Labelling and Advertising of Complementary Medicines

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Outline

- Legislation
- Labelling
- Naming
- Scheduling
- Advertising
- Closure

Medicines and Related Substances Act, 1965

- Labelling of a medicine for humans:
  - Label of a medicine (Section 18) & (Regulation 8) [**Bilingualism**]
    - [lenient in so far as allowing certain information to appear on the label of the product depending on the size of the presentation 100ml bottle versus 1ml ampoule]
  - Package Insert (Regulation 9) [**Bilingualism**]
  - Patient Information Leaflet (Regulation 10) [**Bilingualism**]
- Labelling of medicines for animals:
  - Label of a medicine (Regulation 48) [**one language**]
  - Package Insert (Regulation 40) [**one language**]

Labelling of medicine for humans Regulation 8

- Proprietary name
- Schedule status
- Registration number **34/20.1/0034**
- Category of medicine (A or D)
- Pharmacological classification
- Dosage form
- Name of the Active Ingredients and quantity
- **Approved** indications
- Dosage
- Discipline of medicine (Homeopathy)
- Disclaimer – If medicine is not registered with the MCC:

  "This medicine has not been evaluated by the MCC. The medicine is not intended to diagnose, treat, cure or prevent any disease"

Labelling of medicines for humans Regulation 8 cont…..

- Batch number
- Expiry date
- Storage instructions
- Name of the Applicant / Holder of Certificate of Registration
- Any specific warning
- “For external use only”
- “Keep out of reach of children”
- Etc…

Package Insert of medicine for humans Regulation 9

- Proprietary name
- Schedule status
- Registration number **34/20.1/0034**
- Pharmacological classification
- Dosage form
- Name of the Active Ingredients and quantity
- **Approved** indications
- Dosage
- Discipline of medicine (Homeopathy)
- "Disclaimer – If medicine is not registered with the MCC:

  "This medicine has not been evaluated by the MCC. The medicine is not intended to diagnose, treat, cure or prevent any disease"

Package Insert of medicines for humans Regulation 9

- Name of the Applicant / Holder of Certificate of Registration
- Any specific warning
- Known symptoms of overdosage and treatment
- Storage instructions
- Etc…….

Patient Information Leaflet for medicine for humans Regulation 10

- Proprietary name
- Schedule status
- Registration number **34/20.1/0034**
- Composition
- Identification of the medicine
- Instructions on how to use
- **Approved** indications
- Discipline of medicine (Homeopathy)
- Disclaimer – If medicine is not registered with the MCC:

  "This medicine has not been evaluated by the MCC. The medicine is not intended to diagnose, treat, cure or prevent any disease"

Patient Information Leaflet for humans Regulation 10 cont.....

- Name of the Applicant / Holder of Certificate of Registration
- Any specific warning
- “For external use only”
- “Store all medicine out of reach of children”
- Side effects
- Storage information
- Date of publication of the PIL
- Etc……

Medicines and Related Substances Act, 1965: Names

- Proprietary name (Regulation 1)
    - Name which is unique to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of the Act
- The proprietary name is thus the brand name applied for by an applicant or HCR for application to this registered product

Principles of Naming

- In evaluating the safety of a medicine during the registration process, the MCC considers whether the proposed proprietary name of such a product could potentially pose **public health and safety concerns** or if it may be misleading.
- It seeks to prevent, to the greatest extent possible, **potential medical errors** that may occur because of look-alike or sound-alike proprietary names.
- First and foremost issue considered is that of **patient safety**.
- The proposed proprietary name should not be liable to result in any confusion in **print, handwriting or speech** with the proprietary name of another medicine.

Principles of Naming cont...

- When assessing the likelihood for such confusion, the following aspects are considered:
  - the registered indication(s);
  - intended patient population(s);
  - the pharmaceutical dosage form(s);
  - the route(s) of administration;
  - the strength(s);
  - the dosage(s);
  - the setting(s) for dispensing and use;
  - the scheduling status(es) and
  - an assessment of potential for harm to a patient in the event of a dispensing or administration error.

Types of Proprietary Names

- PRODUCT NAMES; the proprietary names of individual, unique, registered medicinal products and their line extensions
- UMBRELLA RANGE NAMES; umbrella names, being collective, invented names of umbrella ranges of co-marketed, dissimilar but complementary products (as distinct from line extensions of single-API products or multiple-API combination products)
- CORPORATE IDENTIFIERS; ‘house brands’ or ‘corporate identifiers’, which are broader than umbrella ranges.

What won't work as or in a proprietary name

- Ordinary English words or phrases as listed, for example, in a standard dictionary will not usually be considered for use as proprietary names of medicines (e.g. 'Whisper').
- Personal names of people, whether first names and/or last names and relating to persons living, dead, or fictional, will not usually be considered for use as proprietary names of medicines (e.g., 'Hippocrates').
- Names comprising one or two letters and/or other characters, or names comprising an abbreviation, cipher or acronym, will not ordinarily be considered for use as proprietary names of medicines. (e.g., "Q", "TPN",).

What won't work as or in a proprietary name cont

Claims in the name

- The invented name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations.

  The following examples are provided to illustrate this point:

  - Sedinax
    for a product for pain/fever – implying "sedative"
  - Painkid
    for a product not registered for use in children
  - Snorro-Plus
    for a product that has no "standard" form
  - Boditol Period Pain
    for a product with other indications
  - Anything-Max or Maxx or Maxxx

What won't work as or in a proprietary name cont...

Claims in the name

- A proprietary name may, therefore, include a reference to a pharmacological/therapeutic class or indication, provided that it is consistent with and of appropriate specificity with regard to the registered indications included in the package insert. However, each application will be evaluated on its merits;
- Care should be taken to ensure that the proprietary name does not give rise to ambiguity or to inappropriate impressions or implicit claims of superiority or of greater potency or efficacy;
- The invented name of a medicine should not be misleading with respect to the composition of the medicine. This is particularly important in relation to "umbrella names".

What won't work as or in a proprietary name cont...

Abbreviations and qualifiers

- The proprietary name should preferably consist of only one word and should avoid qualification by letters or numbers, except where necessary to differentiate between different strengths or routes of administration.
- Where the strength of a medicine is stated, this should be either in the form of an Arabic numeral at the end of the proprietary name, or an Arabic numeral followed by an acceptable abbreviation of the unit concerned.
- If qualifications/abbreviations are to be included, appropriate justification should be provided to the MCC, explaining the meaning of the abbreviation or qualifier and the need for its inclusion.
- When assessing the acceptability of a proposed qualifier/abbreviation, the MCC will take into consideration whether the qualifier/abbreviation conveys characteristics of the medicine which may help healthcare professionals and/or patients to prescribe/dispense/select the appropriate medicine.

Theoretical examples of names that are not “unique”

- E-pill
- Blog’s cough mixture
- Slimming tablets/capsules
- Wellness syrup
- Tranquility/Tranquillité
- Cure/Nasheed/شفاء
- Common abbreviations or shortened forms used in medical practice

Current list

Aq - Aqueous
BD - Twice daily
CFC - Chloro-Fluoro-Carbons (as in CFC-free)
Co - Combination (contains more than one active ingredient)
CP - Chromatographically purified
CR - Controlled release
DPI - Dry Powder Inhaler
DS - Double Strength
EC - Enteric coated
FC - Film Coated
FDC - Fixed Dose Combination
Forte - Higher strength of same active, or additional active
HS - Half Strength
IM - Intramuscular
IV - Intravenous
LA - Long Acting
MDI - Metered Dose Inhaler
MR - Modified Release
ND - Non Drowsy
NS - Nasal spray
OD - Once daily
ORS - Oral Rehydration Solution
S - Suspension
SF - Suspension Forte
SL - Sublingual
SR - Slow Release or Sustained Release
XL or XR - Extended release

Umbrella Names

- The MCC requires applicants to develop unique and distinctive proprietary names for their medicines. Accordingly, the use of umbrella names and development of product ranges is not encouraged,
- Should not be an identifier or house brand
- A proprietary name that includes an umbrella name should not :
  - ❖ be misleading with respect to the therapeutic effects of the medicine, the composition of the product or its safety profile;
  - ❖ lead to confusion of the medicine with other medicines
  - ❖ suggest superior therapeutic efficacy, superior quality, or a superior safety profile.

Umbrella Names cont...

- Particular problems arise when an umbrella name is to be used in the proprietary name of a medicine which contains different active ingredient(s) and/or is for use in a different therapeutic area than the existing medicine using the same umbrella name. Such applications would require extensive and convincing motivation and would not easily be approved.
- **Therapeutic area for all medicines with the same umbrella name should be the same.**
- **Medicines covered by the same umbrella name should contain a single, common active ingredient, with additional active ingredients suitably identified. Exceptions to this rule will be considered on their merits.**

Problems with Umbrella Names

- Potential safety issues when parents/ caregivers are confused as to active ingredients – e.g. Aspirin
- Using umbrella names to circumvent advertising restrictions for Schedule 2 or higher medicines

Standard reasons for rejection

- Proposed proprietary name is similar to an existing proprietary name (cite name) when spoken or written.
- Proposed proprietary name contains too great a proportion of an international non-proprietary name (INN) or is a homophone of an international non-proprietary name.
- Proposed proprietary name is not unique and distinctive and is vague for generalization.
- Proposed proprietary name contains an international non-proprietary name (INN) stem.
- Proposed proprietary name is misleading in relation to either the composition, pharmacological action or expected therapeutic effect.
- Proposed proprietary name contains an inappropriate promotional message or makes a medicinal claim that is not in line with the approved package insert.
- Proposed proprietary name contains an unacceptable abbreviation or qualifier.
- Proposed proprietary name contains an unacceptable identifier.
- Proposed proprietary name contains an invented name together with an identifier.

Guideline: Proprietary Names

- Implemented guideline 2.15 available on MCC website
- Update to guideline in process
- Guidance on criteria and procedure

MEDICINES CONTROL COUNCIL

PROPRIETARY NAMES FOR MEDICINES

This document provides guidance to applicants regarding the acceptability of proposed proprietary names of products submitted for registration as medicines. Approved by Council, it represents the Medicine Control Council's current thinking on naming policy, how naming policy is intended to inform treatment choice, promote health and protect the public in the safe and effective use of medicines and how it contributes to the safety, quality and efficacy of medicines prescribing, dispensing, administration and usage by healthcare professionals and the public of South Africa. It is not intended to be an exhaustive listing and elaboration of all of the factors considered during the registration process or of the relative weighting attached to any such factor. Council considers the information and any motivation provided by applicants when assessing the proposed proprietary names of medicines and reserves the right to request any additional information or motivation. The same policies and principles apply in respect of proposed name changes as apply to the proposed names of new products. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of their applications.

Guidelines and application forms are available from the office of the Registrar of Medicines and on the MCC website.

Version 1 - First publication released for comment	December 2008
Due date for comment	28 February 2009
Call for additional Comment from Professional Bodies	28 February 2010
Version 2 for further comment	July 2010
Due date for comment	30 September 2010
Version 3 – Final Version	31 March 2011
Version 4 – Alignment with Legal Opinion	30 September 2011
Implementation Date	With Immediate effect

MS M HELA
REGISTRAR OF MEDICINES

Medicines and Related Substances Act, 1965: Scheduling

- Control of medicines and Scheduled substances (Section 22A)
    - The Minister may, on the recommendation of the Medicines Control Council, prescribe the Scheduled substances
- **Control over access** to medicines and substances is provided by the process of scheduling, and the control measures provided for in the Act and Regulations.

Context for Scheduling

- A 'Scheduled substance' is defined as:

  "any medicine or other substance prescribed by the Minister under section 22A"

- The official Schedules will always be those that have been published in the Government Gazette or amended by subsequent notice in the Gazette;
- All medicines are subject to a scheduling process on the basis of the substances (active ingredients) they contain.

Criteria for Scheduling

- Toxicity of the substance
- Evidence of Safety in use
- Proposed indication for the substance
- Need for medical diagnosis/ professional intervention
- Potential for abuse
- Need for access to the substance

Multi-schedule status

- Substances may be listed in one or more of eight Schedules based on dosage form, route of administration, strength, indication, dose, duration of treatment or a combination of these factors
- BUT, No product can be labelled with more than one Schedule status

Schedule 2

Hexoprenaline -

a. except when contained in respirator solutions; (S3) and

b. except when intended for injection or for the prevention or delay of labour. (S4)

Homatropine; preparations and mixtures thereof, except ophthalmic preparations. (S3)

Hormones (natural or synthetic, including recombinant forms), with either hormonal, prohormonal or anti-hormonal action unless listed elsewhere in the Schedules,

a. when intended for human vaginal use, and

b. when specifically intended for emergency postcoital contraception. (S3, S4, S5)

Matching Label and PI(L) to Schedule

If the Schedule is dependent on a restricted

- Indication
- Maximum dose
- Maximum duration
- Route of administration

then the packaging (including pack size), PI and PIL must be in line with the labelled Schedule

Applications for Re-scheduling

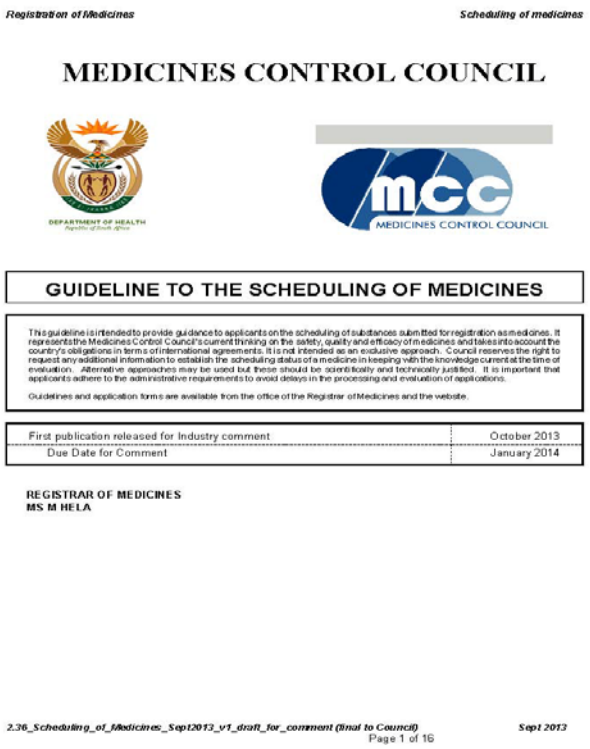
- Substance that is already been listed in the Schedules
- May be submitted by individuals, private sector firms, organisations, law enforcement agencies or specific departments of directorates within the public sector
- Can apply to reschedule only selected indications of a specific product to a lower Schedule,
- A unique name and a separate registration dossier will also be required for such a product.

Criteria for assessing an application for down-scheduling

- Based on those applied by stringent regulatory authorities (e.g. MHRA)

Guideline: Scheduling of Medicines

- Draft guideline 2.36 published for comment
- Guidance on criteria and procedure



Registration of Medicines *Scheduling of medicines*

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH

MEDICINES CONTROL COUNCIL

GUIDELINE TO THE SCHEDULING OF MEDICINES

This guideline is intended to provide guidance to applicants on the scheduling of substances submitted for registration as medicines. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines and takes into account the country's obligations in terms of international agreements. It is not intended as an exclusive approach. Council reserves the right to request any additional information to establish the scheduling status of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar of Medicines and the website.

First publication released for Industry comment	October 2013
Due Date for Comment	January 2014

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2.36_Scheduling_of_Medicines_Sept2013_v1_draft_for_comment (final to Council) *Sept 2013*
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Medicines and Related Substances Act, 1965: Advertising

- Labels and Advertisement (section 18)
    - No person shall advertise any medicine or Scheduled substance for sale unless such advertisement complies with the prescribed requirements

Medicines and Related Substances Act, 1965: Advertising

- Advertising of a medicine (Regulation 48) to the **public**:
  - Medicine with no scheduled substance
  - Medicine with a substance in Schedule 0
  - Medicine with substance in Schedule 1

Medicines and Related Substances Act, 1965: Advertising cont…

- Advertising of a medicine (Regulation 48) to the **profession** (practitioners, medical practitioners, dentist, pharmacists, veterinarians, **persons authorised to prescribe**)
  - Medicine with substance in Schedule 2, 3, 4, 5, 6

Medicines and Related Substances Act, 1965: Advertising cont…

- Content of the advertisement (Regulation 48):
  - Evidence **approved** by the Medicines Control Council on the Safety, Quality and Efficacy of the medicine
  - Must be incorporated in the **approved** package insert

Medicines and Related Substances Act, 1965: Advertising cont…

- Written advertisement shall state (Regulation 48):
  - Proprietary Name
  - Name and quantity of the Active ingredient
  - Registration number or medicine reference number allocated by Registrar
  - Animal medicines: statement *for veterinary use*
  - Homeopathic medicine: statement to *use it in accordance with homeopathic principles*

  - *Note: [amendment to regulation required to include all CAMS disciplines]*

Medicines and Related Substances Act, 1965: Advertising cont…

- General Advertising requirements (Regulation 48):
  - Medicine with more than **one** Active ingredient
    - No specific reference to one of the ingredients
  - When advertised to the profession for the 1st time
    - The MCC approved Package Insert to be provided

Medicines and Related Substances Act, 1965: Sampling

- Sampling (Section 18B)
  - No persons may sample any medicine
  - At an exhibition: sample of the medicine may be available but may not be handed out (Regulation 48)

Closure

- Sale and access of a medicine dependant:
  - Indication of a medicine
  - Scheduling status of the medicine
  - Advertising of the medicine
  - Label of the medicine
  - Package Insert of the medicine
  - Patient Information Leaflet
- Joint venture between the Applicant and MCC

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