

Update on dispensing

Part II: Current Legislation

— M H Cassimjee



Dr M H Cassimjee, LL.M RCP, LL.M RCS(Ireland) MPrax Med(Natal) MFGP(SA)
106 Retief Street
Pietermaritzburg
3201.

Curriculum vitae

Dr Cassimjee has been in active family practice for the last 18 years. He has been part time Senior Lecturer in Family Medicine at the University of Natal since 1988. Presently he is working toward an Honours degree in medical science in Pharmacology at the University of Durban, Westville. As an executive member of the Natal Inland Branch of the Academy of Family Practice/Primary Care he is convenor of the committee for continuing medical education. His personal interests are in the economics of general practice and the legal issues relating to dispensing by doctors in South Africa.

On the 21st December, 1984, the Medical Dental and Supplementary Health Services Professions Amendment Act No 58 of 1984 became law. This amendment introduced only one new principle and that was the introduction of a Register, by the South African Medical and Dental Council, for dispensing doctors. This meant that any doctor who dispensed medicines as defined in Section 52(1)(a) on the 21st December, 1984, had to complete an application form and submit it with a registration fee of R25,00 to the Registrar of the South African Medical and Dental Council before 20th March, 1985. Practitioners who wished to dispense

Summary

This article discusses the different legislative provisions which were made to regulate dispensing by doctors since 1984, and what the implications and requirements of all the different acts and amendments are.

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medicines in the future in terms of section 52(2)(b) in the practice of their professions contemplated in Section 52(1)(a) were also required to complete the application form for registration and forward it together with the prescribed registration fee of R25,00 to the Registrar of the South African Medical and Dental Council. Such practitioners could only commence with dispensing activities once their application for registration has been finalised. Some 3 300 doctors requested registration to dispense.

In response to the initial application, the Registrar of the South African Medical and Dental Council sent an official certificate to practice, in May, 1986. The certificate makes available to practitioners convenient proof of current registration as dispensing doctors, as prescribed by Section 52 of the Medical Dental and Supplementary Health Service Professions Amendment Act No 58 of 1984.

This certificate to practice is valid for only one year. Such a certificate in future will be issued upon payment of the annual fee to persons as evidence that they are registered with the Council. The Registrar of the South African Medical and Dental Council in his notification which accompanied the certificate to practice, has given

guidelines for the dispensing of medicines by a general practitioner or dentist.

These guidelines will be discussed more fully later.

The dispensing of medicines in general practice is governed by:

1. The Medicines Control Act (Act 101 of 1965)
2. The Medical, Dental and Supplementary Health Services Professions Amendment Act No 58 of 1984.
3. Ethical Rule 28 of the South African Medical and Dental Council which states "*A Doctor should not place himself in economic competition with a pharmacist*"
4. The Pharmacy Act of 1974 (Act 53 of 1974).

The various Acts and their implications are discussed below.

THE LEGAL REQUIREMENTS FOR THE DISPENSING OF MEDICINES

The Department of National Health and Population Development, and the South African Medical and Dental Council, have compiled certain guidelines for the dispensing of medicines by doctors.

(1) The Medicines Control Act (Act 101 of 1965)

Certain aspects of the legal requirements are discussed in terms of the practical implications for dispensing doctors.

(a) *Effective control over the selling of medicines and listed substances*

In accordance with the stipulations of Section 22 of the Act and Section 52 of the Medical, Dental and Supplementary Health Services Professions

Medicine stock (schedule 7 substances) must be physically checked and certified by the dispensing doctor himself

Act (Act 56 of 1974, as amended) a doctor may personally dispense medicine to his or his partner's patients only. Furthermore, in order to ensure effective control, in the doctor's absence, unauthorised persons should not have access to medicines and listed substances - he must, for example, have adequate lockup facilities.

It is therefore illegal for any employee, who is

not a medical doctor to dispense medicine. The layout of the practice, and of the pharmacy in particular, is also of the utmost importance in preventing unauthorised access as mentioned above.

In this regard note must be taken of Section 33 of the Medicines Control Act, viz, that an employer will be deemed responsible for any act or omission on the part of an employee, unless, among others, it can be proved that (i) the employer did not connive with or permit the act

Medicines may be dispensed only if the doctor or his partner have prescribed them

or omission and (ii) the employer took all reasonable precautions to prevent such an act or omission. The fact that an employer had forbidden a specific act or omission will in itself not be accepted as adequate evidence that he had taken all reasonable steps to prevent such an act or omission.

(b) *Pre-packing of medicines*

Section 14 and Regulation 15 made in terms of the Act stipulate that it is not permissible to pre-pack medicine in the dispensary of the practice because this process is subject to the registration requirements of the Medicines Control Council. It is therefore illegal, for example, to re-pack medicines from bulk packaging into smaller containers with a view to selling it at a later stage. However, it is permissible to dispense from bulk packaging to a *specific person*, a supply not exceeding the *quantity required for treatment*.

It must be borne in mind that dispensing in this manner, will only be possible if adequate facilities exist. The basic requirements are a spacious working slab, easily accessible shelves, comfortable desk and adequate lighting.

The obvious intention of the act is that the quality level required during the production process must be maintained during the distribution process. In terms of the stipulation of Section 14 it can be concluded that the conditions under which medicines are stored in the pharmacy or dispensary must receive close attention as well, eg exposure to sunlight or high temperatures, the availability of a fridge for the storage of sensitive vaccines, insulin, etc and cleanliness in general.

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c) Labelling of medicines and the keeping of a prescription pad

Every medicine dispensed must be labelled (Section 18) and the following information must appear on labels:

- (i) The name of the medicine, except in cases wherein the interest of the patient, the doctor wishes to withhold it.
- (ii) The name of the patient.
- (iii) Complete directions for the use (if applicable).
- (iv) The name and business address of the doctor.
- (v) The reference number, cross reference to the permanent record of the prescription (the date of dispensing can be used as a reference number).

In terms of Section 22 A and Regulation 28 a prescription pad or other permanent record must be kept.

The following information must be recorded:

- (i) The name and address of the patient.

- (ii) The preparation form and quantity of the medicines.

- (iii) Date of dispensing.

- (iv) Reference number of label (see comment above).

A further important point is that all samples received and dispensed must be labelled and recorded in the prescribed manner.

(d) The keeping of a register for Schedule 7 substances

In terms of Sections 22 A (9) (b) (iii) and 9 (e) and Regulation 25 a register must be kept of Schedule 7 substances in the prescribed manner. Registers conforming to the prescribed lay out and that are suitable for use in an average practice with a low turnover in these substances, can be obtained from the local pharmaceutical wholesalers.

Each receipt and handout must be recorded in the register on the date of the transaction. The register must be balanced on the last day of March, June, September and December, which means that the stock must be physically checked and



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that the doctor must certify by means of an inscription against these dates that the stock and register tally. The doctor must also keep a record of receipts of all schedule 5 and schedule 6 substances and must retain such records for at least three years. (Regulation 24).

(e) *Dispensing of medicine of which the due date has expired*

The Act defines the expiry of medicine as the date whereafter the strength and other characteristics indicated on the label of the medicine will not be preserved. *After this date the medicine may no longer be sold to the public.*

The safety, quality, and therapeutic effectiveness of the medicine cannot be guaranteed after the expiry date and it is therefore a contravention of the law to sell such medicine.

(f) *Record of Medicines Dispensed*

From the Regional Director, Department of National Health and Population Development, Durban.

It is incumbent upon the dispensing doctor that relevant records should be kept. Such record may be in the form of a card, file or book-record. If an entry is made on the patient's record-card, this could result in problems of confidentiality arising when Inspectors appointed in terms of Section 26 of Act 101/65 require to have access to the dispensing record. It could even occur that such record is required as "an exhibit" which can also cause embarrassment. The Regional Office of the Department of National Health and Population Development will appreciate the necessary co-operation of all doctors who undertake dispensing.

Dispensing must be incidental to his practice

(2) **The Medical Dental and Supplementary Health Services Professions Amendment Act 58 of 1984**

The relevant section of the Gazette reads as follows:-

"52(1)(a) Every medical practitioner or dentist whose name has been entered in the register contemplated in subsection (2) shall, on such condition as the Council may determine in general or in a particular case, be entitled to person-

ally compound or dispense medicines prescribed by himself or by any other medical practitioner or dentist with whom he is in partnership or with whom he is associated as principal or assistant or locum tenens, for use by a patient under treatment of such medical practitioner or dentist or of such other medical practitioner or dentist: provided that he shall not be entitled to keep an open shop or pharmacy.

Very wide powers were accorded to the Investigating Officer - which the medical fraternity did not appreciate at all!

(b) The Council may, on such conditions as it may determine, exempt any medical practitioner or dentist from the requirement of registration contemplated in paragraph (a), and may, after an investigation, withdraw such exemption.

(2) The registrar shall keep a register in which he shall enter, at the direction of the Council, the name and such other particulars as the Council may determine of a medical practitioner or dentist.

(a) who within three months after the commencement of the Medical, Dental and Supplementary Health Services Professions Amendment Act, 1984, submits proof to the satisfaction of the registrar that at such commencement he compounded or dispensed medicine as contemplated in subsection (1)(a) in the practice of his profession; or

(b) who informs the registrar in the prescribed manner of his intention to compound or dispense medicine in the practice of his profession as contemplated in subsection (1)(a).

"52 (3) The Council may, after an investigation, direct that the name of any person be removed from the register contemplated in subsection (2), or prohibit him for a specified period from making

Hier's die welkome een van Wellcome vir neuskongestie...



use of the right contemplated in subsection (1).

- (4) The Council may determine fees to be paid for the entering of a name in the register contemplated in subsection (2)".

South African Medical and Dental Council Guidelines on Methods of Dispensing

"Medicines may be dispensed by a medical practitioner or dentist provided:

- (i) It is done on such conditions as the Council may determine in general or in a particular case.
- (ii) The medicine must be prescribed by himself or his partner.
- (iii) The medicine must be for the use of his own (or his partner's) patients.
- (iv) The medicine must be personally compounded.
- (v) The dispensing must be incidental to his practice.

For the purpose of the above guidelines the Council has defined dispensing as:

"The compounding, preparation or mixing of medicine, or medical or chemical substances to

be sold or supplied as medicine and the mixing or sale or supply of medicine."

General Conditions for Dispensing

"In terms of Section 52(1)(a) Council has determined that practitioners could only dispense under the following general conditions:

A complete record of medicine (except medicine and injections dispensed in consultation rooms) must be kept in which the following is reflected:

- (a) Substantiated with invoices, the price, quantity and name of the supplier.
- (b) Medicine in stock which must be balanced at the end of each year, ie the end of February."

(3) Implications of legislations governing dispensing of medicines

Section 41(a) of Act No 58 of the Medical Dental and Supplementary Health Services Professions Amendment Act of 1984 empowers the Registrar of the South African Medical and Dental Council to appoint an investigating officer with the approval of the President of the Council. His job will be to carry out investigations at the instance of the Registrar.

An investigation may be instituted:

1. Into alleged contravention of, or failure to comply with any provisions of the Act.
2. In order to determine if any provision of this Act applies to a registered person.
3. Into a charge, complaint, or allegation of improper or disgraceful conduct by a registered person.
4. Into the affairs or conduct of a registered person, if requested to do so by a person by reason of allegation confirmed upon oath.

The registrar or investigating officer will have very wide powers of entry of any premises and seizure of books, documents and other objects. In terms of the Act the investigating officer may enter premises at any time "reasonable to the proper performance of his duty". He may enter a premise with the approval of the President and without prior notice to the person involved. Failure on the part of the practitioner to produce a book, etc, or to furnish an explanation to the registrar or investigating officer will constitute a criminal offence punishable by a stiff fine and/or imprisonment.

The amendment was certainly not welcomed by

the dispensing medical fraternity, particularly in regards to the wide powers accorded to the investigating officer.

Expert legal opinion on this Section 41(a) is discussed below:

● Investigating Officer

- (a) In terms of section 41 A (8) (a), the Investigating Officer is required to submit a report of his investigations to the Registrar of the Medical Council.
- (b) This report which is equivalent to a complaint only cannot be challenged in a court of law because it is only a report and not a *finding*. This report is devoid of any legal status.
- (c) The Medical Council alone is empowered to make a finding provided that the procedures to enable it to arrive at such a finding are properly carried out in the first place.
- (d) If the Medical Council finds a practitioner guilty of misconduct, its finding can be attacked in the Supreme Court only on two grounds.
 - (i) *On procedural grounds:*
For example where the Medical Council

...en vir kongestie van die eustachio-kanaal.

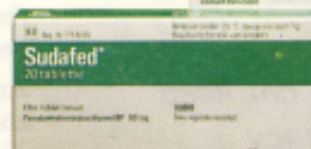
• Een aktiewe bestanddeel. • Een wat sistemies werk en beskadiging van die slymvliese voorkom. • Een wat effektiewe ontstewing van die neus, sinusse, eustachio-kanaal en die boonste lugweë verskaf. • Een ontstummiddel vir volwassenes sowel as kinders. • Een wat nie lomerigheid veroorsaak nie.



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based its findings simply on statements submitted to it by the Investigating Officer and without having the statements of witnesses tested by cross examination of such witnesses.

- (ii) Where the decision of the Medical Council is so grossly unreasonable that no reasonable man could have come to that conclusion. This is a particularly heavy onus to discharge. It is on this ground that the decision of the South African Medical and Dental Council in the Biko case was challenged in the Supreme Court and eventually reversed on an application brought by Professor Frances Ames, Professor Tobias and Dr Variawa.
- (e) The qualifications of the Investigating Officer are left *unstated*.
- (f) The period over which books and documents have to be retained is not specified in the Act. The maintenance of registers of drugs by doctors and pharmacists may be governed by Acts such as the Medicines Control Act No 101 of 1965 and the Pharmacy Act of 1974. The practical solution may lie in the retention of books and documents over a reasonable period.
- (g) In making his investigation, the Investigating Officer is entitled to have access to such documents as relevant evidence of disgraceful conduct. Although not relevant per se, documents relating to profits and loss and income and expenditure may become relevant in investigations relating to profiteering, overcharging and other similar offences.
- (h) The reference to the Criminal Procedure Act in Section 41 (a) (7) (c) finds applicability

The dispensing doctors may not keep an open shop or pharmacy

where the practitioner consents to the admission of the statements. The said section relates to those statements which can be handed in without the witness being subjected to cross examination. To sum up this aspect, the expert legal view is that whereas in the past, the Medical Council had no real teeth to investigate contraventions, the new section now provides the teeth by means of the Investigating Officer and the Registrar.

● *Dispensing and Compounding*

(a) Section 52 (A) relates to the supply of any medicines mentioned in Schedule 1, 2, 3 or 4 to the Medicines and Related Substance Control Act 101 of 1965, by a registered nurse in accordance with the direction of a Medical Practitioner in circumstances where the consulting rooms of the Practitioner are not situated within a reasonable distance of a retail Pharmacy. Here no new principle is introduced because the

No definite guidelines on the costing of medicines have been given as yet

question of a reasonable distance from a retail pharmacy was inherent in the 1974 Act.

Whereas previously the Secretary for Health had the power to grant authority, now the power rests in the Council. Whereas previously the person who could supply was an *enrolled nurse*, now it has to be a registered nurse.

(b) Section 52(A) or for that matter the entire Medical Dental and Supplementary Health Services Professions Amendment Act No 58 of 1984, cannot be attacked in a court of law.

Unlike certain other legal systems, such as that of United States of America, in South Africa an Act of Parliament cannot be attacked on grounds of unreasonableness or vagueness. The only exception is, if a law impinges on the equality of the English and Afrikaans languages.

(c) Section 52 (1) (A)

(i) The basic change is that whereas previously the right to personally dispense and compound medicines flowed from the fact that the person was a medical practitioner, *now* that right will flow only after the name has been entered in a register.

(ii) Any doctor who has been dispensing and compounding would as of *right* have his name placed on the register.

(iii) The *only new principle introduced* is the Register and Registration is facilitated, because it is quite unnecessary to show public interest. The existence of a number of pharmacies in the immediate vicinity will be irrelevant.

(iv) a. The potential problem is the attitude of the Medical Council to the Act, whether it understood the law before the amendment and whether it intends enforcing its provisions. In other words, will the

Medical Council take a closer look at Section 52?

- b. If by "personally compounding and dispensing" means that one has to act like a pharmacist, dispensing doctors will have a problem whether the present amendment is there or not because the requirement was present in the 1974 Act.
- c. On the other hand "compounding and dispensing" needs to be examined more thoroughly. In 1928 medicines were mainly compounded medicines. Presently most medicines are manufactured and packed by highly skilled pharmaceutical organisations. Therefore the concept of compounding and dispensing must be examined in the light of this change.

Although most medicines are prepacked, the doctor has still to exercise some discretion. For example, in expectation of epidemics and ordinary ailments, if the practitioner packs the shelves with bottles and packets of medicines and tablets clearly labelled, then he can, after examining the patient, direct his nurse, whether she is a registered nurse or not, to write on the label the name of the patient and simple directions and to hand it to the patient, then the practitioner can be said to be "personally dispensing" the medicines. All that is required of his assistant is that he/she be able to read and to perform simple clerical duties of writing out the name of the patient and the directions.

The legal experts definition of dispensing in 1986 is:

"Distribution of medicine and drugs through expert and controlled discretion".

This certainly differs from the South African Medical and Dental Council's definition of dispensing "the compounding, preparation or mixing of medicines, or medical or chemical substances to be sold or supplied as medicines and the mixing or sale or supply of medicines". This definition had relevance in 1928.

If therefore the abovementioned steps are taken, it is the legal expert's view that the doctor has "personally compounded and dispensed" and can be a basis for a defence against a disciplinary charge.

(d) Section 52 (A)

It is the legal expert's view that this section showed most promise provided the basis of the exemption is widened. As it stands now, once authority is granted, the practitioner needs simply to direct the registered nurse to supply the particular medicines to the patient. The present basis of the

exemption is the absence of a pharmacy within a reasonable distance from a doctor's consulting rooms. If the basis can be extended to include economic, physical and financial hardship to patients, then practitioners serving the poor sections of the community could apply for necessary authority from the Medical Council.

● *Trading and Profiteering*

Section 52 (1) (a) of Act 58 of the Medical Dental and Supplementary Health Services Professions Amendment Act 1984 stipulates that a registered dispensing doctor shall not be entitled to keep an open shop or pharmacy. By inference, an "open shop or pharmacy" refers to trading and hence by implication, profiteering.

The dispensing doctor's all-inclusive fee of medicines plus consultations to his private patient is well below the recommended consultation tariff of the Medical Association of South Africa. The problem arises with the medical aid patient, who is charged a gazetted tariff for his consultation and Mims price for medicines supplied to him. It is on issues such as these that pharmacists accuse the dispensing doctors of trading and profiteering.

However, it is the author's contention that the costing of medicines to Medical Aid patients be a separate subject of research at some later stage, the mechanics of which will not be discussed presently. Suffice it to say that neither the South African Medical and Dental Council nor the Medical Association of South African have given definite guidelines on the question of costing of medicines. A joint declaration in 1981 by the Medical Association of South Africa and the Pharmaceutical Society of South Africa vaguely indicates that the "Medical practitioner may only recover his basic costs as well as the direct variable cost on the medicines handled by him; he may not, however, dispense with profit as his motive."

The formula for determining the various cost structures has never been determined and hence this joint declaration has no scientific bases or validity.

The question of the prohibition against profiteering on the supply of medicines was discussed with the legal experts, as the Act and the Amendment does not specifically prohibit the making of profit.

The legal experts opinion was:

1. It is true there is nothing in the Act which says that a Medical Practitioner cannot make a profit on the sale of medicines but if it is found there is profiteering on a substantial

scale, that practitioner can be found guilty of disgraceful conduct.

2. A medical practitioner can make *reasonable* profit on the sale of medicines provided that such profit does not form a substantial portion of his income.
3. The rule of thumb percentage of 25 would be considered as reasonable, eg 75% of income from consultation and 25% of income from the sale of medicines.

Two points emerge from the opinion viz:

- (a) The profit per script must not be unreasonable.
- (b) The proportion of total income must not emanate predominantly from profit on sale of medicines.

In the important notice to all medical practitioners and dentists on "Dispensing of Medicines" sent by South African Medical and Dental Council in February 1985, five guidelines were determined by them for medical dispensing:

- (1) It is done on such conditions as the Council may determine in general or in a particular case.
- (2) The medicine must be prescribed by himself or his partner.
- (3) The medicine must be for the use of his own (or his partner's) patients.
- (4) The medicine must be personally compounded.
- (5) The dispensing must be incidental to his practice.

For reasons best known to the South African

Medical and Dental Council, guidelines (4) and (5) stipulated above have been omitted in the notification which accompanied the certificate to practice as a dispensing doctor, received in May, 1986. However, the February, 1985 guidelines under general conditions of dispensing remains unaltered in the May, 1986 notification.

Why the omission of Guidelines (4) and (5)?

What inferences can one draw?

What conclusions can one deduce?

These are some of the questions to which answers may not be presently forthcoming. Only a test case trial in the near future will throw some light on this legalistic maze.

Part III of this article will be on "The most recent guidelines as stipulated by the Department of National Health and Population Development."

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