

Useful Links

Medicines Control Council (for reporting of adverse events, accessing MCC guidelines, etc.)

Address: Private Bag X828, Pretoria 0001
Tel: 012 4471618
Fax: 012 448 6181
Web: <http://www.mccza.com>

Health Professions Council of SA (regulatory body controlling health care professionals (medical practitioners, dentists, etc.))

Address: PO Box 205, Pretoria 0001
Tel: 012 338 9300
Fax: 012 325 2074
Web: <http://www.hpcsa.co.za>

Council for Medical Schemes (regulatory body of medical schemes)

Address: Private Bag X34, Hatfield 0028
Tel: 012 431 0500
Fax: 012 430 7644
Web: <http://www.medicalschemes.com>

South African Pharmacy Council (regulatory body controlling pharmacy profession)

Address: PO Box 40040, Arcadia 0007
Tel: 012 319 8500
Fax: 012 321 1492
Web: <http://www.pharmcouncil.co.za>

Innovative Medicines South Africa (IMSA)

Address: PO Box 2008 Houghton 2041
Tel: 011 880 4644
Fax: 011 8805947
Web: <http://www.innovativemedicines.co.za>

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"South African pharmaceutical industry association promoting the value of medicine innovation in healthcare" (Formed 2003)

What health care practitioners should know about the Medicines and Related Substances Act and the Medical Schemes Act

This document has been prepared by Innovative Medicines South Africa to provide information to health care practitioners on the legal frameworks created by the Medicines and Related Substances Act, as amended, and the Medical Schemes Act, as amended, particularly as it pertains to dispensing practice and compliance with these specific legislative requirements.

PROVISIONS PERTAINING TO THE MEDICINES ACT

When should dispensers substitute medication?

Dispensers are obliged to substitute an "interchangeable multi-source medicine" and *take reasonable steps to inform the prescriber* of that fact. No substitution may take place in the following cases:

- The patient forbids substitution;
- The prescriber writes "no substitution" in his or her own handwriting next to each line item;
- The generic is more expensive than the ethical product; or
- The medicine is declared non-substitutable.

The issue of substitution brought about by medical scheme formularies is addressed below.

What may be substituted?

Only an "interchangeable multi-source medicine" may be used, which refers to -

"medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed"

"Therapeutic equivalence" is described as where both medicines -

- (a) are pharmaceutically equivalent, i.e., contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; and
- (b) after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same.

Therapeutic equivalence is determined from comparative bioavailability, pharmacodynamic, clinical or *in vitro* studies which meet the requirements and accepted criteria for bioequivalence as determined by the Council.

Non-Substitutable Medicines

The MCC issued the following Guidelines in December 2003

1. This guideline replaces Circular 16 of 1994 (LIST OF NON-SUBSTITUTABLE MEDICINES). This list will be updated as new information on generic substitution becomes available. The absence of any substance from this list must not be construed to mean that such a substance will be substitutable. The attention of all health practitioners who dispense or administer medicines is drawn to this list to assist in taking decisions where one or more alternatives are available or when switching from one medicine to another.
2. The interchangeable use of different brands of chemically equivalent medications (i.e. those which contain the same active pharmaceutical ingredients, the same quantities thereof, in the same pharmaceutical dosage form or, as more commonly named, "generics") could under certain circumstances compromise therapeutic response and safety of the patient.

3. The Medicines Control Council, having considered the matter in depth on both a local and international level, recommends that substitution should not occur when prescribing and dispensing "generic" medicines that:

- i) have a narrow therapeutic range;
- ii) have been known to show erratic intra- and interpatient responses;
- iii) are contained in dosage forms that are likely to give rise to clinically significant bioavailability problems, e.g. extended or delayed release preparations, as well as those known to be super bioavailable; or
- iv) are intended for the critically ill and/or geriatric and paediatric patient.

4. In terms of the aforementioned factors, the following list of medicines have on occasion, been known to present bio-equivalence problems and should ideally not be interchanged with other "generics" unless adequate provision is made for monitoring the patient during the transition period.

- Alendronate tablets or capsules
- Amiodarone tablets or capsules
- Atenolol tablets or capsules
- Carbamazepine tablets
- Chlorpromazine tablets
- Dexamethasone tablets
- Diethylstilboestrol tablets
- Digoxin tablets
- Disulfiram tablets
- Ethinyl Oestradiol tablets
- Fluoxymesterone tablets
- Furosemide tablets
- Glibenclamide tablets
- Hydralazine, Hydrochlorothiazide and Reserpine combination tablets
- Hydralazine and Hydrochlorothiazide combination tablets
- Hydrocortisone tablets
- Hydrocortisone Acetate injection
- Isoproterenol Metered Dose inhaler
- Isoethrane Metered Dose inhaler
- Isosorbide Dinitrate sustained release tablets and capsules
- Itraconazole tablets or capsules
- Levodopa tablets and capsules
- Nifedipine: all extended/delayed release formulations
- Oestrogens, Conjugated tablets

- Oestrogens, Esterified tablets
- Penicillin G Benzathine injection
- Phenytoin tablets and capsules
- Phytomenadione injection
- Prazosin Hydrochloride tablets 5mg*
- Prednisolone tablets
- Prednisolone Acetate injection
- Prednisolone Tebutate injection
- Prednisone tablets
- Promethazine tablets
- Propylthiouracil tablets
- Reserpine tablets
- Reserpine and Chlorothiazide combination tablets
- Reserpine and Trichloromethiazide combination tablets
- Sotalol tablets or capsules
- Tamoxifen tablets of capsules
- Theophylline controlled release tablets/capsules
- Triamcinolone tablets
- Trichloromethiazide tablets
- Warfarin Sodium tablets

The list is subject to periodic review and alteration at the discretion and recommendation of the Medicines Control Council.

PROVISIONS PERTAINING TO THE MEDICAL SCHEMES ACT

What are the PMB's and the CDL?

The Prescribed Minimum Benefit (PMB) conditions are listed in Annexure A to the Regulations of the Medical Schemes Act and include 270 diagnosis and treatment pairs and 25 chronic conditions in a chronic disease list (CDL). According to regulation 8 to the Medical Schemes Act, schemes must pay in full and without co-payment for the diagnosis, treatment and care costs (including medicine) of the PMB (see exceptions below).

To what extent must schemes fund the PMB and CDL?

The rules of a medical scheme must provide the level and scope at which the PMB's must be funded, but this may not be lower than the descriptions found in the PMB list. For the 270 diagnoses it is set in general terms, e.g. that the scheme must pay for the "medical management", "surgical management",

"hospital-based management" of a particular condition. This may never drop below what a patient in the public sector would have been entitled to, according to public sector protocols. As far as the 25 chronic conditions are concerned, the scheme must at least provide for the treatment to the extent prescribed in the algorithm.

May a scheme have a protocol, formulary or other managed care limitations?

Yes, but the regulations contain various provisions in this regard. According to the Council for Medical Schemes' managed care policy document, the provisions of regulation 15 on managed care also apply where these strategies are used for PMB conditions. All formularies and protocols have to be set, first and foremost on evidence-based medicine (as defined in the regulations), and cost-effectiveness and affordability may be considered.

Exceptions to protocols and formularies

In terms of regulation 15H & I, appropriate exceptions must be made to protocols and formularies if they are ineffective in a particular patient or cause, or would cause harm (in the case of a protocol, which includes the algorithms) or cause, or would cause an adverse reaction in a patient. The scheme may not impose any penalty on such a patient.

Where a pharmacist notices that a medicine, as prescribed, will not be funded by a scheme due to that scheme's rules, formularies or a lack of pre-authorization, s/he should:

- Establish if the particular medicine had not been prescribed pursuant to regulation 15H / I.
- Inform the patient that the scheme will not fund the particular medicine, and, depending on the nature of the circumstances, recommend that s/he obtain the necessary information from their doctor in order to motivate for the prescribed medicine to be funded.
- Discuss the advantages, disadvantages, benefits and financial implications of the treatment with the patient (as part of the practitioner's duty to obtain informed consent) and offer the patient the choice of

paying for the medication.

- Take reasonable steps to inform the prescriber of the substitution, i.e. contact the prescriber to discuss the choice of medication and obtain verbal or telephonic approval if a change of medication is appropriate. The pharmacist must ensure that this intervention is followed up in the form of a legal written script.
- Bear in mind the provisions of the Medicines Act and MCC in terms of medicines and verbal scripts- and circumstances relating to non-substitution.

Co-payments

The regulations to the Medical Schemes Act allow for a scheme to levy a co-payment in the following circumstances:

- If the patient *voluntarily* sees a non-Designated Service Provider (DSP).
- If the patient *knowingly declines* a clinically effective and appropriate drug (not applicable in cases where the medicine is clinically ineffective or inappropriate, in which case regulation 15I applies).

Co-payment must equal real difference in price as closely as possible, i.e. must be reasonable, according to the Council for Medical Schemes Managed Care Policy document. Co-payments may also not be paid out of a patient's medical scheme savings account.

No co-payments may be required where patients involuntarily have to go to a non-DSP. These circumstances include where-

- The service is not available from a DSP or would not be provided without unreasonable delay.
- Immediate medical or surgical treatment for a PMB is required under circumstances or at locations which reasonably preclude obtaining such treatment from a designated service provider.
- No DSP is available within reasonable proximity to the beneficiary's ordinary place of business or personal residence.