Vitamins, Minerals and Probiotics

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1. Background

• Medicine

as per Medicines and Related Substances Act, 1965 (Act 101 of 1965)

“medicine” means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in -

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine;
• Complementary medicine

as per General Regulations to the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

“complementary medicine” means any substance or mixture of substances that-

(a) originates from plants, minerals or animals;
(b) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and
(c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);

Read together with Reg25A.
1. Background

• Foodstuff

“foodstuff” means any article or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) ordinarily eaten or drunk by a person or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance;
1. Background

• Vitamins and Minerals

Minimum levels that indicate levels of oral medication subject to registration in GG 9620 no. 559 15 March 1985, GG 11792 no. 600 31 March 1989.

Vitamin: An organic compound required by an organism as a vital nutrient in limited amounts.

Mineral: An inorganic element that is essential to the nutrition of humans, animals, and plants.

• Probiotics

are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host (FAO & WHO, 2006)
1. Background

**CM Registration Efficacy Requirements**

**FIRST:** qualification as a CM substance belonging to one of the disciplines as defined (identified in an accepted source / reference), which allows:

LOW RISK – evidence of Traditional Use (pharmacopoeias, monographs, 3 independent histories, citations from other studies) AND/OR clinical evidence

HIGH RISK – clinical evidence AND evidence of Traditional Use (pharmacopoeias, monographs, 3 independent histories, citations from other studies)
1. Background

• Traditional Use

Use of a designated active ingredient that is well-documented, or otherwise reliably established, according to the accepted philosophy or accumulated experience of a particular discipline that may be verified in any of the listed accepted references which may apply to each discipline and accords with well-established traditional procedures of preparation, application and dosage. New combinations of active ingredients previously used separately or in different combinations, must be suitably justified according to the philosophy / principles of the associated discipline.

MCC GUIDELINES: COMPLEMENTARY MEDICINES - QUALITY, SAFETY, AND EFFICACY
1. Background

• CM Consideration – Vitamins and Minerals
  • Entrance to CM by way of origin and traditional use by citation in accepted reference.
  • Vitamins, Minerals and Probiotics are not inherently related to any identifiable TM or CM philosophy only.
  • May by way of convenience be regulated as “CM type” products internationally – regard for SA system of registration.
1. Background

ALTHOUGH:

• Used by a number of professions registered with the AHPCSA

Regulations of the Allied Health Professions Act, 1982 (Act 63 of 1982)

ALSO:

• used by any other health professional (S0) and where permitted by scope of practice (>S0).

AND:

• rely on biomedical model (supplemental or direct effect)
2. CMC - MCC Position

Vitamins and minerals will be permitted future Category D registration as a Complementary Medicine (CM) only when part of a “combination product” and if its specific dosage level is below the prescribed maximum food levels and provided that no medical claim is made related to those vitamins and minerals.

**Combination product**

means a single product that contains:

(a) a mixture of substances of various discipline specific origin or philosophy, or

(b) a mixture of at least one substance of discipline specific origin and other allowable substances which make no therapeutic claim.
2. CMC - MCC Position

“Combination products” are intended to be handled as follows:

In the case of combination products:

• applicants will need to demonstrate explicit, cogent philosophies of use amongst all ingredients or will be referred for Category A registration;

• the registration –sub-category will be “Combination Product” and the discipline(s) it relates to;

• where vitamins, minerals or other substances of food origin are included in a combination product (see definition) and where such items fall below prescribed maximum food levels and provided that no medicinal claim is made, CM registration will be permitted, and

• where classified foods further purport to make medical claims or are above prescribed maximum food levels, these products will be referred for Category A registration.
2. CMC - MCC Position

Where any medical claims are made on any vitamin or mineral (or probiotic) or the prescribed level is above maximum food levels (as identified by the schedules), the product will be referred for Category A registration.
2. CMC - MCC Position

ADDITIONAL RATIONALE:

• Vitamins and minerals are not prescribed according to any specific, exclusive traditional CM philosophy or principle and may in fact be prescribed or used by any health professional with the requisite scope of practice if scheduled (HPCSA, AHPCSA and others), and

• Quality, Safety, Efficacy – unchanged when claims are made due to lack of Traditional use component and adherent discipline specific philosophy.

• High dose food products (including vitamins and minerals) will be best evaluated by a category A registration where claims are associated with their use in full evaluation of safety, quality and efficacy.
2. CMC - MCC Position

UNLESS:

Vitamin, Mineral (and Probiotic) prepared and shown to be of use and origin in a specific discipline with DIRECT relation to the identified discipline in the form presented and used medicinally.

Identified schedule status will still apply.
3. MCC Reaction

Appropriate Maximum Food Levels?
Revision of Schedules based on motivation of stakeholders for review of Vitamins, Minerals and Probiotics

Joint Review:
- Naming and Scheduling Committee;
- Complementary Medicines Committee, and
- Food Control (Department of Health)
3. MCC Reaction

Based on stakeholder recommendation of review of upper values prompting medicine registration

**Effect:**

- widens the scope for Vitamins, Minerals and Probiotics utilising Food Claims
- Medical claims conform to definition of medicine which require registration
- Levels above those published will be associated with specific schedule value

Through further work by Naming and Scheduling Committee and MCC: to be published soon…
4. Result

Greater potential impact for nutrition provision as medicines or supplements and responsible probiotic provision with the use of food based claims.

Category A/D registration – access control by way of scheduling (if applicable)
Access should be granted to all health professionals where they “may prescribe only the Scheduled substances identified in the Schedule for that purpose” by way of scope of practice. (Annexures to Schedules)
5. Summary

AMENDED SCHEDULES
Define minimum oral dose that qualifies vitamins, minerals as a medicine.

If (all) below these levels with food based claims

FOODSTUFF OR MEDICINE S0

If (any) above these (or qualifying) levels, or make medicine claims

MEDICINE >S1 CATEGORY A

If part of a “combination product”:
MEDICINE CATEGORY D
5. Summary

AMENDED SCHEDULES
Define minimum oral dose that qualifies *probiotics* as effective.

If above stated doses with **health** claims in pharmaceutical form

*MEDICINE S0*
CATEGORY A

If above stated levels with **medicinal** claims in pharmaceutical form

*MEDICINE >S1*
CATEGORY A

Can be added to FOODS with NO claims and NO use of the word “probiotic”.
END

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