Introduction

There have recently been a number of examples of incorrect labelling posted on Facebook which are extremely embarrassing for the profession. I have seen cases which had the potential to cause serious harm to the patient, e.g. an antibiotic dispensed for a sensitive, sickly toddler with a label indicating 3 times the normal dose, a S5 sleeping tablet labelled, “Take 1 tablet in the morning” and oral painkillers labelled “Take 1-2 tablets every 6 hours per rectum”!

In a previous article titled, “A Good Label……not just a pretty picture!” (see SAPJ July 2010), I spelt out the minimum requirements for correct labelling of dispensed medicine, and outlined in some detail the reasons for these minimum requirements. The patients’ rights to correct information and pharmacists’ ethical obligations were also included. In this article I wish to elaborate on the pharmacist’s obligation to provide accurate information about the medicine dispensed and the potential consequences of providing misleading or inaccurate instructions on the use of the medicine.

Pharmacist’s obligations

In adhering to the first principle of the Code of Conduct namely, “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”, a pharmacist is expected to provide all the information necessary, in a suitable format and appropriate language for the patient to fully understand the purpose of the medicine, how to use it correctly, storage conditions, any significant side-effects and what to do when experiencing any adverse reactions. The pharmacist must ensure that the information provided is both accurate and understood.

The pharmacist is required by law to fulfil these obligations by labelling medicine supplied accurately, including auxiliary warning labels, and providing patient information leaflets, package inserts and counselling. The most basic of these requirements is adequate, accurate labelling.

These requirements are spelt out in the following Pharmacy Act Regulations:

Regulations Relating to the Practice of Pharmacy:2

3. Acts specially pertaining to the profession of a pharmacist.—
   (c) furnishing of information and advice to any person with regard to the use of medicine;

Rules relating to Good Pharmacy Practice3

2.7.1 Dispensing Procedures

   • 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

2.7.1.2.2 Labels

a. Labelling of dispensed products must be clear, legible and indelible. Lettering must as far as possible be mechanically printed.

b. The following information must be indicated on the label in accordance with Regulation 8 (4) of the General Regulations published in terms of the Medicines Act:
   i. the proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
   ii. the name of the person for whose treatment such medicine is sold;
   iii. the directions in regard to the manner in which such medicine should be used;

From my Little Black Book of pharmacy practice
iv. the name and business address of the person authorised to sell such a medicine;
v. date of dispensing; and
vi. reference number.

2.8 Minimum Standards for Patient Information and Advice

In terms of the **Medicines and Related Substances Act 101 Of 1965,** the following sections apply:

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

In the **General Regulations** to this Act the following sections are applicable for the provision of instruction and information about the medicine supplied:

- **8. Labelling of medicines intended for administration to humans**
- **9. Package inserts for medicines for human use.**
- **10. Patient information leaflet.**

The **Consumer Protection Act** also applies.

The following paragraph from a previous article, “Patient counselling and medicine information... just how far do you go?” (SAPJ Vol80 No 6 2013) bears repeating here:

On his website “Forensic Corner”, Rene Doms Dip Pharm Adv. Dip (B&A) BL B FPS, also emphasizes the need for providing the patient with adequate information about medicines supplied if liability is to be avoided. He writes; “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. No medicine is risk free. It is by character, an inherently unavoidably unsafe product. 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.

What about liability?

Consider the following scenario:

The anxious mother of an allergic, sickly baby has an antibiotic prescription dispensed at six in the evening. The PA labels the medicine at 3 times the normal dose. The baby develops nausea and vomiting, the original condition gets worse during the night and needs to be admitted to hospital with severe dehydration. Asked if the pharmacist signed off the script, mother reports that he did the entire script unsupervised and called the pharmacist from his office at the back just before handing over the medicine. The pharmacist signed off the copy script after giving it a cursory glance, not checking it against the original, and with no counselling of the mother.

It must be borne in mind that conduct which causes physical harm is generally regarded as **prima facie** unlawful.  

In this case the patient suffered physical harm as a result of inaccurate labelling as well as inappropriate supervision by the pharmacist and no counselling of the patient. Under such circumstances the pharmacist could clearly be held delictually liable. (A delict is a wrongful act, usually an intentional or negligent breach of a duty of care, committed against another person in such circumstances as to render the perpetrator liable for damages to the wronged person in a civil action.)

The purpose of accurate labelling information is to ensure that the course of medicine is taken correctly, safely and to be as effective as possible. Furthermore, a professional relationship exists between the pharmacist and the patient, in terms of which the patient relies on the special skills, knowledge and duty of care of the pharmacist and subsequently on the accuracy of the information and instructions given with regard to the dispensed medicine.

Pharmacists who fail to comply with the labelling requirements as set out in GPP, and level of patient care as required by the Code of Conduct, could be subject to disciplinary sanction by the SAPC in terms of **Ethical Rule 1. Dispensing practices.**— **Failure to furnish advice or information for the safe and effective use of medicines supplied by him and also in failing to practice pharmaceutical care in breach of the first principle of the Code of Conduct.**

Pharmacists are also under a statutory duty to avoid making misleading statements. The **Medicines Act** provides that any person, who, when selling a medicine or scheduled substance, makes a false or misleading statement in connection therewith, or sells any medicine or scheduled substance in a container upon which a false or misleading statement pertaining to that substance is written, will be guilty of an offence (s29(h)-(i)).

In these circumstances such a person could be found to be criminally liable, and upon conviction, be liable to a fine or imprisonment not exceeding 10 years (s30).  

Clearly pharmacists are both ethically bound and under a serious legal duty to avoid harm to the patient by taking steps to ensure the accuracy of the information they provide when supplying medicine, particularly with regards to labelling.

What to do about it?

As can be seen from the example above, many labelling errors can be avoided through teamwork and checking. Technology such as scanning, automatic dispensing units, and improved computer systems can always be helpful, but, understanding and appreciation of the importance of accurate labelling, the benefits of teamwork, and the habit of checking at every level will go a long way to preventing errors.

**Suggested preventative measures include:**

- **Review of systems**
  - Bearing in mind the legal requirements for labelling of dispensed medicines regularly review the technology available to produce a good label. See my previous article, “A good label... not just a pretty picture!” (see SAPJ July 2010 or PSSA website), for guidance in enhancing your current labelling technique and teaching staff to appreciate the importance of accurate labelling.

- **Team work**
  - Too often both pharmacists and PAs display resentment in having their work checked. The RP should organise dispensary
staff into work teams of compatible people who show mutual respect and appreciation towards each other. The team members must appreciate each member’s role in each of the three phases of dispensing as well as the advantages of having your worked checked by a colleague. Well organised teams get more prescriptions dispensed, more accurately and in less time. Train all staff in the latest GPP Minimum Standards Relating to the Supervision of Pharmacy Support Personnel.

- **Check, check, check and check again!**
  The following minimum checks should be made when dispensing a prescription:
  1. The pharmacist to check the labelling instructions when initially assessing the prescription in Phase one of dispensing.
  2. After accurately capturing the prescription on computer, the printed labels must be checked against the *original prescription*.
  3. Once the label has been attached to the container, it should be checked again to ensure that the correct label has been used.
  4. When handing over the medicine to the patient with instructions and counselling, read the label to the patient as a final check.

**Conclusion**

In an article appearing in *Pharmacopeia Forum* 2 Vol. 37(1) [Jan.–Feb. 2011], it was reported that, “Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread. Studies have found that 46% of patients misunderstood one or more dosage instructions, and 56% misunderstood one or more auxiliary warnings. The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy. In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels*.

The minimum requirement must be accurate labelling. Failure to label medicine correctly is not only a failure to fulfil an important ethical obligation, a contravention of GPP Rules and the legal requirements of the Medicines Act, but can lead to harmful effects on the patient which makes the pharmacist susceptible to a delictual liability claim.

**Label accurately, with care, and check, check, check and check again!**

**Disclaimer:** This document is a guideline and does not necessarily reflect official policy of the Pharmaceutical Society of SA. Any person wishing to implement proposals made in this document, must do so in accordance with the requirements of the Pharmacy Act, Medicines & Related Substances Act and all other relevant legislation, and, if necessary, should seek legal advice to ensure compliance.

For copies of the references or any further information please contact gary@pssacwp.co.za

**References**

1. Rules relating to Code of Conduct (Refer PSSA Pharmacy Law Compendium page PRE-327)
2. Regulations Relating to the Practice of Pharmacy (Refer: PSSA Pharmacy Law Compendium page PRE-60)
3. Rules relating to Good Pharmacy Practice (Refer: PSSA Pharmacy Law Compendium page PRE-213)
6. The Consumer Protection Act (CPA) interpretation Rene Doms Forensic Corner
7. Aspects of Delictual Liability in Pharmacy Practice. Melissa Geane Lewis Rhodes University, December 2006(Pages 101 t0 103)
8. Rules relating to acts or omissions in respect of which the council may take disciplinary steps (Refer: PSSA Pharmacy Law Compendium page PRE-14)