product in a way it was intended to be used as a result of a defect in design, labelling or manufacture of which plaintiff was not aware that made the product unsafe for its intended use.

The Medicines Act requirements

In deciding whether or not the registration or availability of any medicine (registered or not including CAM) is in the public interest, consideration must only be given to the safety, quality, therapeutic efficacy and suitability of the medicine for its intended purpose. Medicines must comply with all these provisions. All medicines must be labelled correctly which would include the addition of a package insert (PI) and patient information leaflet (PIL) that clearly points out both the benefits (indications) and foreseeable risks (contra-indications, warnings etc) associated with the use of a product. No medicine is risk free. It is by character, an inherently unavoidably unsafe product.

Liability for damage caused by goods

To avoid CPA liability, all medicines must:

a) Be effective and safe for its intended purpose;

b) Be of good quality (correctly made) throughout its shelf-life; and

c) Have adequate instructions and warnings (label, PI and PIL) provided to the consumer pertaining to danger arising from or associated with the use of the medicine.

This is irrespective of whether the harm resulted from any negligence (damages product caused, regardless of any "fault") on the part of the producer, importer, distributor or retailer, as the case may be. Strict liability applies.

Avoiding CPA liability

a) Preparation: If the medicine is ineffective then it is defective, so if adulterated. It must be manufactured correctly and be stable;

b) Marketing: The product must be appropriately marketed. If the directions accompanying the product are faulty, or if the product is sold with inadequate warnings; it may not fall within the exception;

c) Utility vs Risk: The utility or usefulness of the medicine must outweigh its risk of danger. So, for example, if a medicine cures a mild case of hiccups but causes death in half the people who use it, it may not qualify as being safe;

d) Available alternatives: If there is an alternative medicine that would be as effective in accomplishing the purpose of the product then the product may not be safe. In the case of the hiccup cure, a bottle of water would be a safe alternative product making the hiccup cure unlikely to qualify as a safe product.

Pharmacists

Pharmacists can now be held liable for all medicines they sell in their pharmacies irrespective of the registration status of such medicines (including complementary medicines) if they do not comply with the requirements as outlined.

The fact that any medicine is supplied from the pharmacy means that the pharmacist is satisfied that the product is safe, of good quality, efficacious and suitable for its intended purpose. If not then an alternative medicine should be sold. A medicine is not a commodity of trade and must be treated with professional respect and caution

Ref 5

MEDICINES AND RELATED SUBSTANCES ACT NO. 101 OF 1965

18. Labels and advertisements.—(1) No person shall sell any—

(*a*) medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars; and

(*b*) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical, stating the prescribed particulars.

(2) No person shall advertise any medicine or Scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.

(3) The label referred to in subsection (1) shall be approved by the Authority.

(4) The Authority may authorize a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labelling of medicines, medical devices or IVDs.

GN 859 of 25 August 2017: General Regulations
(*Government Gazette* No. 41064)

10. Labelling of Medicines Intended for Human Use – see pages MRE-14 to MRE-18 of the PSSA Pharmacy Law Compendium

12. Patient Information Leaflet - see pages MRE- 21 to MRE- 23 of the PSSA Pharmacy Law Compendium

42. Advertising of medicines - see pages MRE- 50 to MRE- 51 of the PSSA Pharmacy Law Compendium

Ref 6

Regulation Relating to the Practice of Pharmacy

Chapter I

3. Acts specially pertaining to the profession of a pharmacist.—Except as provided for in section 29 (3) of the Act, and sections 23 (2) (a) (i) and 34 of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), the following acts shall be regarded to be acts specially pertaining to the profession of a pharmacist—

(1) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:

(a) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;

(b) dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine;

(c) furnishing of information and advice to any person with regard to the use of medicine;

(d) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met; and

(e) the provision of pharmacist initiated therapy;

Ref 7

Duty of Care

Rene Doms FPS

The duty of care doctrine involves two components or elements, namely a duty to take care and a breach of that duty. These two components are usually referred to as the "duty issue" and the "negligence issue". According to the doctrine negligence simply is not sufficient to found liability: the defendant must have had a duty to conform to reasonable standards of care.

The test

The traditional test for ascertaining the existence of a duty of care in a particular case is the foresight of a reasonable person. One owes a duty of care only to persons to whom harm may reasonably be foreseen. The foreseeability formula comprises two separate but related inquiries:

a) would a reasonable person in the same circumstances have foreseen the possibility of harm occurring to the plaintiff and, if the answer is in the affirmative,

b) would a reasonable person have taken measures to guard against the occurrence of such foreseeable harm?

If the answer to the second question is also in the affirmative, then the duty to take care is established. If the duty is breached this means that the conduct was unlawful and the defendant was at fault.

The duty issue

The duty to take care is specific in that it is owed to a particular person or persons, or to a particular class of persons. This implies that a defendant owes a duty of care to persons to whom harm may reasonably be foreseen. Whether the conduct of the defendant was of such a nature that harm to someone was reasonably foreseeable, depends entirely on the particular circumstances of the case.

Negligence issue

Once the existence of a duty of care has been established, the question arises of whether it has been breached by the defendant. In practice the content of the duty and the quality of the defendant's actual conduct is usually examined by application of the criterion of the foresight of a reasonable person: would a reasonable person in the same circumstances have foreseen the possibility of harm occurring and would he or she have taken precautionary measures? If the answer is in the affirmative, the defendant failed to comply with the standard of a reasonable person and is therefore negligent.

Some factors to consider

The following factors may independently or in combination, give an indication of the existence or non-existence of a legal duty:

a) A legal duty to supply correct information may be imposed by statute.

A legal duty may arise from an express or implied

a) contractual undertaking to supply correct information (in other words a guarantee).
b) A legal duty may arise from a contractual relationship existing between the representor and representee.
c) A legal duty may arise from the fact that the representor possesses skill in the particular field in which he or she gives advice, or professes such skill.
d) The fact that the information falls within the peculiar knowledge of the representor or that the representee is in a position in which he or she must necessarily rely on the representor for information, may indicate the existence of a legal duty.
e) The fact that physical injury or damage results from the giving of incorrect information is an indication of the existence of a legal duty.
f) The purpose for which the information was supplied may give an important indication whether the defendant owed and breached a legal duty vis-à-vis the plaintiff.

g) The question whether the potential loss which may result from the misrepresentation is finite or indeterminate is an important factor in the determination of the existence of a legal duty

Ref 8

3.7 Specific Situations

3.7.1 Failure to Warn or Counsel

3.7.1.1 The Classification of Information According to its Purpose

There are two distinct purposes for providing patients with information. The first is to decrease the risk of side effects and increase the benefits of a course of drug therapy.[237] The provision of this form of information has, in other words, the objective

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[232] *Ehmhe v Grunewald* 1921 AD 575 at 581. See also *Borgin v De Villiers and Another* 1980 (3) SA 556 (A) 577D-E.

[233] *De Waal v Ziervogel* 1938 AD 112 at 123:

> '[T]he question which the Court has to decide ... is not was the defendant in fact speaking from a sense of duty but did the circumstances in the eyes of a reasonable man create a duty or an interest which entitles the defendant to speak?'

See also *Jansen van Vuuren v Kruger* 856D-E; *Borgin v De Villiers* 577E-G.

[234] *Argus Printing and Publishing Co Ltd v Inkatha Freedom Party* 589F.

[235] Van der Walt and Midgley par 98.

[236] *Borgin v De Villiers* 577G; *Argus Printing and Publishing Co Ltd v Inkatha Freedom Party* 589F-G.

[237] Asbury 939. As stated by Gonzalez (53):

> 'The complexity of modern drug therapy expounds the reality that providing patient instructions and warnings is often as critical to successful drug treatment as the accurate dispensing of the prescription.'

This is also recognised in rule 2.8 of the Rules Relating to Good Pharmacy Practice.

of achieving risk management. It is thus known as 'risk management information' or 'risk minimisation information'.[238] The second purpose of counselling is to enable patients to assess the risks and benefits of drug therapy and for healthcare professionals to thereby obtain informed consent. This is achieved by providing a patient with 'risk assessment information'. It is obviously necessary for patients, at some stage, to be provided with both risk minimisation and risk assessment information. The issue which arises is whether *pharmacists* should be held responsible for the provision of information, and, if so, which kind(s) of information pharmacists should be expected to provide. This essentially involves two questions:

a) Can pharmacists incur delictual liability for failing to ensure that patients understand *how to use* drugs (ie for failing to provide risk minimisation information)? This forms part of the greater question concerning whether pharmacists are required to actively promote safe and effective drug use.

b) Can pharmacists incur delictual liability for failing to ensure that patients are aware of the possible *side effects* of medications (ie for failing to provide risk assessment information)?

The failure to provide either kind of information clearly constitutes an omission. As such, liability will only ensue should a duty to speak be established. There are, however, a number of preliminary matters that must be understood before exploring the duties of pharmacists in this regard.

Firstly, the classification of information as either risk assessment information or risk minimisation information will not always be as clear-cut as one might like. Some degree of overlap does occur. It can, for example, be accepted that information concerning the side effects of drugs constitutes risk assessment information. Information concerning what to do in the event of an adverse reaction would, on the other hand, constitute risk minimisation information. In order to communicate the latter kind of information effectively, one will, however, often need to explain the

[238] This information may even have the purpose of minimising risks to third parties (eg advising a patient not to drive or operate heavy machinery whilst on a particular course of drug therapy protects the safety of not only the patient, but third parties as well).

Ref 9

Rules relating to Good Pharmacy Practice

2.7.1 DISPENSING PROCEDURES

This section must be read and applied in the context of its relevance and pertinence to the various persons authorised to participate in the dispensing process in terms of their scope of practice.

The dispensing process is divided into three phases, namely:

Phase 1: Interpretation and evaluation of the prescription.
Phase 2: Preparation and labelling of the prescribed medicine.
Phase 3: Provision of information and instructions to the patient to ensure the safe and effective use of medicine.

2.8 MINIMUM STANDARDS FOR PATIENT INFORMATION AND ADVICE

Patient information is of vital importance in the correct use of medicines. Lack of information and misunderstanding contribute to the failure of the therapy, thus wasting resources and adding to the costs of care.

2.8.1 PURPOSE

Patient information must respect patient autonomy, improve health and enhance the outcome of medical treatment by:

(a) empowering consumers to make informed decisions about their medical treatments and take responsibility for their own health care;
(b) improving communication between patients and health care providers; and
(c) aiding and encouraging effective use of medicines.

2.8.2 GENERAL CONSIDERATIONS

(a) Pharmacists and other persons registered with Council must (within their scope of practice) give advice and information to patients on how to use medicines safely and effectively to maximise therapeutic outcomes.
(b) Pharmacists must have access to as much information as they require within their ethical and professional judgement to meet the individual needs of patients. Such information should include the patient's medical/clinical records.
(c) Although specific presentation and language must be adapted to local communities and public comprehension, information presented to patients must as far as possible be nationally consistent.
(d) Pharmacists must assess and, where appropriate, comment on promotional materials for medicines and other products associated with health.
(e) Upon receipt of a prescription, or a request for dispensing of medicine on own initiative, a pharmacist must counsel each patient or patient's caregiver on matters which, in the pharmacist's professional judgement, will enhance or optimise the medicine therapy prescribed.

(g) Care must be taken to assess the wishes of the prescriber and the information and counselling needs of individual patients.
[Editorial Note: Numbering as per original Government Gazette.]

(h) Written information must be used to supplement verbal communication as appropriate.

(i) The pharmacist must assess each patient's ability to understand the information imparted by question and answer and must be able to modify his/her approach accordingly. Care should be taken with counselling where understanding is likely to be a problem.

(j) Confidentiality of the patient must be respected.

(k) The provision of advice must take place in a suitable environment and the patient should be put at ease, especially with regard to sensitive information.

Ref 10

Rules relating to acts or omissions in respect of which the council may take disciplinary steps

1. **Dispensing practices.**—Failure to furnish advice or information for the safe and effective use of medicines supplied by him.

Ref 10(contd)

Aspects of Delictual Liability in Pharmacy Practice

Melissa Geane Lewis Rhodes University, December 2006

drug-related pharmaceutical knowledge,[267] without knowledge of the medical history of the patient concerned.[268] Dwyer lists the following as examples of the kind of information about which pharmacists should be expected to provide warnings:

- the need to be alert for adverse effects;
- the need to avoid other drugs (including alcohol) or kinds of food that may interact with the drug which has been prescribed; and
- the need to take care if conducting certain activities (such as driving or operating heavy machinery) during the course of drug therapy.[269]

All of these examples involve the provision of risk minimisation information which is not necessarily dependant on the medical history or condition of a particular patient.

The second problem with denying liability on the basis of lack of patient-specific knowledge is that, whilst, traditionally, pharmacists may not have had access to patient-specific information, in modern times, they are generally required to maintain extensive patient profiles.[270] The Rules Relating to Good Pharmacy Practice stress that pharmacists must have access to as much information as is needed to meet the individual needs of each patient, including the medical records of that patient,[271] and must be aware of the essential medical information about each person to whom they render a service.[272] Rule 2.9 provides certain minimum standards for the keeping of patient medication records whilst rule 2.25.1 deals with patient information. These two rules provide that patient medication records must be developed (preferably with the use of computer technology)[273] and must contain certain information, including a list of all prescription and OTC medications obtained by the patient from the pharmacy in the past year, any allergies, chronic conditions or diseases which the patient may have, and any reactions or possible reactions of the patient towards medicine.[274]

[267] Brushwood *Drake LR* 29-30.
[268] Casmere 444; Milot 1019.
[269] Dwyer 742-743. See also Cruz 242.
[270] Gonzalez 60.
[271] Rule 2.8.2(b).
[272] Rules p3.
[273] Rule 2.9.1(a).
[274] Rule 2.9.1(c).