Complementary Medicines (CMs) in the new dispensation

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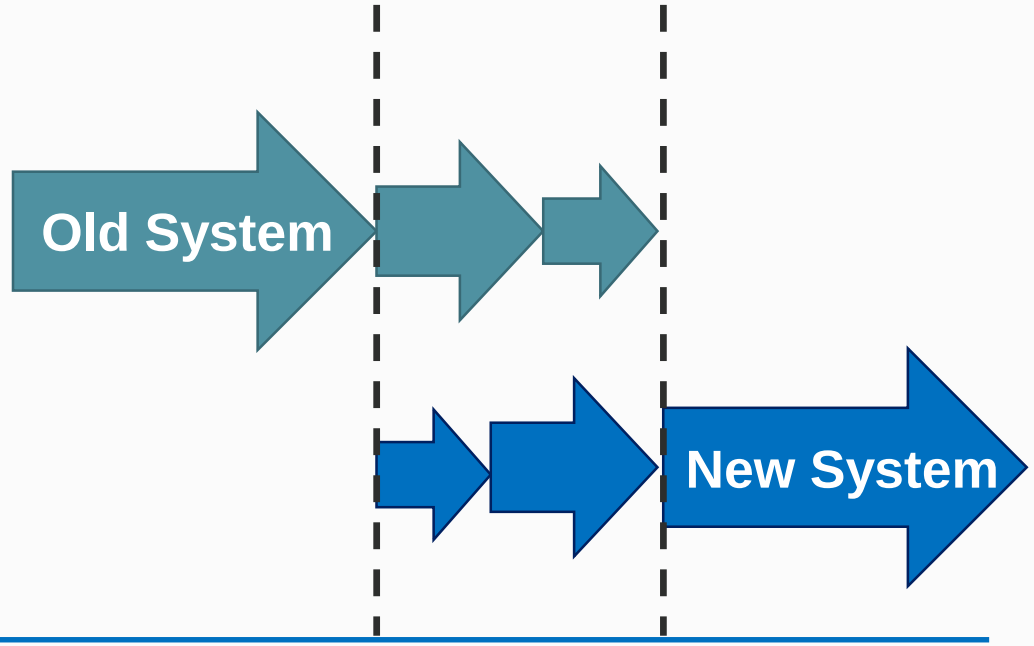
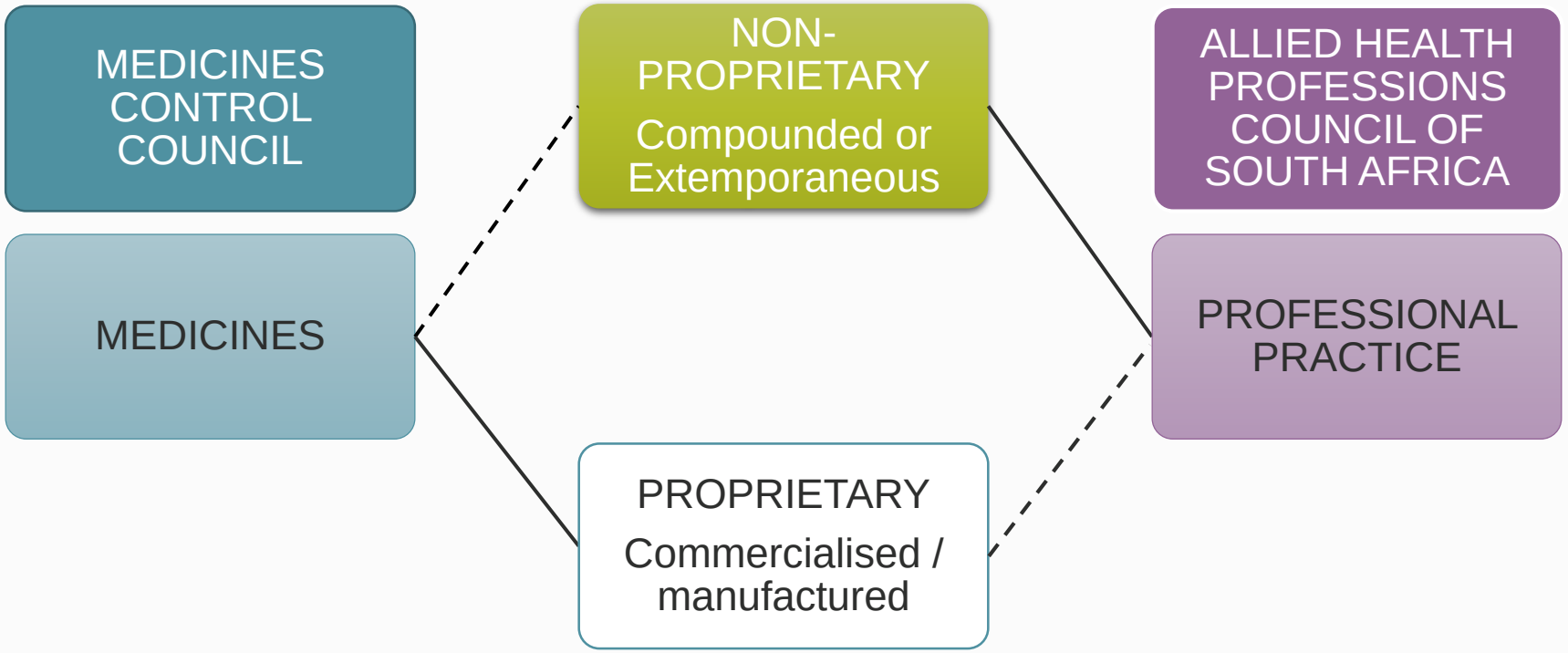
Introduction

- Complementary Medicine in South Africa
- Principles
- CM Regulation in South Africa
- Towards SAHPRA
  - Application Process



Complementary Medicine in South Africa



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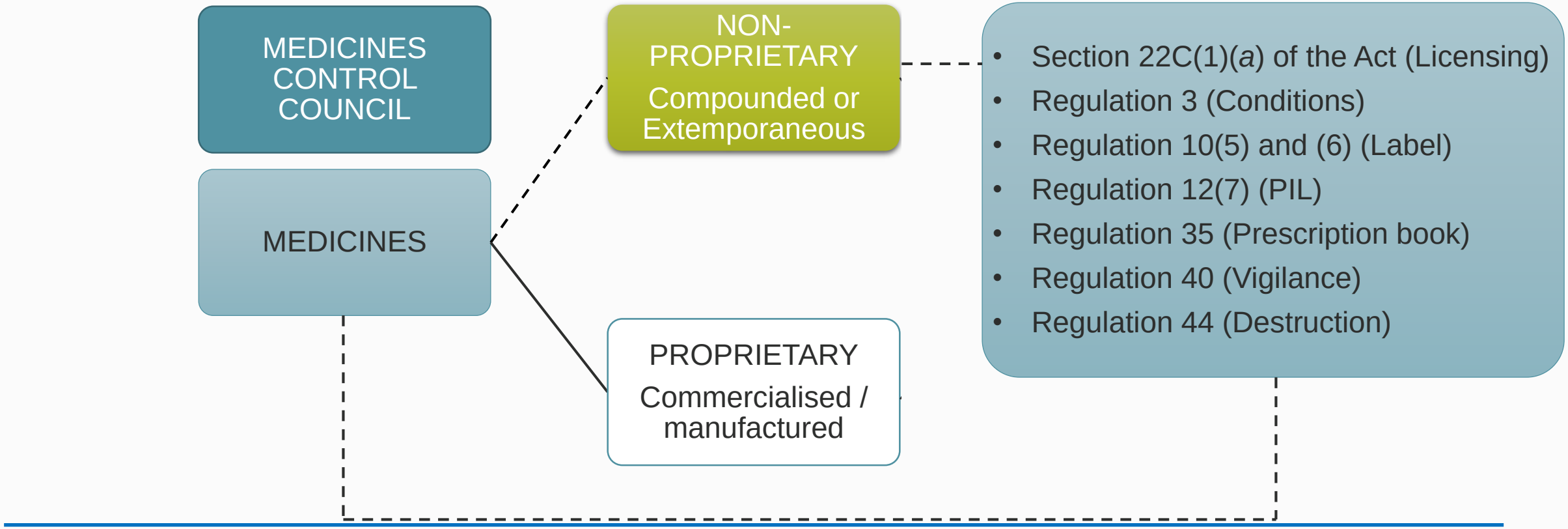

Alignment with WHO Definitions
Traditional *vs* Complementary Medicine

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/

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INTERATIVE MEDICINE?

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 million
- 2003: was estimated at R 1.35 billion
- 2010: SA Market size approx. R 7.8 billion - representing approx. 0.7 % of world market
- 2017: ???

HPA. (2010). CAMs in South Africa, Alan Tomlinson; https://goo.gl/eAQB6O

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]

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

“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**]

Categorisation and Classification

Regulation 9 – Categories and classification of medicines

Category A, B, C

Category D – Complementary Medicines

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

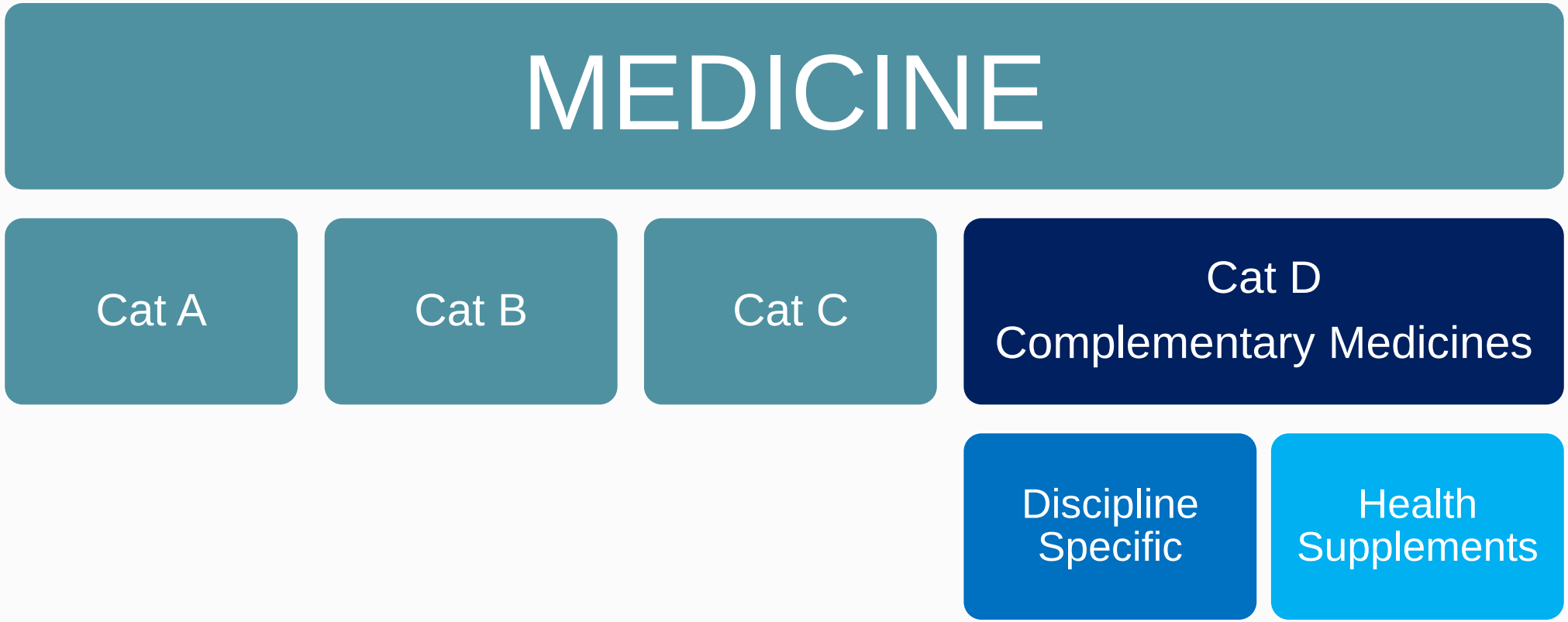
(2) Medicines in Category D shall be classified into the following sub-categories:

(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**]

Categorisation



Classification

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**]

Does not preclude the use of any other class, particularly for HIGH risk indications if required.

Classification

ANNEXURE 1 - Classes of Complementary Medicine

33. Complementary Medicines: Discipline-Specific Traditional Claims

33.1 Aromatherapy
33.2 Homeopathy
33.3 ~~Phytotherapy~~ **Ayurveda**
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**]

Must be used for Health Supplements – otherwise Category A.

Classification

ANNEXURE 1 - 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**]

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

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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

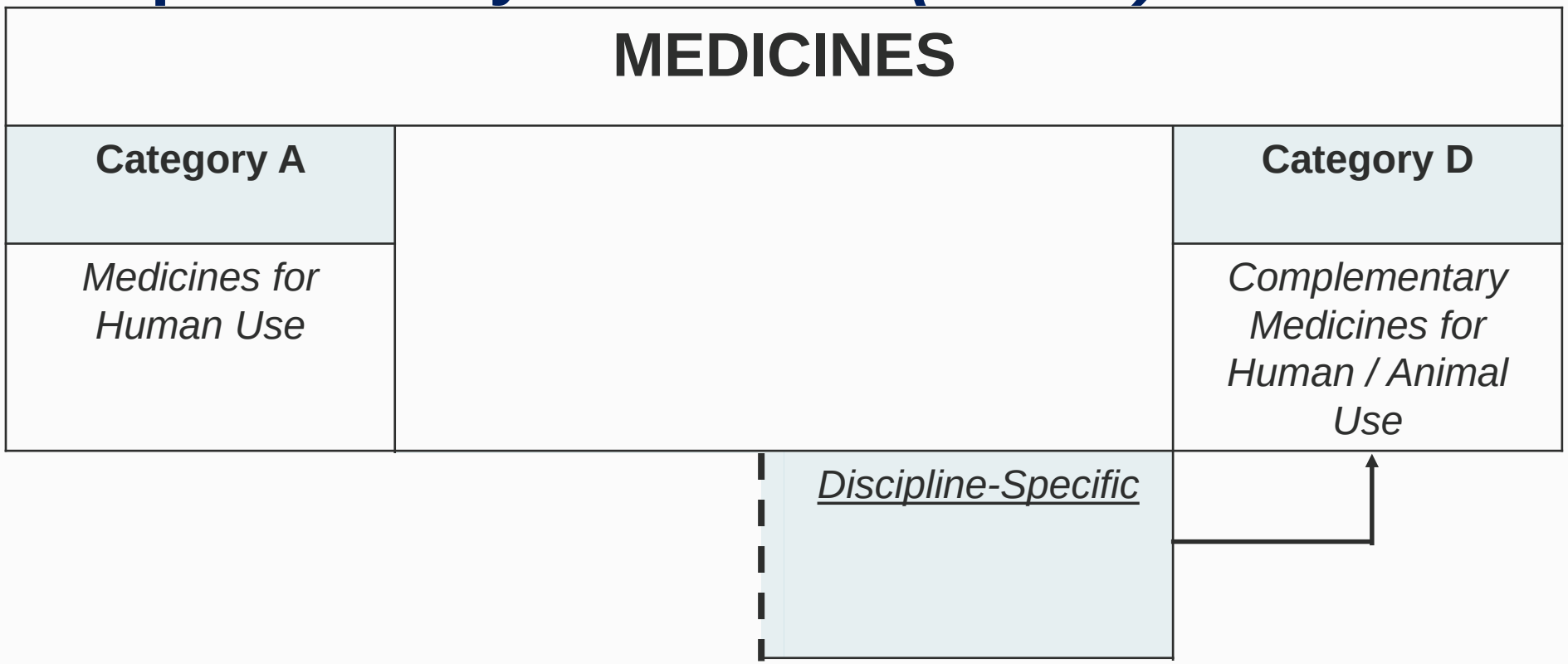
Principles
Complementary Medicines *(Cat. D)*

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

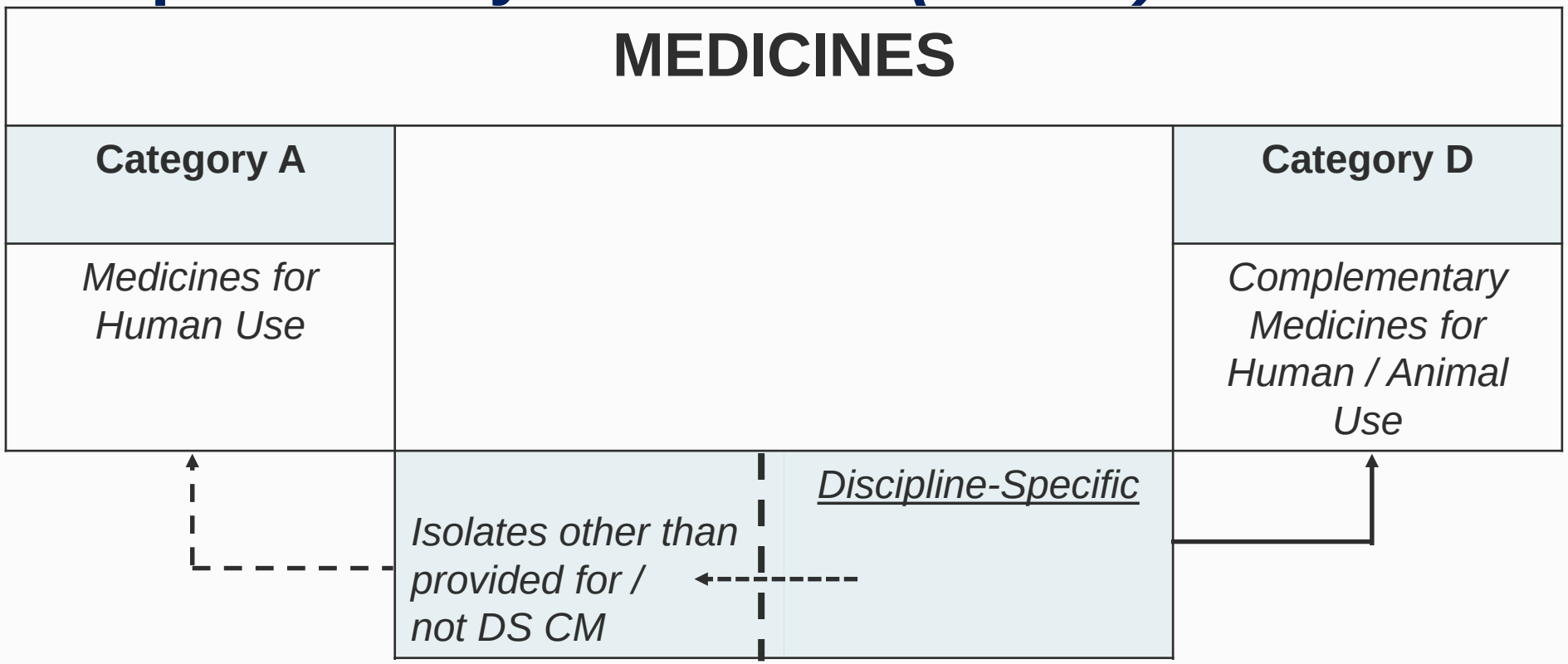
Complementary Medicines *(Cat. D)*

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

Complementary Medicines *(Cat. D)*



Complementary Medicines *(Cat. D)*



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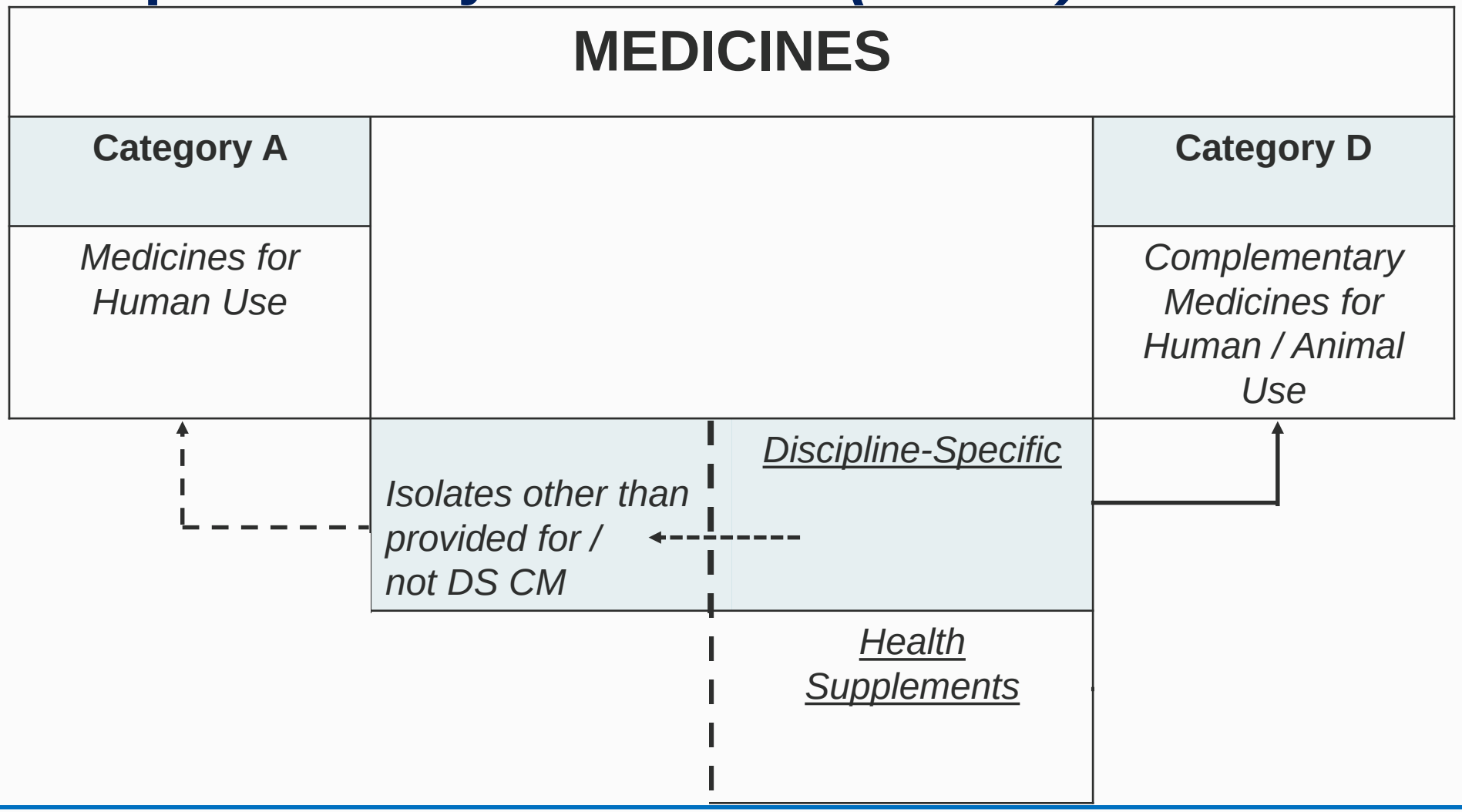

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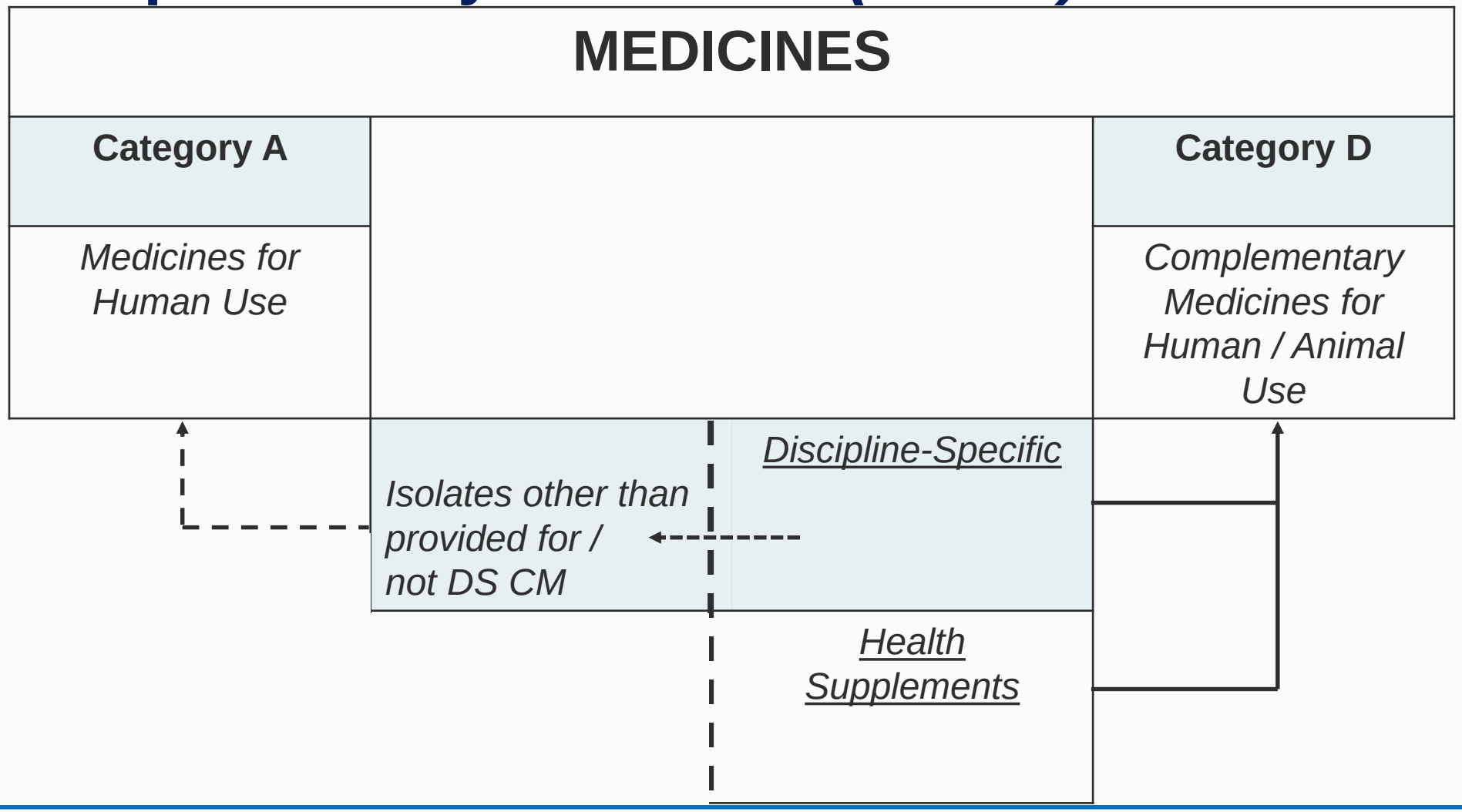

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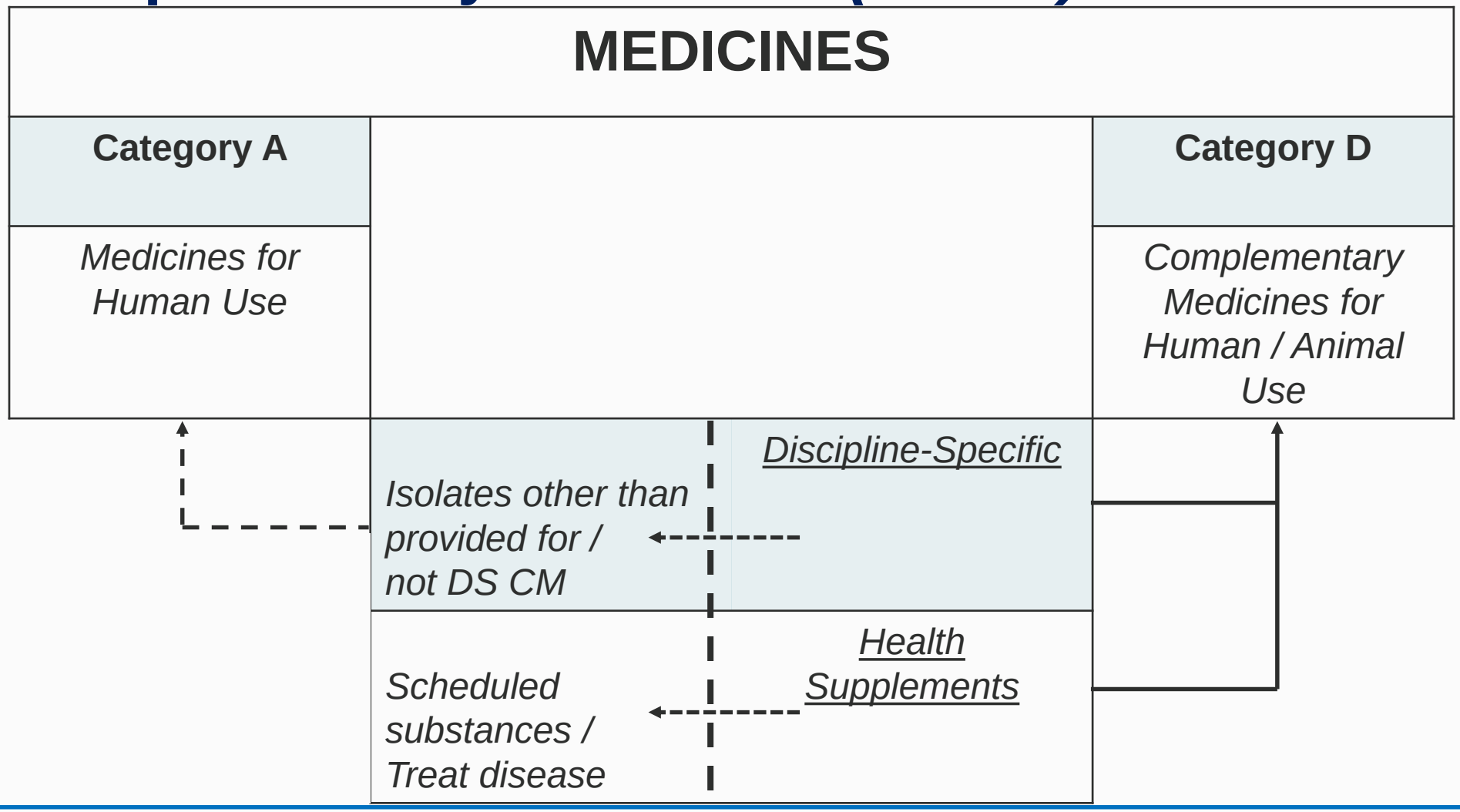

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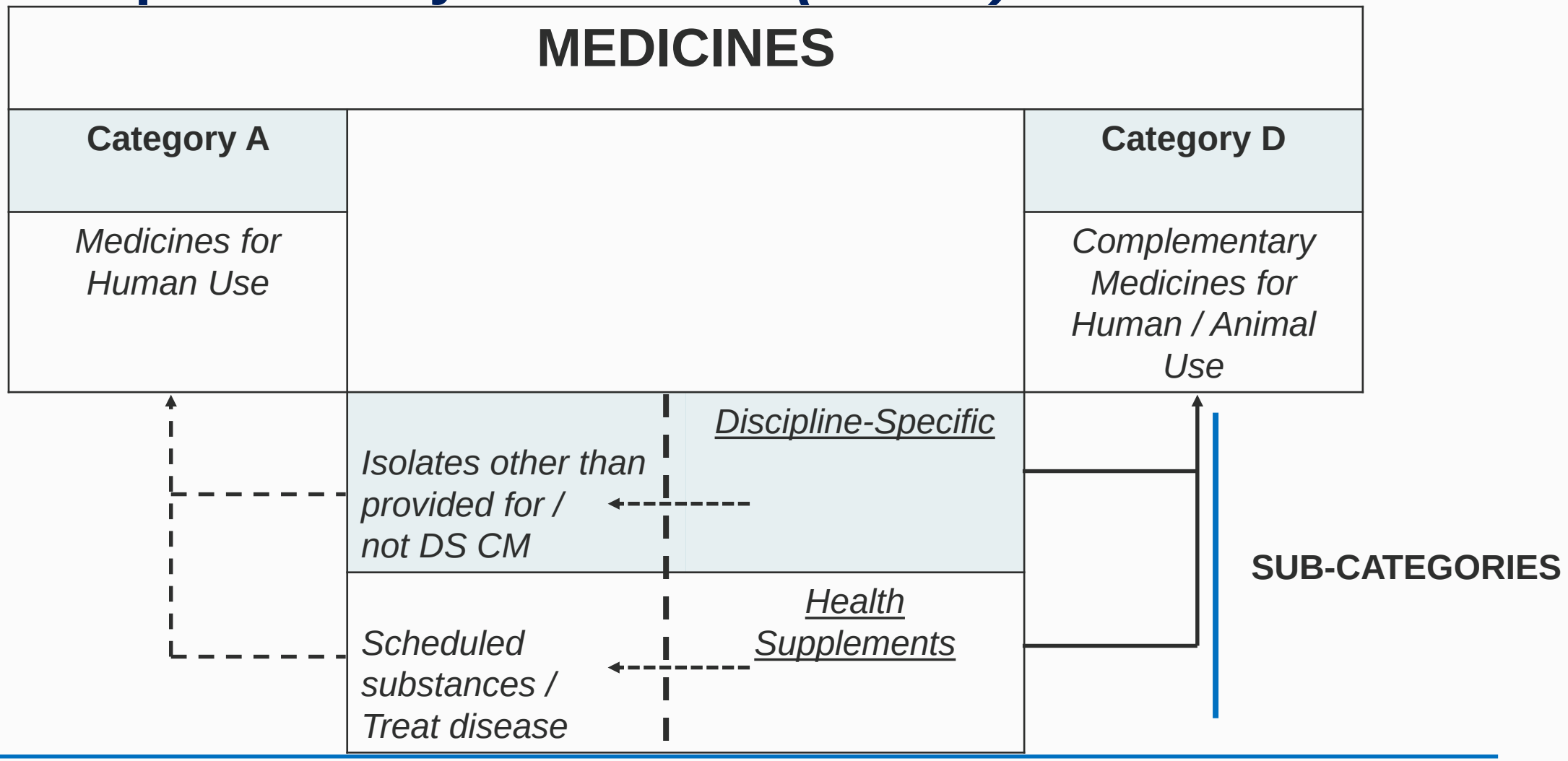

Principles
WHO – Risk

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

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

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

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

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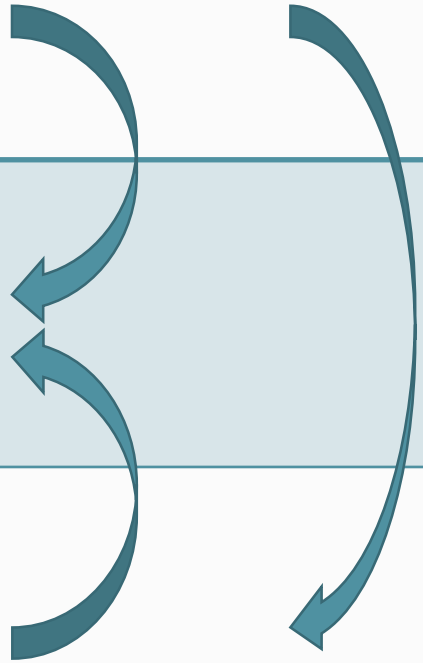
Efficacy
- Works in way intended / promised
- Benefit
- Specific product

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



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 • Class (old Pharmacological Classification): Annexure 1 and 2 (of Gen Regulations)
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

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**

South African Health Products Regulatory Authority (SAHPRA)

Medicines and Related Substances Amendment Act, 2008 (Act 72 of 2008) – **01 June 2017**

- Medicines and Related Substances Amendment Act, 2015 (Act 14 of 2015)
- 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

Towards SAHPRA

- Concept of an Authority *vs* Council
  - Way of doing business
  - Way of making decisions
  - Way of communicating

SYSTEM CHANGE?

- South African Health Products Regulatory Authority (SAHPRA)
  - Regulations
  - Guidelines
  - Policies and Notices
  - Communications

REPRESENTING THE CHANGE

Towards SAHPRA

- **9. CATEGORIES AND CLASSIFICATION OF MEDICINES**
  - Categories A-D
  - Category D: sub-categories of HS and DS
  - Division of medicines in Categories A, C and D subdivided into **classes**

    [Pharmacological Classifications]

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**]

Towards SAHPRA

- **10. LABELLING OF MEDICINES INTENDED FOR HUMAN USE**
  - ***"sweetener"*** *means any additive or excipient other than sugar which is used or intended to be used to impart a sweet taste to medicines;*
  - **10(1)(*h*)** In medicines for oral administration **– declaration** of sugar and sweetener other than sugar (name and quantity)
  - **10(1)(*cc*)** Complementary Medicines:
    - **(i)** The words **"Complementary Medicine"**
    - **(ii)** A statement identifying the **discipline** or the words **"Health Supplement"**
    - **(iii) "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."**
    - **(iv)** containing at least 5 percent of genetically modified organisms the following warning "contains genetically modified organisms".

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**]

Towards SAHPRA

- **10. LABELLING OF MEDICINES INTENDED FOR HUMAN USE**
  - *If the medicine package bears both, an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label: Provided that it shall be sufficient to contain on the immediate container label—*

    10(3)(*b*) Complementary Medicines:

    (i) intended for administration by injection < 5 ml,

    (ii) ointment, cream, gel or powder < 10 grams,

    (iii) in the form of liquid, solution or suspension 1 ml-5 ml,

    (iv) in the form of a liquid, solution or suspension <1 ml,

    (v) packed in blister or similar packaging

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**]

Towards SAHPRA

- **11. <u>PROFESSIONAL INFORMATION</u> FOR MEDICINES FOR HUMAN USE**
  - **11(1)(*a*)** PI shall be made available in hard copy or electronically <u>(provided that details of how to access to the PI are provided for in the PIL)</u>
    - The PI is still an integral part of any application and use of the product by prescribers regardless of scheduling status. Therefore it must still be part of the CTD dossier and assessed as such.
  - **11(1)(*b*)** English
  - **11(1)(*t*)** Complementary Medicine
    - Same requirements as for **labelling**
  - **11(5)** Nothing contained in subregulation (4) *"shall be construed as prohibiting the inclusion of professional information with any medicine."*

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**]

Towards SAHPRA

- **12. PATIENT INFORMATION LEAFLET**

12(1) Each medicine shall have a PIL

12(2) English and another official language

12(2)(*n*) Complementary Medicine

- Same requirements as for **labelling**

12(2)(*p*) the manner in which the corresponding professional information as per regulation 11 may be obtained.

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**]

Towards SAHPRA

- **33. PARTICULARS WHICH MUST APPEAR ON PRESCRIPTION FOR MEDICINE**
- **35. PRESCRIPTION BOOK OR PERMANENT RECORD**
- **36. REGISTER FOR SPECIFIED SCHEDULE 5 OR SCHEDULE 6 MEDICINES OR SUBSTANCES**

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**]

Towards SAHPRA

- **40. VIGILANCE**

*A person who has applied for registration of a medicine in terms of section 15 of the Act, a holder of a certificate of registration in respect of a medicine or Scheduled substance, or a holder of a licence in terms of section 22C(1)(*b*) must inform the Authority, in the manner and within the time frame as determined by the Authority, of any—*

(a) new or existing quality, safety or effectiveness concerns related to any medicine or scheduled substance, including but not limited to adverse drug reactions; and

(b) risk management activities associated with paragraph (a).

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**]

Towards SAHPRA

- **42. ADVERTISING OF MEDICINES**

42(1) S0 and S1 may be advertised to the public

42(5) Contents of advertisements:

- the proprietary name of such medicine;
- written advertisement—
  - the approved name and quantity of each active ingredient
  - of a registered medicine, the registration number allocated to it in terms of section 15(5) of the Act;
  - of a medicine in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by the Authority, followed by the words “Act 101/1965”; and

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**]

Towards SAHPRA

- **42. ADVERTISING OF MEDICINES**
  - written advertisement—
    - where a name other than the proprietary name is also used, such other name shall be in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement; and

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**]

Towards SAHPRA

- **42. ADVERTISING OF MEDICINES**

  42(5)(*c*) in the case of a—

  - complementary medicine—
    - a statement identifying the **discipline** of the medicine where relevant;
    - an indication that the medicine must be used in accordance with the applicable complementary discipline and principles where relevant; and
    - if the medicine has not received registration with the Authority the following disclaimer:

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

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**]

Towards SAHPRA

- **44. DESTRUCTION OF MEDICINES OR SCHEDULED SUBSTANCES**

  44. (1) A medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).

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**]

Towards SAHPRA

- **DELETION OF REGULATION 48C**
- Replacement of the registration deadlines with:
  - Call Up(s) for Discipline-Specific Medicines *ito* the classes as defined for Category D;
    - 2019 deadline maintained
  - Call Up(s) for Health Supplements *ito* the classes as defined for Category D
    - A recognition that that this a large and complicated sub-category;
    - It may involve DS substances as “Combination products”;
    - Single substance formulations to be Called Up first;
    - Multiple substance formulations to be called up at the conclusion of the implementation of the Annexures.
  - Compliance with labelling and continued rights of sale

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

Application Process

- Licensed manufacturer, wholesaler, distributor
  - Licensing support phase over 5 years to compliance
- 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

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 Relevant Summaries	Module 2 Relevant Summaries
Module 3	Module 3
Not required – *unless necessary*	Module 4
Not required – *unless necessary*	Module 5 Clinical Evidence

Towards SAHPRA

- **s2B Functions of the Authority**

…

(2) The Authority may-

(a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, ***require the necessary information from****,* ***exchange information with*** *and* ***receive information from*** *any such authority or institution in respect of-*

(i) matters of common interest; or

(ii) a specific investigation; and

(b) ***enter into agreements to co-operate*** *with any regulatory authority in order to achieve the objects of this Act.*

Towards SAHPRA

- **HARMONISATION AND COOPERATION**
  - International Regulatory Cooperation for Herbal Medicines (IRCH)
    - MCC Membership 2016
    - Formalising network status with the WHO
  - Recognition and Reliance
  - International
  - Regional

Towards SAHPRA

- **CM GUIDELINES**
  - Modify according to new regulations
  - Cater for SAHPRA
  - Amend according to findings from current evaluations
  - Explicit monographic links for single substance medicines
- **FEES**

Towards SAHPRA

- **LOW RISK CMs**
  - Fast evaluation
  - Template PI and PIL
- **CROSS-OVER SKILLS**
  - *Herb-derived* regulatory questions
  - Risk apportionment to OTCs
- **CLINICAL TRIALS OF CMs**

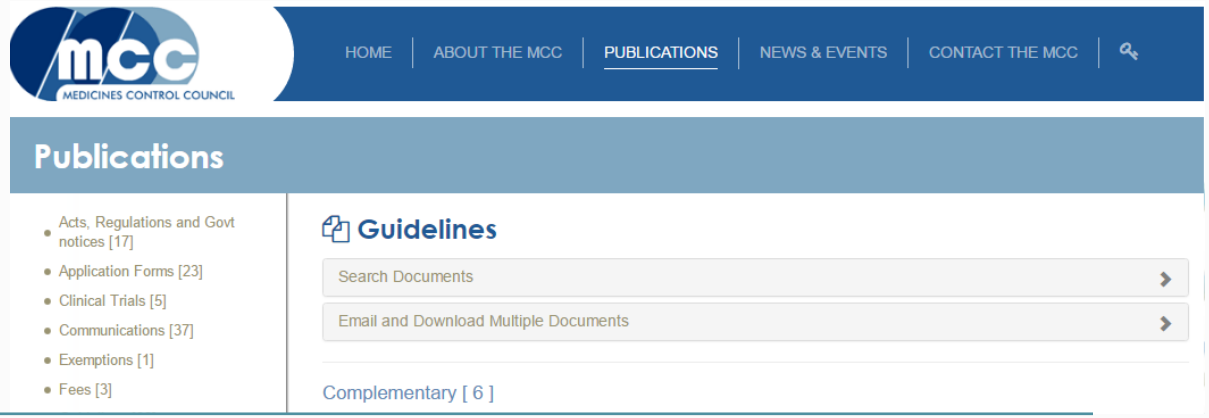
Challenges

- LOW vs HIGH Risk
  - Future intentions / grading
- Maintenance of functional review turnaround times
- Policy Maintenance
- Use of DS substances in food
  - Guidance
- Veterinary Products
- Platform for Pharmacovigilance
  - AHPCSA

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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