Regulation of herbal, complementary and traditional medicines in South Africa

An overview of the *status quo*

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Member: Medicines Control Council
Chairperson: Complementary Medicines Committee
Member: Legal Committee, Good Practices Compliance Committee

Introduction

- Healthcare in South Africa
- Complementary Medicine in South Africa
- What makes a medicine a medicine?
- Principles
- CM Regulation in South Africa

Healthcare in South Africa

South African Healthcare Environment

- Population > 50 million people
- Non-socialised
  - public; and
  - private (majority associated with employment)
- State does not currently provide **all** healthcare services

Healthcare in South Africa

Regulatory Structure

- Investigations of implementation of National Health Insurance (Universal Health Coverage)
- National Department of Health (NDoH) *(policy/resources)*
- Provincial Departments (9) *(delivery)*

Healthcare in South Africa

Statutory Councils

- Allied Health Professions Council of South Africa
- Council for Medical Schemes
- Health Professions Council of South Africa
- Medicines Control Council
- The National Health Laboratory Service
- South African Dental Technicians Council
- South African Medical Research Council
- South African Nursing Council
- South African Pharmacy Council

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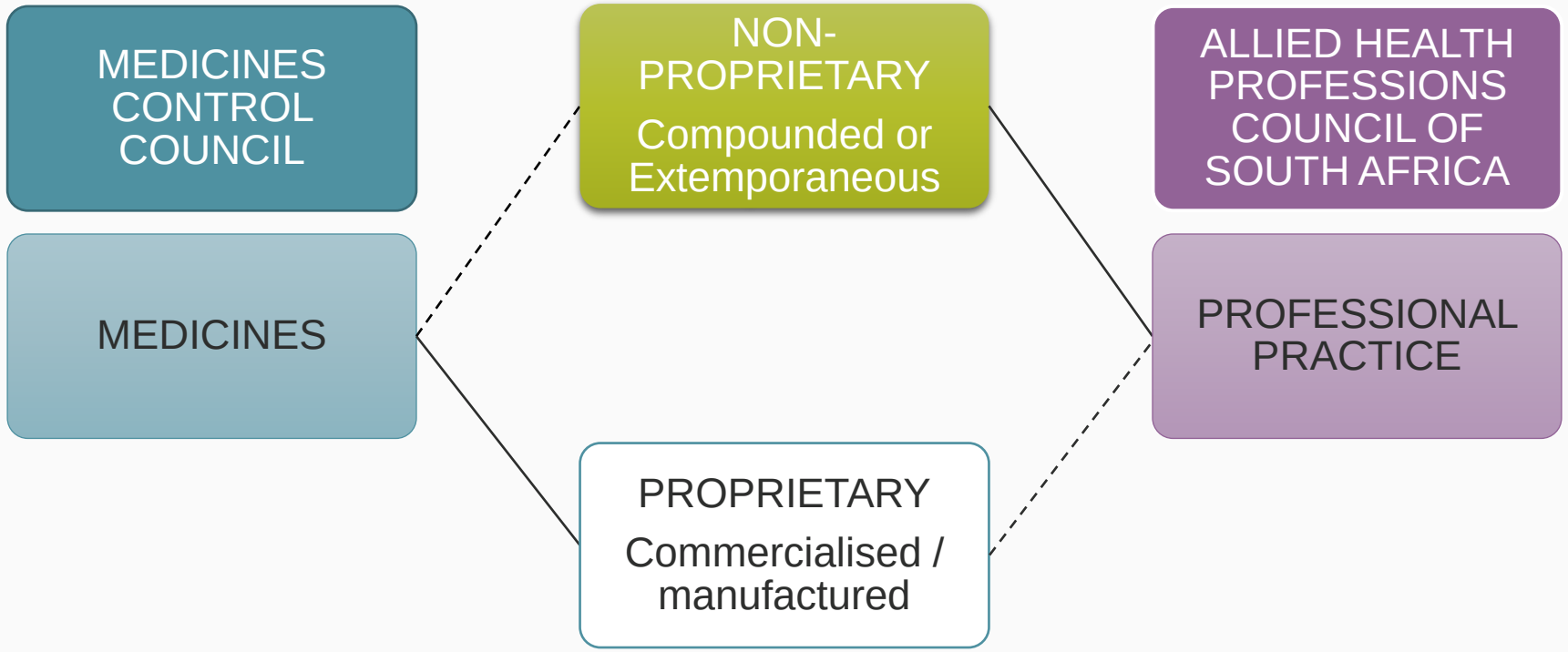
Complementary Medicine in South Africa



Complementary Medicine in South Africa

ALLIED HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

PROFESSIONAL PRACTICE

PROFESSIONAL PRACTICE

Allied Health Professions Council of South Africa

- Allied Health Professions Act, 1982 (Act 63 of 1982)
- Regulation of professionals:
  - Ayurveda, Chinese Medicine and Acupuncture, Unani-Tibb
  - Chiropractic, Osteopathy
  - Homeopathy, Naturopathy, Phytotherapy
  - Therapeutic Aromatherapy, Therapeutic Massage Therapy, Therapeutic Reflexology

Allied Health Professions Council of South Africa

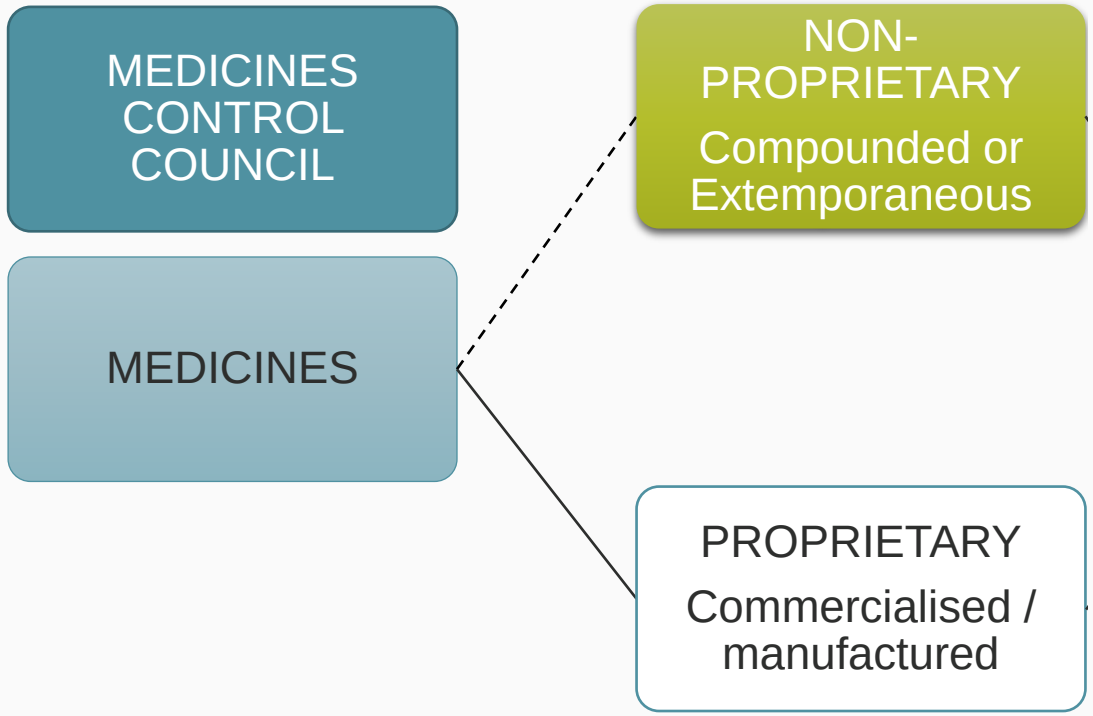
Practitioners

Therapists

- Education Standards,

  e.g.: Homoeopathy (5 Years – Masters), Phytotherapy (5 Years – Bachelors), Chinese medicine and Acupuncture (5 Years – Bachelors)
- Standards of practice
- Continuing Professional Development
- Ethical Guidelines
- “Protection of the public”
- Relevance to medicine regulation insofar as registered, trained professionals exist for prescription purposes with designated levels of responsibility

Complementary Medicine in South Africa



Medicines Control Council of South Africa

Medicines and Related Substances Act, 1965 (Act 101 of 1965):

- The registration of medicines and related substances for human and animal use
- The establishment of the MCC
- The control of medicines and scheduled substances

MINISTER: Appointment of MCC, Appeal Committee, Pricing Committee and Promulgation of regulations

DIRECTOR GENERAL: Release of Information, Issuing of Permits for Psychotropics & Narcotics, Licensing premises, other and delegated powers

Medicines Control Council of South Africa

Structure

- Staff: DoH
  - Various Directorates
- Members: Max. 24
  - Specific Expertise stipulated as minimum
- Expert Sub-Committees
  - Established and Appointed by Council

Medicines Control Council of South Africa

COUNCIL		
Chairperson		**Vice-Chairperson**
Registrar		
Pharmaceutical and Analytical Committee	Veterinary Clinical Committee	Clinical Trials Committee
Names and Scheduling Committee	Complementary Medicines Committee	Central Clinical Committee
Pharmacovigilance Committee	Biological Medicines Committee	Legal Committee
Good Practices Committee		Medical Devices Committee

Medicines Control Council of South Africa

Complementary Medicines Committee

- Variety of Expertise
- Drawn from variety of background and employment
- Advise Council of any matter related to CM
- At present: responsible for conducting reviews of applications

South African Health Products Regulatory Authority (SAHPRA)

Medicines and Relate Substances Amendment Act, 2015 (Act 14 of 2015) – **01 June 2017**

- Board structure
- Chief Executive Officer (CEO)
- Incorporation of multiple units – increased mandate
- Liaise, cooperate or exchange information with an other regulatory institution
- Enter into agreements that meet the stated objectives of SAHPRA

Traditional *vs* Complementary Medicine

Traditional medicine

AFRICAN TRADITIONAL MEDICINE

Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and **experiences indigenous to different cultures**, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Complementary/alternative medicine (CAM)

NON-INDIGENOUS DISCIPLINES

The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices **that are not part of that country's own tradition** and are not integrated into the dominant health care system.

WHO. (2017). Traditional Medicine: Definitions. http://who.int/medicines/areas/traditional/definitions/en/

Recent History of CM Regulation

Date	Regulation	Status
22 July 2011	Publication of proposed amendment to the General Regulations Definition of Complementary Medicines	For Comment 3 Months
15 November 2013	Implementation of General Regulations Definition of Complementary Medicines Category D Associated registration deadlines Inclusion in labelling requirements	Implemented
15 September 2014	Publication of proposed amendments to the General Regulations for comment Definition of Complementary Medicines to include Health Supplements Associated considerations for such inclusion.	For Comment 3 Months

Recent History of CM Regulation

Date	Regulation	Status
25 July 2016	Publication of proposed amendments to the General Regulations for comment including the intentions of the prior publication and incorporation of the definition of Health Supplement	For Comment 3 Months
16 January 2017	Publication of proposed amendments to the General Regulations Provision for function of SAHPRA (see amended Act) Proposed global changes CMs: CM Definition, HS Definition, matters connected herewith	For Comment 3 Months
25 August 2017	Implementation of General Regulations	Implemented

CM Market Size

- 1996: the market share was R 900 m (EUR 60 m)
- 2003: was estimated at R 1.35 billion (EUR 90 m).
- 2010: SA Market size approx. R 7.8 billion - representing approx. 0.7% of world market (EUR 520 m)
  - Increased importation
  - Increase local manufacture
- 2017: ???

HPA. (2010). CAMs in South Africa

Definitions

Section 1(3)

*(3) In determining whether or not the registration **or availability** of a **medicine** is in the public interest, regard shall be had **only** to the safety, quality and therapeutic efficacy thereof in relation to its effect on the **health** of man or any animal, as the case may be.*

[Sub-s. (3) substituted by s. 1 of Act 17/79]

Medicines and Relates Substances Act, 1965 (Act 101 of 1965) [as amended]

Definitions

“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;

[Definition of “medicine” substituted by s. 1 of Act 17/79]

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

and includes any veterinary medicine; [2]

[Definition of “medicine” substituted by s. 1 of Act 17/79]

Medicines and Relates Substances Act, 1965 (Act 101 of 1965) [as amended]

Definitions

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

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority;

(b) is used or purporting to be suitable for use or manufactured or sold for use-

(i) in maintaining, complementing or assisting the physical or mental state; or

(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and

(c) is used-

(i) as a health supplement; or

(ii) in accordance with those disciplines as determined by the Authority;

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions

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(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and

(c) is used-

(i) as a health supplement; or

(ii) in accordance with those disciplines as determined by the Authority;

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions

“health supplement” means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by-

(a) complementing health;

(b) supplementing the diet; or

(c) a nutritional effect,

and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act;

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions

Regulation 9 – Categories and classification of medicines

Category A, B, C

Category D – Complementary Medicines

Regulation 9(2) – sub-categories of Category D

(2) Medicines in Category D shall be classified into the following sub-categories:

(a) discipline-specific medicines with such disciplines as determined by the Authority; and

(b) health supplements.

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions

Regulation 9(3) – Classes of Medicines

(3) Medicines in Categories A and D (human complementary medicine) are subdivided into **classes** as per Annexure 1.

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions

Classes of Complementary Medicine

33. Complementary Medicines: Discipline-Specific Traditional Claims

33.1 Aromatherapy
33.2 Homeopathy
33.3 Phytotherapy
33.4 Traditional Chinese Medicine
33.5 Unani Medicine
33.6 Western Herbal Medicine
33.7 Combination Product
33.8 Other Herbal

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions

Classes of Complementary Medicine

34. Complementary Medicines: Health Supplements

34.1 Amino acids

34.2 Aminosaccharides

34.3 Animal Extracts, Products and Derivatives

34.4 Carotenoids

34.5 Enzymes

34.6 Fats, Oils and Fatty Acids

34.7 Minerals

34.8 Polyphenols (including Bioflavonoids)

34.9 Probiotics

34.10 Saccharides (including prebiotics)

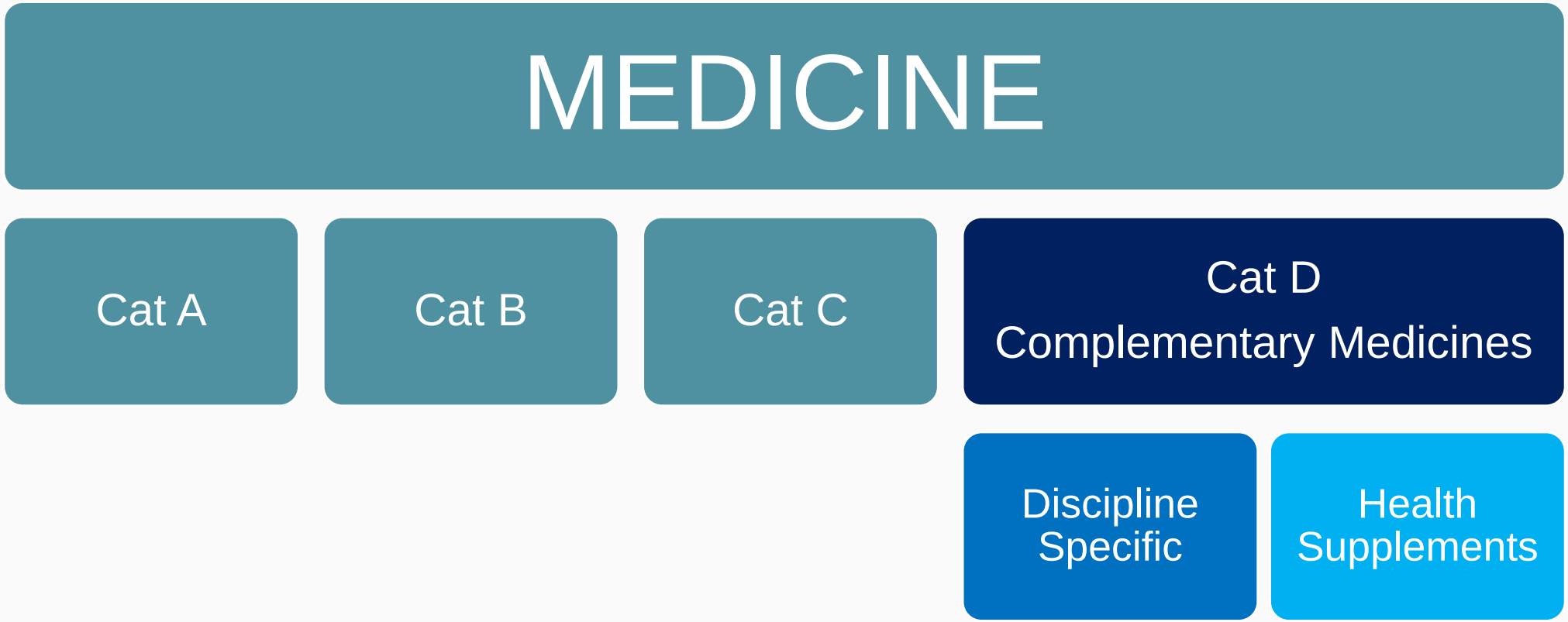
34.11 Vitamins

34.12 Multiple substance formulation

34.13 Other

General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [Gov.Not. 859 in GG 41064 of **25 Aug 2017**]

Definitions – Medicines



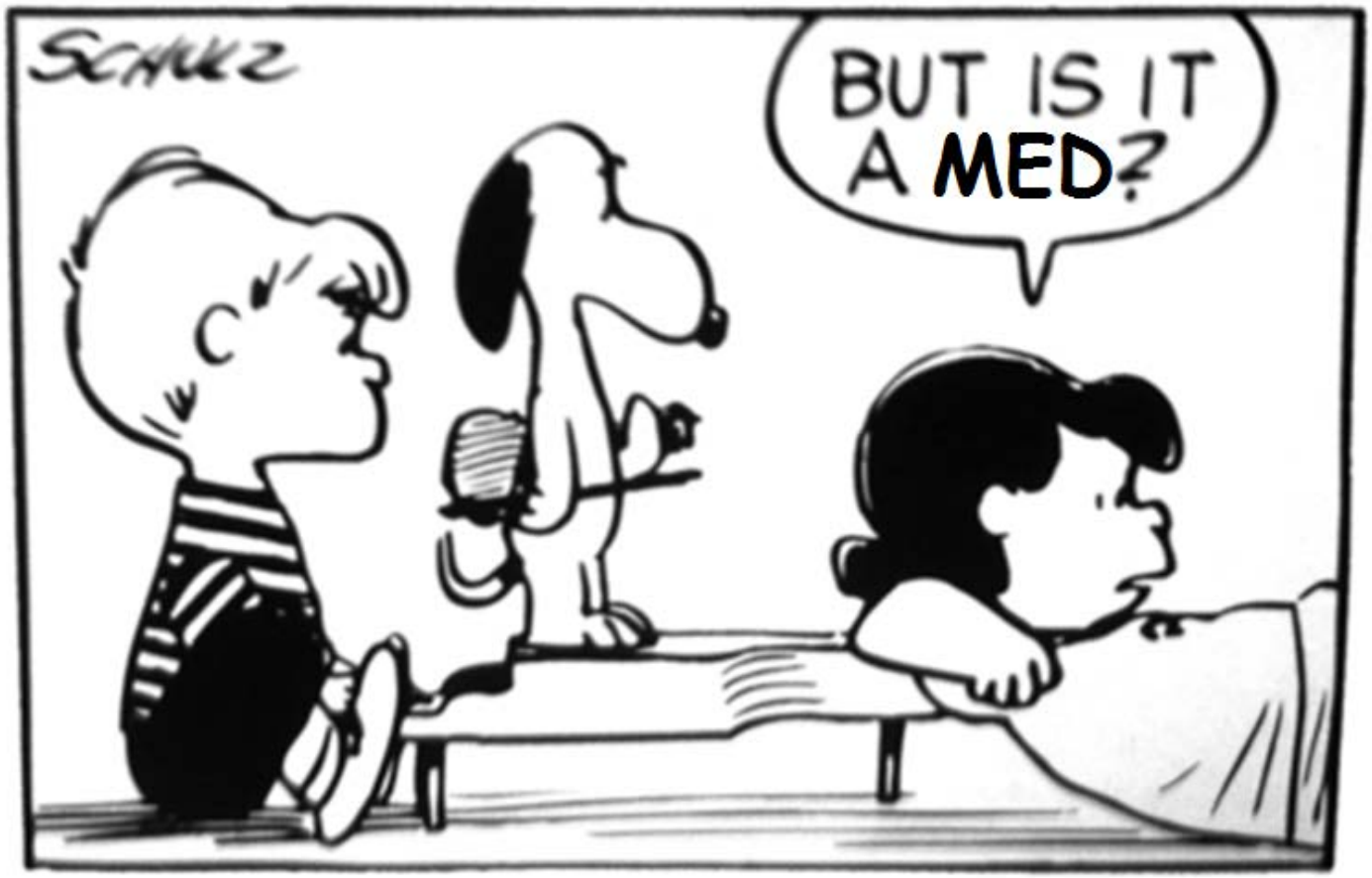


Image taken from: http://weheartit.com/entry/81978830 and adapted

Definitions

“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;

[Definition of “foodstuff” substituted by s. 1 of Act 39/2007]

Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) [as amended]

Definitions

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Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) [as amended]

Definitions

“cosmetic” means any article, preparation or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance; [9]

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Definitions – Trend?

Foods and Cosmetics

- Are what they are when they are not medicines!
- And THEN they must have a purpose as defined
  - Foods: *ordinarily eaten or drunk by a person or purporting to be suitable, or manufactured or sold, for human consumption*
  - Cosmetics: *for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance*

Principles – What Now?

"[31] … The question whether or not any particular substance is a medicine must be determined with reference to the provisions of the Act and when its identity is being questioned. The attributes of the substance and the claims made in respect of the substance will determine if it is a medicine within the meaning of the Medicines Act."

Treatment Action Campaign and Another v Rath and Others (2008) 4 ALL SA 360 (C); Judge Dumisani Hamilton Zondi,13 June 2008

Principles

Attribute:

A quality or feature regarded as a characteristic or inherent part of someone or something.

Form? Delivery? etc

But: what if the form/delivery is “non-pharmaceutical”?

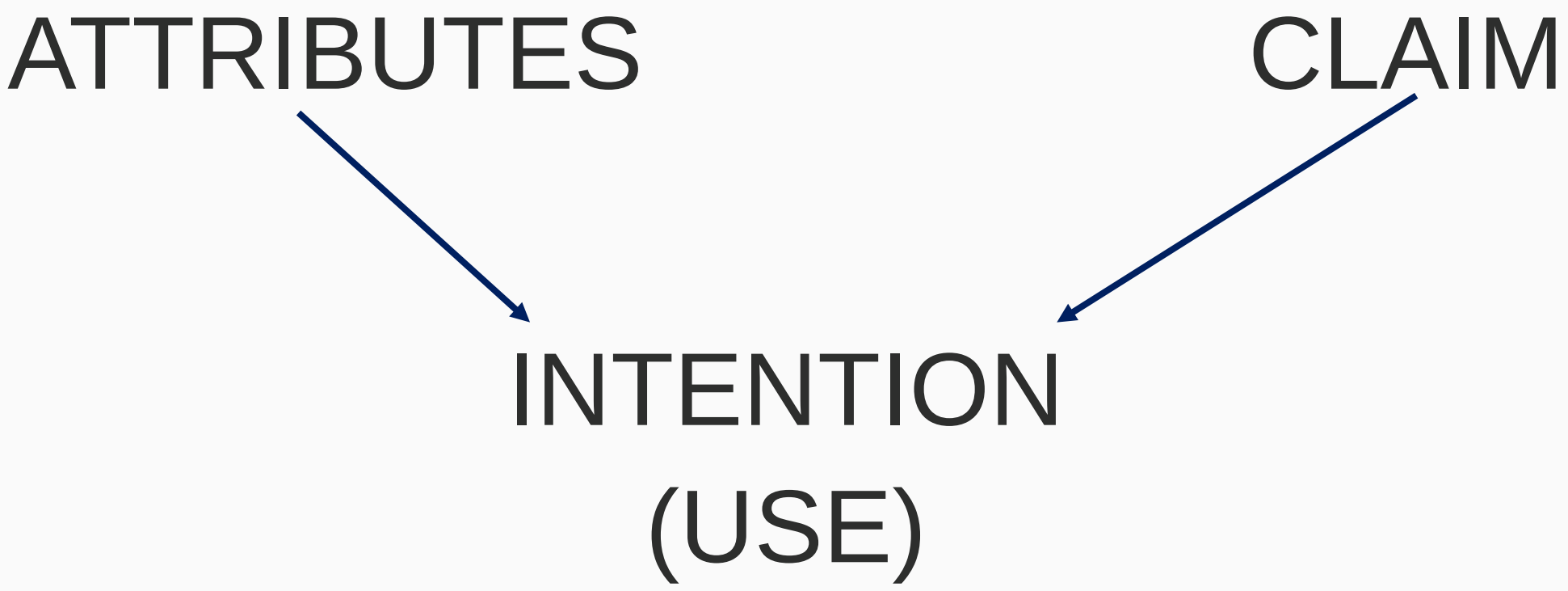
Oxford Dictionary

Principles

"[42] The purpose of the Act is to protect the public against quackery through assessing and controlling the quality, efficacy of the medicines. It is not the intention of the Legislature to control substances which are ordinarily drunk by man such as Rooibos Tea as long as such substances are ordinarily used and there are no claims of their medicinal efficacy. **In my view the use of a particular substance is the determining factor in deciding whether or not it is a medicine."**

Treatment Action Campaign and Another v Rath and Others (2008) 4 ALL SA 360 (C); Judge Dumisani Hamilton Zondi,13 June 2008

Principles



Principles

- Regulation of Complementary Medicine industry in SA
  - Clearly not a new industry
  - ANY regulatory standard will be a new benchmark
  - **Progressive realisation** of these standards with minimum principles / behaviour standards
  - Guided system with inherent flexibility based on motivation of the applicant and acknowledgement of the inherent characteristics of the field
- Applicant as the Expert
  - Manufacturer / applicant has developed the product with rationale, indications, formulation, ideas, standards
  - Application: provide this rationale by providing the best available data to demonstrate the best possible product

Principles

- Food Supplement, Dietary Supplement
  - Nomenclature does not exist within the framework of the MCC nor Food Directorate
  - “Supplements” are medicines in terms of their attributes, intention and when regard is had for the various definitions
  - Health supplements will contain what substances are listed for them to contain
  - Health supplements that contain herbal substances will be treated as Discipline-Specific medicines – i.e.: the value of the herbal substance must be assessed
- Attributes AND/OR indication determine status as a medicine

Principles
Complementary Medicines *(Cat. D)*

	DISICIPLINE SPECIFIC (DS)	HEALTH SUPPLEMENTS (HS)
Types	Aromatherapy Ayurveda Homoeopathy Traditional Chinese Medicine Unani (Unani-Tibb) Western Herbal Medicine Other Herbal Combination Products	Probiotics Prebiotics Vitamins Minerals Amino Acids Animal Extracts, Products and Derivatives Fats, Oils and Fatty Acids Carotenoids Polyphenols (including Bioflavonoids) Aminosaccharides Saccharides Enzymes Other Single substance formulations Multiple substance formulations

Principles
Complementary Medicines *(Cat. D)*

	DISICIPLINE SPECIFIC (DS)	HEALTH SUPPLEMENTS (HS)
Types	Aromatherapy Ayurveda Homoeopathy Traditional Chinese Medicine Unani (Unani-Tibb) Western Herbal Medicine Other Herbal Combination Products means a single product that contains: a) a mixture of substances of various discipline-specific origin or philosophy;	Probiotics Prebiotics Vitamins Minerals Amino Acids Animal Extracts, Products and Derivatives Fats, Oils and Fatty Acids Carotenoids Polyphenols (including Bioflavonoids) Aminosaccharides Saccharides Enzymes Other Single substance formulations Multiple substance formulations

Principles
Complementary Medicines *(Cat. D)*

	DISICIPLINE SPECIFIC (DS)	HEALTH SUPPLEMENTS (HS)
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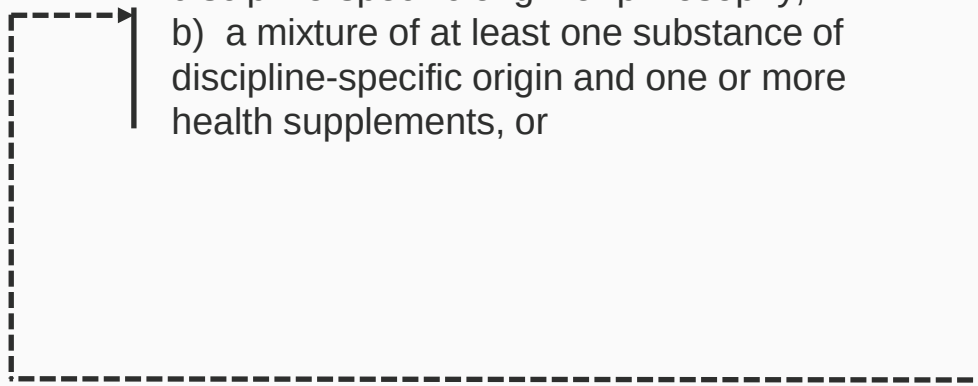
	Combination Products means a single product that contains: a) a mixture of substances of various discipline-specific origin or philosophy; b) a mixture of at least one substance of discipline-specific origin and one or more health supplements, or	Single substance formulations Multiple substance formulations



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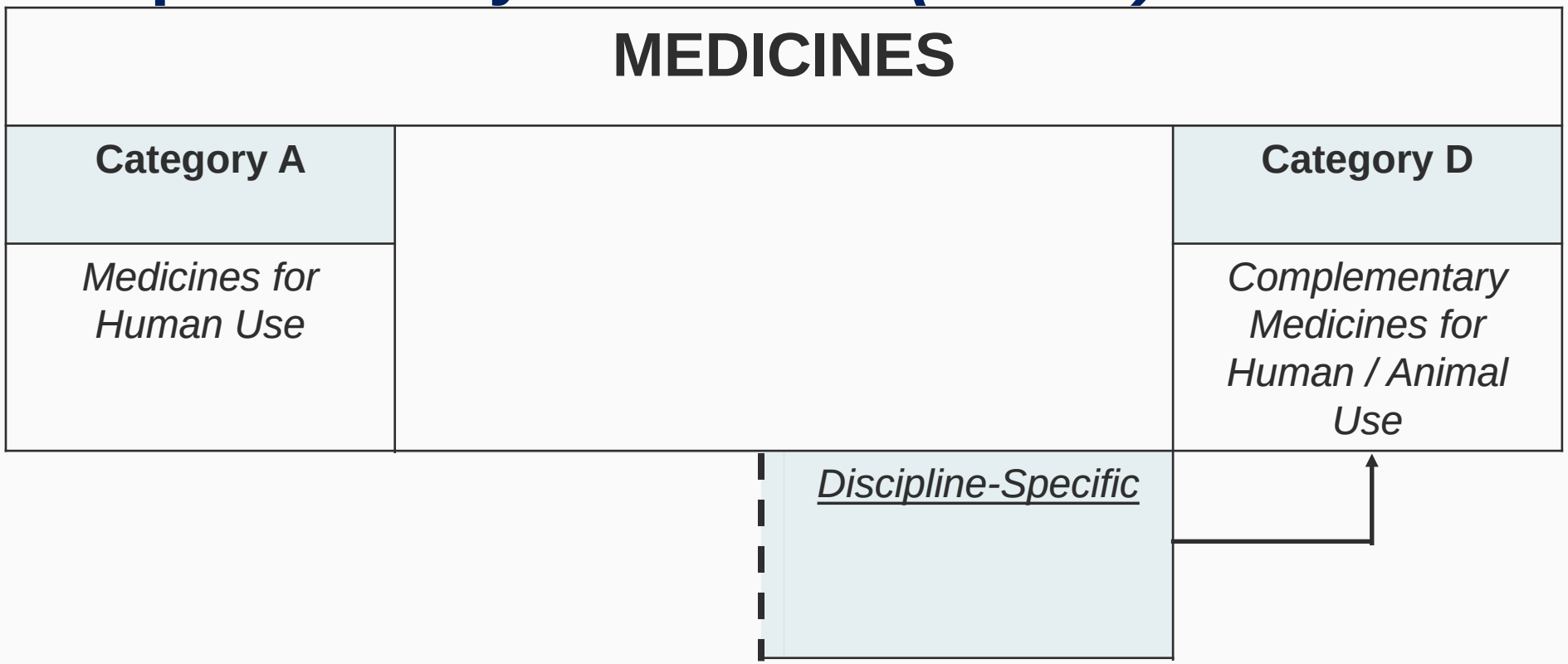
	Combination Products means a single product that contains: a) a mixture of substances of various discipline-specific origin or philosophy; b) a mixture of at least one substance of discipline-specific origin and one or more health supplements, or c) a mixture of at least one substance of discipline-specific origin and one or more of its isolated constituents. *[NOT IN ATTEMPT TO PASS AS CM BUT AS RATIONALE PART OF THE COMPLEX]*	Single substance formulations Multiple substance formulations

Complementary Medicines *(Cat. D)*

MEDICINES		
Category A		**Category D**
Medicines for Human Use		*Complementary Medicines for Human / Animal Use*

Complementary Medicines *(Cat. D)*



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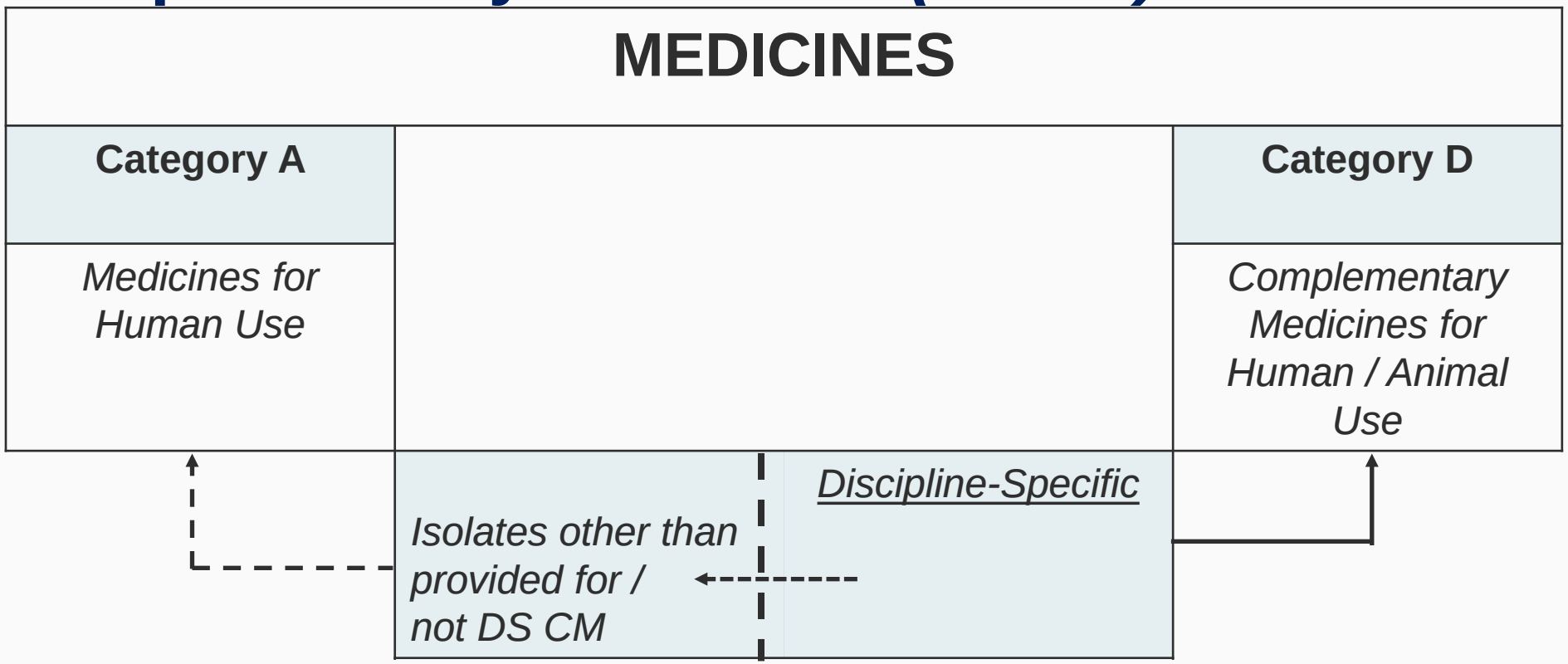

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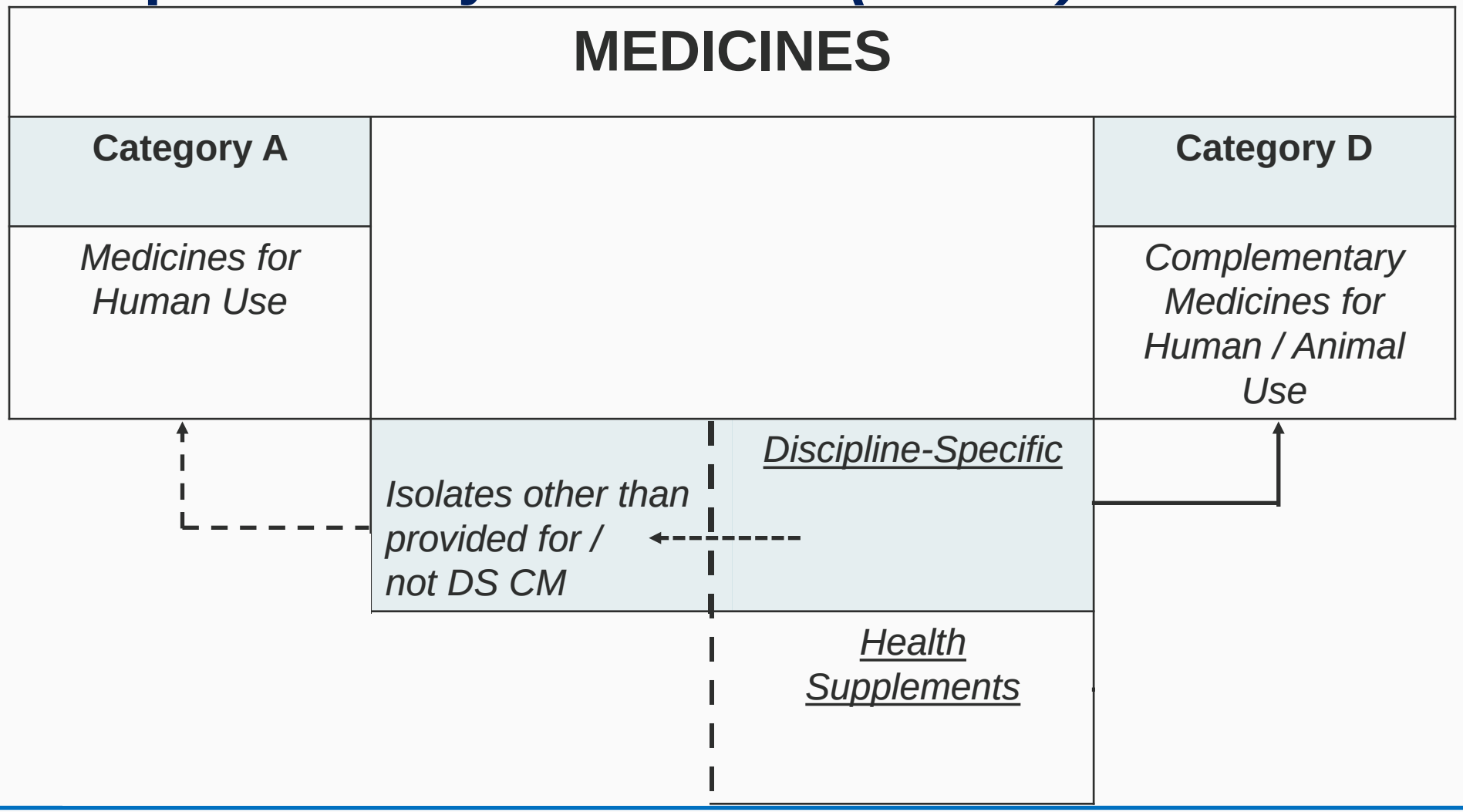

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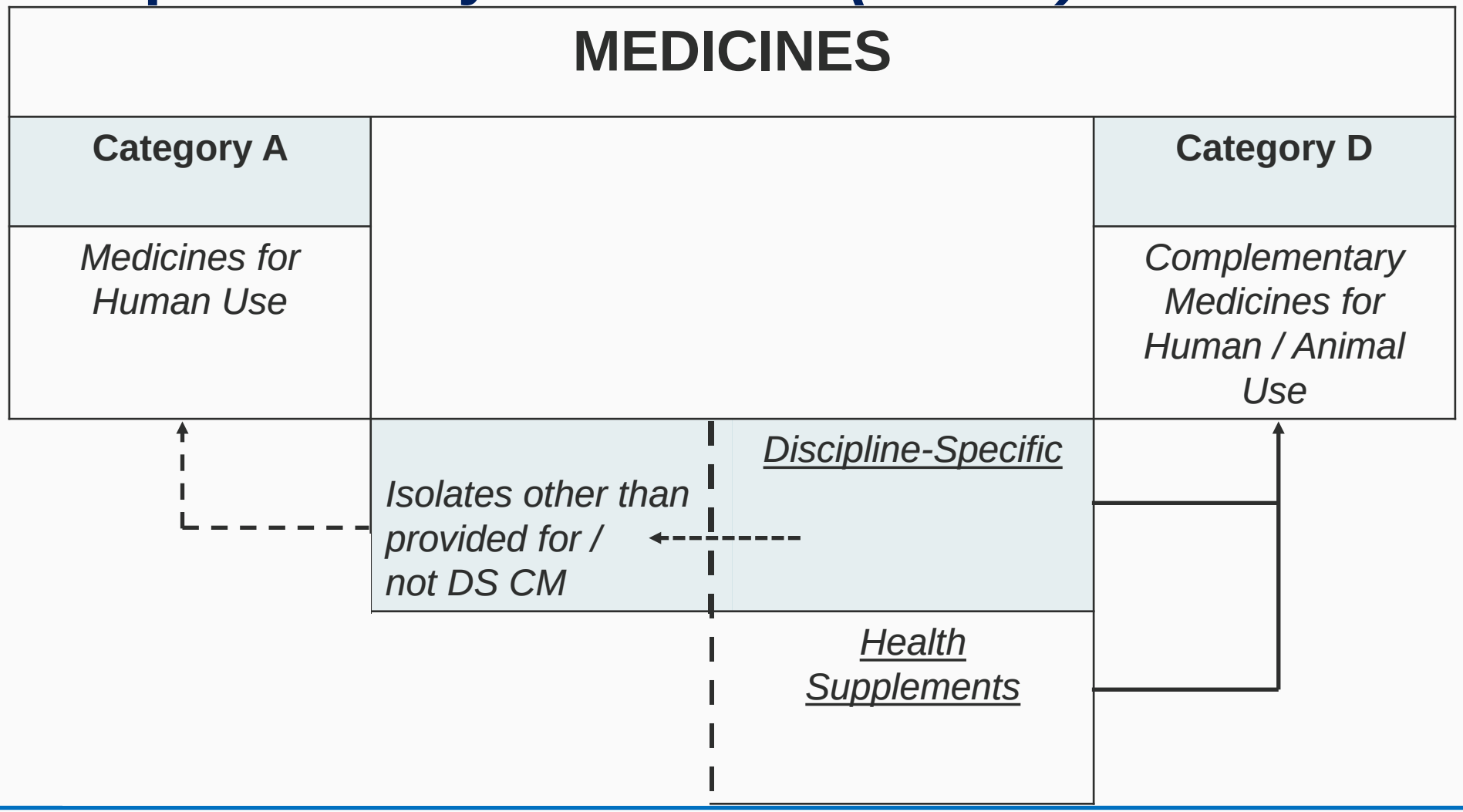

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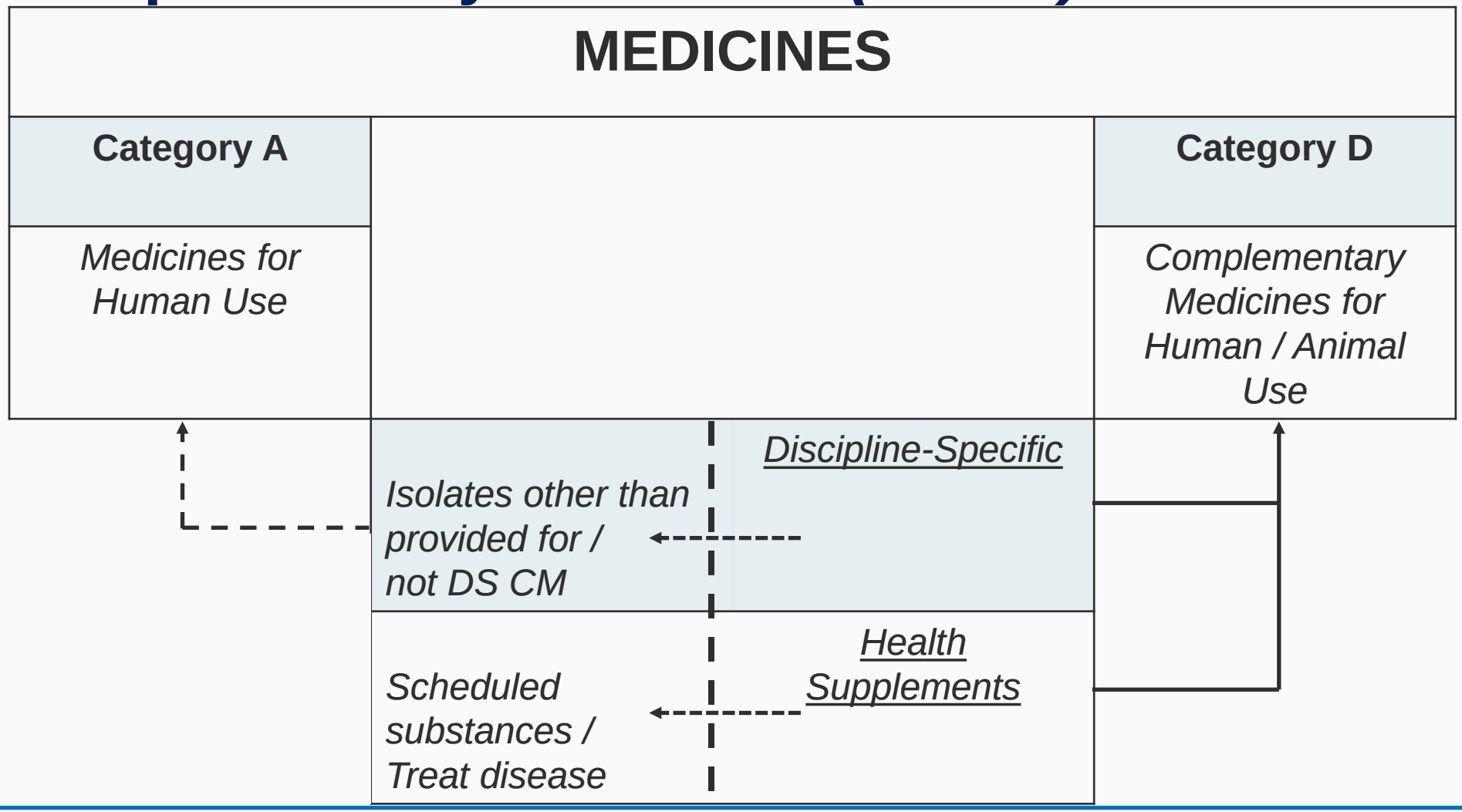

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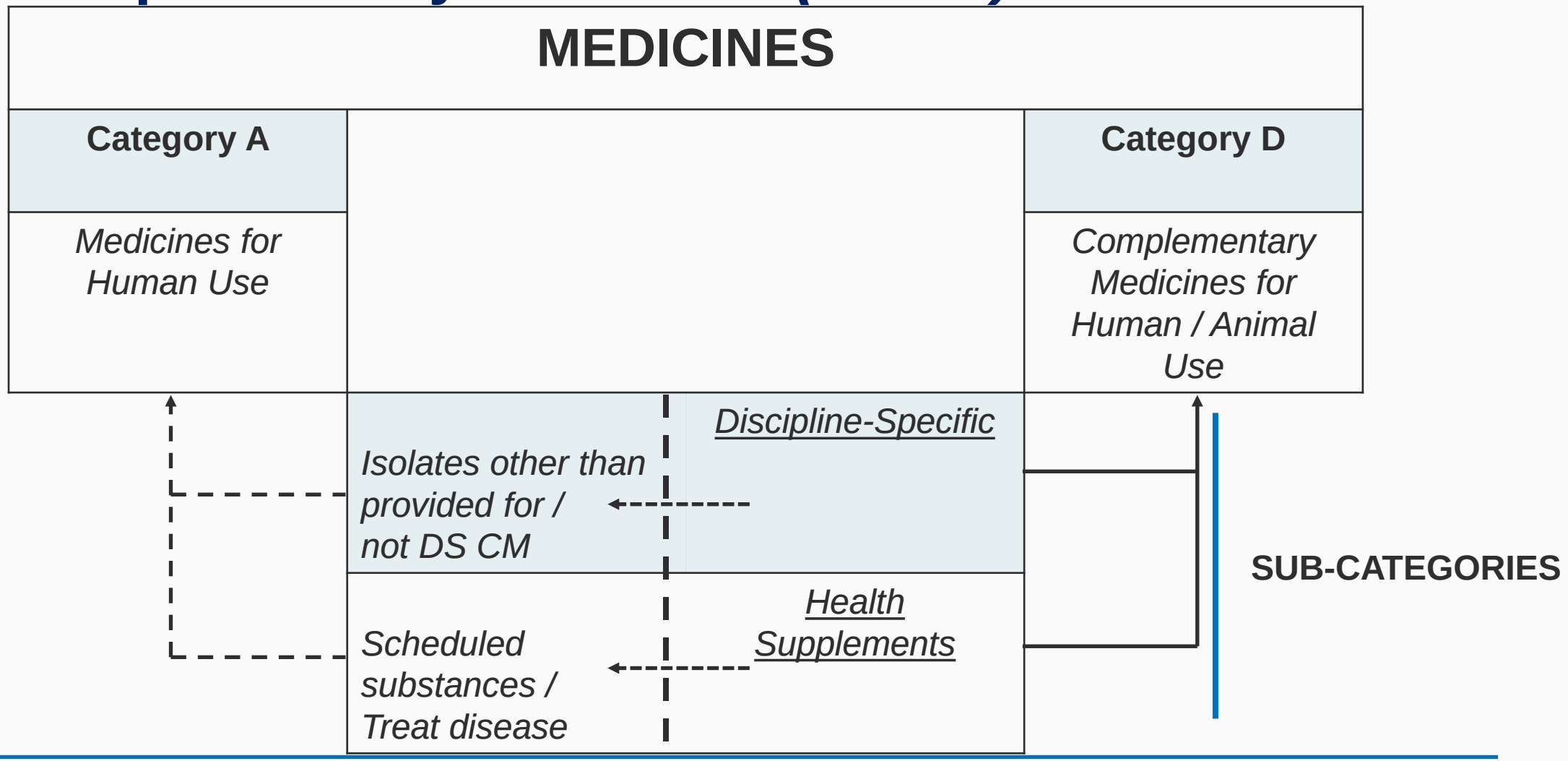


Principles
Risk Exposure

Quality

- Has what it should have
- Does not have what it shouldn’t
- It lasts (expiry)
- Works in way intended once taken

Principles
Risk Exposure

Quality

- Has what it should have
- Does not have what it shouldn't
- It lasts (expiry)
- Works in way intended once taken

Safety

- Safe to take
- Risk – benefit ratio
- Long term use
- Interactions, ADRs, Contraindications

Principles
Risk Exposure

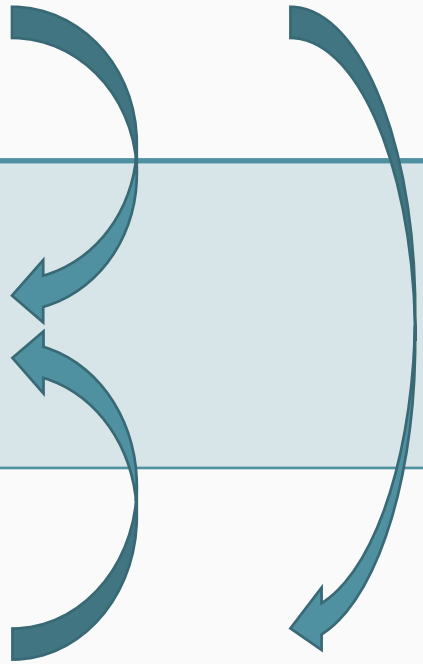
Quality
- Has what it should have
- Does not have what it shouldn't
- It lasts (expiry)
- Works in way intended once taken

Safety
- Safe to take
- Risk – benefit ratio
- Long term use
- Interactions, ADRs, Contraindications

Efficacy
- Works in way intended / promised
- Benefit
- Specific product

Principles
Risk Exposure

Quality • Has what it should have • Does not have what it shouldn't • It lasts (expiry) • Works in way intended once taken	RISK
Safety • Safe to take • Risk – benefit ratio • Long term use • Interactions, ADRs, Contraindications	RISK
Efficacy • Works in way intended / promised • Benefit • Specific product	RISK



Principles
WHO – Risk

*Described risks associated with T&CM **products**, practitioners and self-care:*

- *Use of poor **quality**, adulterated or counterfeit products;*
- *Misdiagnosis, delayed diagnosis, or failure to use effective conventional treatments;*
- *Exposure to **misleading** or **unreliable** information;*
- *Direct adverse events, side effects or unwanted treatment interactions.*

WHO. (2014). WHO – Traditional Medicine Strategy: 2014-2023

Complementary Medicines *(Cat. D)*

Risk Level	Type of Claim	Evidence required to support claim
HIGH RISK	• Treats/cures/manages any disease/disorder. • Prevention of any disease or disorder. • Reduction of risk of a disease/disorder. • *Aids/assists in the management of a named symptom/disease/ disorder.* • *Relief of symptoms of a named disease or disorder*[2] • Treatment of proven vitamin or mineral deficiency diseases.	• Clinical data to be evaluated [3]. **AND** • Two of the following four sources that demonstrates adequate support for the indications claimed: 1 Recognised Pharmacopoeia [4]; 2 Recognised Monograph [4]; 3 Three independent written histories of use in the classical or traditional medical literature, or 4 Citations from other in vivo, in vitro studies, case reports or others.
LOW RISK	• General health enhancement without any reference to specific diseases [1] • Health maintenance, including nutritional support. • Relief of minor symptoms (not related to a disease or disorder) [2] • ***Vitamin or mineral supplementation*** *(added for purposes of presentation)*	• Clinical data to be evaluated [3] **AND/OR:** • Two of the following four sources that demonstrates adequate support for the indications claimed: 1 Recognised Pharmacopoeia [4]; 2 Recognised Monograph [4]; 3 Three independent written histories of use in the classical or traditional medical literature. [5,6], or 4 Citations from other in vivo, in vitro studies, case reports or others.

7.01 – MCC Guideline – Complementary Medicines – Discipline Specific - Safety and Efficacy (2016) V3

Complementary Medicines *(Cat. D)*

	DISICIPLINE SPECIFIC (DS)	HEALTH SUPPLEMENTS (HS)
Efficacy & Safety	**LOW RISK** Traditional Use AND/OR Clinical Evidence	**LOW RISK** Schedule 0 only Prescribed indications (single substance) Prescribed guidelines on claim generation (multiple substance formulation) **No treatment of disease.**
	HIGH RISK Traditional use AND Clinical Evidence	
Quality	As prescribed – Guideline CM Quality	
Classes	Disciplines: • established by Reg 9; • provided for in Guideline CM DS: SE; and • Class (old Pharmacological Classification) of medicines	Health Supplements: • provided for in Guideline CM HS: SE; and • Annexure 1 and 2 (of Gen Regulations) - Class (old Pharmacological Classification)
Registration	1. Registration deadlines (Reg 48C) prescribed by risk – associated classification 2. Consider call up per discipline	1. By Single Substance as annexures available 2. Call up combinations

Regulatory Compliance – Original Roadmap

Registration Submission Deadline	Class
15 May 2014:	20.2.8 (Antiviral agents) 21.2 (Oral hypoglycaemics) 6 (Cardiac medicines) 26 (Cytostatic agents)
15 November 2015:	32.3 (Slimming preparations) 7.1, 21.7 (Male sex hormones) 21.8 (Female sex hormones) 21.9 (androgen-oestrogen combinations) claiming sexual stimulation and sexual dysfunction
15 May 2016:	32.16 (Other) and claiming immune stimulation or expressions of similar connection 17 (Medicines acting on muscular system) 22 (Vitamins) claiming to be sport supplements and exceeding the upper limit of vitamins and minerals as published by Council
15 May 2019:	All CMs submitted

Regulatory Compliance – Amended Roadmap

Registration Submission Deadline	Class
TBC	**1. Complementary Medicine (CM) - Health Supplement (HS)** ***- Single Substance Formulations (SSF)*** ***- Multiple Substance Formulations (MSF)*** **2. Discipline-Specific** ***- Combination Products*** Vitamins Minerals Probiotics Prebiotics Amino acids Carotenoids Fats, Oils and Fatty Acids Aminosaccharides Animal Extracts, Products and Derivatives Enzymes Polyphenols (including Bioflavonoids) Other

Health Supplement Annexures

- **Completed:**
  - Annexure C – Probiotics
  - Annexure D – Prebiotics
  - Annexure E – Vitamins
  - Annexure F – Minerals
- **Public Comment:**
  - Annexure G – Proteins and Amino Acids
  - Annexure I – Fats, Oils and Fatty Acids
  - Annexure J – Carotenoids
  - General Policy – Caffeine
  - General Policy – Menthol

Health Supplement Annexures

- **Development:**
  - Annexure H – Animal Extracts, Products and Derivatives
  - Annexure K – Bioflavonoids and Polyphenols
  - Annexure L – Aminosaccharides
  - Annexure M - Saccharides
  - Annexure N – Enzymes
  - Annexure O – Other
  - General Policy – Camphor
- **Guideline review**

Application Process

- Applicant – licensed manufacturer, wholesaler, distributor
- Follow all relevant Guidelines on Application
  - **SE Guideline for CM: DS (Jun 2016)**
  - **SE Guideline for CM: HS (Jun 2016)**
  - **Quality Guideline for CM (Jun2016)**
  - Other Guidance: application costs, checklists

Application Process

- **Traditional use** – *proof of*

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.

Application Process

- Reference sources:
  - European Pharmacopoeia (standards, monographs, chapters)
  - WHO Guidelines and Monographs
  - EMA Monographs or equivalent standing
  - Health Canada Monographs
  - Discipline-Specific Medicines:
    - British Herbal Pharmacopoeia
    - Pharmacopoeia of the People's Republic of China
    - Ayurvedic Pharmacopoeia of India
    - The Unani Pharmacopoeia of India
  - Other Accepted sources: as listed

Application Process

- CTD Format
  - As per CTD Checklist in consultation with guidelines
- Pre-screening, Screening, Review
- Review

Application Process

LOW RISK	HIGH RISK
Module 1	Module 1
Module 1.5.1 Traditional Use / Low Risk Rationale	Module 1.5.1 Traditional Use
Module 2	Module 2
Module 3	Module 3
Not required – *unless necessary*	Module 4
Not required – *unless necessary*	Module 5

Regulatory Compliance

- Labelling, Inserts, Leaflets
  - DS: Medicines on the market prior to 15 November 2013
  - HS: Medicines on the market prior to TBC

  may continue sale, provided that:

  Must include the wording on label (pre-registration):

  "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."

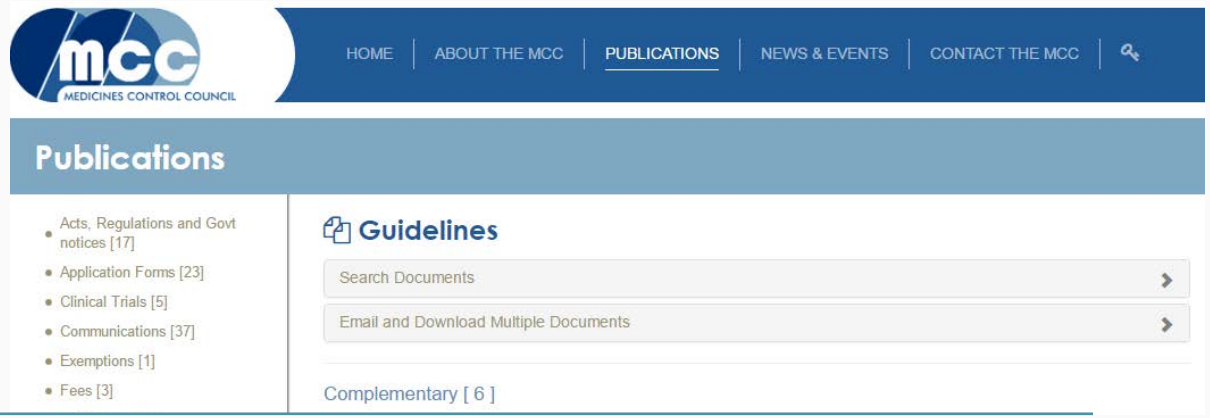
Challenges

- Use of DS substances in food
  - Food regulations tightening on use of substances with “medicinal” effects
- Veterinary Products
  - Discipline Specific (DS)
  - Health Supplements (HS)
    - Intention similar framework for humans
- LOW vs HIGH Risk
  - Future intentions / grading
- Platform for Pharmacovigilance
- Maintenance of functional review turnaround times

Guidelines

www.mccza.com

Guidelines



Name	Guideline
Complementary Medicines – **Discipline-Specific** – Safety and Efficacy	7.01_CMs_SE_DS_Jun16_v3 MCC
Complementary Medicines – Road Map	7.02_Roadmap_for_CAMs_Dec13_v1
Complementary Medicines – ZA-CTD Format	7.03_CAMs_ZACTD_Jun16_v3 MCC
Complementary Medicines – **Health Supplements** – Safety and Efficacy	7.04_SE_Health_Supplements_Jun16_v2 MCC
Complementary Medicines – **Quality**	7.05_CMs_Quality_Jun16_v1 MCC

ZA-CTD orientation built into the guidelines to assist registration

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