





Status of SAHPRA & CAMS Regulations



MCC & SAHPRA

- SAHPRA is the South African Health Products Regulatory Authority
- The Medicines and Related Substances Act, 1965 (Act 101 of 1965), was amended by:
 - Act 72 of 2008 → Establishment of SAHPRA
 - This provided for the establishment of South African Health Products Regulatory Authority (SAHPRA)
 - Schedule 3A public entity, which operates as a separate juristic entity, outside of the National Department of Health (NDoH).
 - Focus on Medicines, Medical Devices, Veterinary Products
 - Act 72 was enacted on 1 June 2017, which then enacted Act 14 of 2015
 - Act 14 of 2015
 - Appointment of Governance Board
 - Expanded oversight of Medical Devices to include IVD's
 - Address transitional arrangements from MCC to SAHPRA
 - General Regulations published on 11 August 2017





SAHPRA Background

- SAHPRA is responsible for monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest
- SAHPRA will:
 - Have full-time in-house capacity to support product review & approval and oversee all regulatory functions
 - Establish cooperation and information sharing with the NRAs to support implementation of best practices and timely approval of products
- SAHPRA Board Members were appointed by the Minister of Health on 9 October 2017
- Board had 3 introductory / unofficial meetings with the MCC on 24 November 2017, 13
 December 2017 and 15 January 2018.
- Minister of Health called the first official SAHPRA Board Meeting on 1st February 2018:
 - MCC ceased to exist at this 1st meeting
 - Board appointed an Acting CEO after consultation with the Minister of Health
 - Board appointed committees to assist with work of the Board

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SAHPRA Board

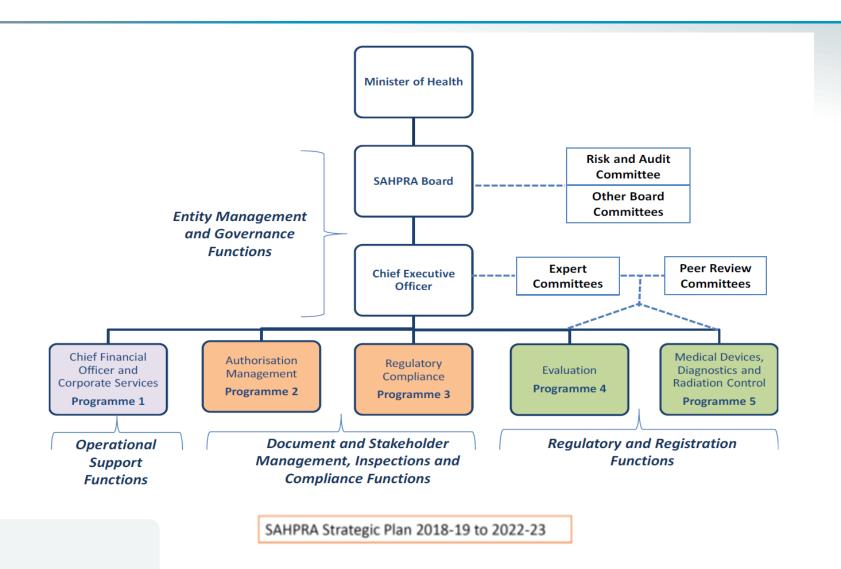
BOARD MEMBERS AND CATEGORY OF APPOINTMENT IN TERMS OF SECTION 2C(1) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965), AS AMENDED

No	Name	Category of appoinment
1.	Prof. Helen Rees (Chairperson)	Section 2C(2)(a) on account of expertise in the fields of
2.	Dr Nonhlanhla Madela - Mntla	medicine, medical devices, IVD, vigilance, clinical trials, good
3.	Prof. Shabir Banoo	manufacturing practice, public health or epidemiology
4.	Dr Henry Leng	
5.	Dr Thapelo Motshudi	
6.	Prof. Kelly Chibale	
7.	Prof. Aimes Dhai	
8.	Prof. Jeffrey Mphahlele	
9.	Dr Ushma Mehta	
10.	Dr Mphane Molefe	
11.	Adv. Hasina Cassim	Section 2C(2)(b) on account of knowledge of the law
12.	Ms Mandisa Hela (Vice-Chairperson)	Section 2C(2)(c) on account of knowledge of good
		governance
13.	Ms Lesibana Fosu	Section 2C(2)(d) on account of knowledge of the financial
		matters and accounting
14.	Mr Norman Baloyi	Section 2C(2)(e) on account of knowledge of information
		technology
15.	Prof. Craig Househam	Section 2C(2)(f) on account of knowledge of human resource
		management

In the interim, the Minister and the SAHPRA Board have appointed Mrs Portia Nkambule, previously a Director in the Cluster: Food Control, Pharmaceutical Trade & Product Regulation, as the Acting SAHPRA CEO.



SAHPRA Structure





SAHPRA Goals

- **Goal 1:** Publicly demonstrate responsiveness and accountability as an effective and efficient high performance organisation.
- **Goal 2:** Timeous regulatory decision taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance.
- **Goal 3:** Re-evaluate and monitor medicines and medical devices periodically.
- **Goal 4:** Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance.
- Goal 5: Ensure regulatory compliance through a process of active Inspections and investigations.
- Goal 6: Evaluate clinical trial protocols in accordance with defined standards.
- Goal 7: Evaluate the applications for sale of unregistered health products in accordance with defined standards.
- **Goal 8:** Establish and strengthen collaborative initiatives with any other regulatory authority or institutions in order to achieve the objects of the Medicines Act.
- Goal 9: SAHPRA is capacitated by adequate, competent and motivated Human Capital.



SAHPRA Strategic Plan 2018-19 to 2022-23



SAHPRA Envisaged Changes

- SAHPRA plans to have the following changes:
 - Capacity building increased full-time in-house technical capacity
 - Expanding technical and administrative staff members
 - Improving the skills base for newer, emerging technologies
 - Improved peer review system frequency of meetings
 - Specialized areas retainer system for experts
 - Provisional approval on early data is being investigated
 - Reorganize the appeal process to ensure speedier outcomes
 - Website improvements and strengthen communication through dedicated unit
 - Strengthen cooperation with recognized regulatory authorities
 - Frequent engagements with stakeholders





MCC vs SAHPRA

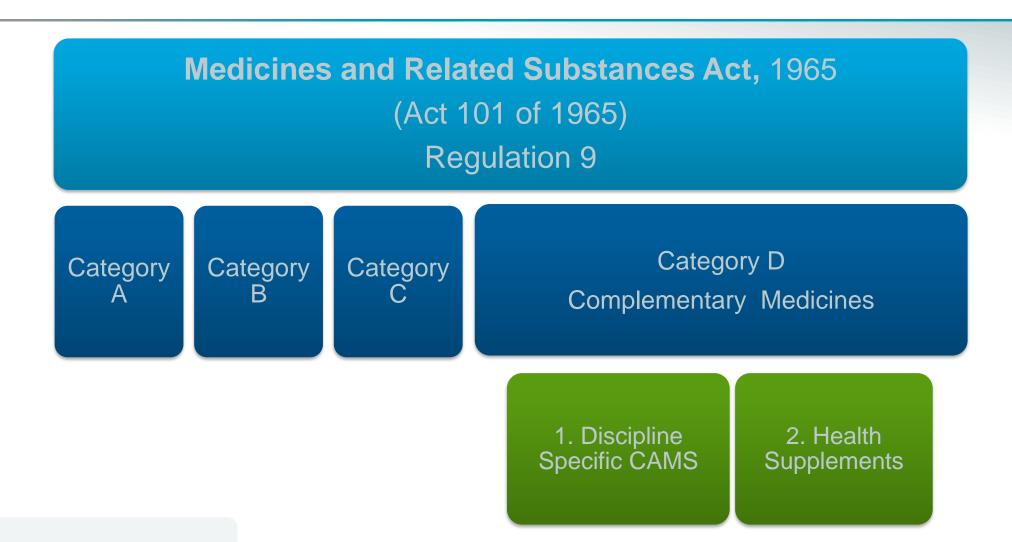
MCC		SAHPRA
• Medicines	•	Medicines, Devices (incl. IVDs & Radiation control), CAMS (DS & HS)
Within DoH	•	Schedule 3A Public entity
 Under resourced? 	•	Sufficiently Resourced
 Limited evaluators (own 20/80) 	•	Increase employed evaluators (80/20)
 Traditional government business functions 	•	Independent business entity model & retained income (70%:30%)
Paper driven	•	System driven
Backlogs	•	Timelines-based



CAMS Status

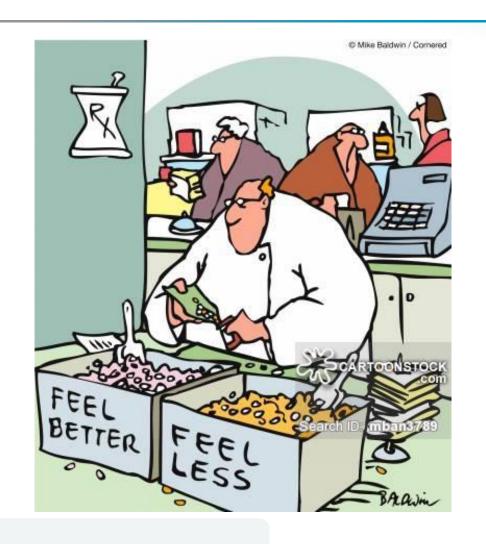


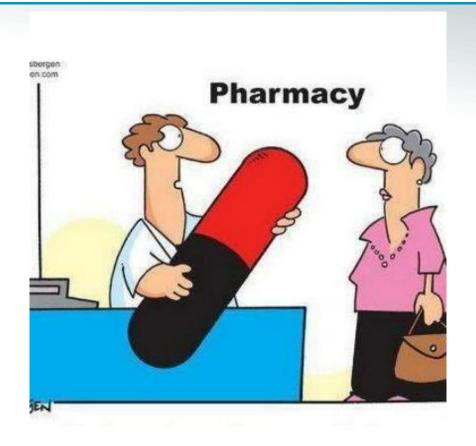
Medicine Categories





Use product for intended purpose





"Each capsule contains your medication, plus a treatment for each of its side effects."



Category A Medicines

Category A Medicines are called:

- Allopathic
- Orthodox
- Western
- Modern



This is the dominant MEDICINE system in SA:

- Widespread use
- Scientific background
- Political support
- Cultural acceptability
- Biological reasoning: anatomy, physiology, biochemistry



CAMS Overview

Alternative

= another treatment for same medical issue

Complementary

- = playing a secondary role
- = complements the body's natural healing tendency

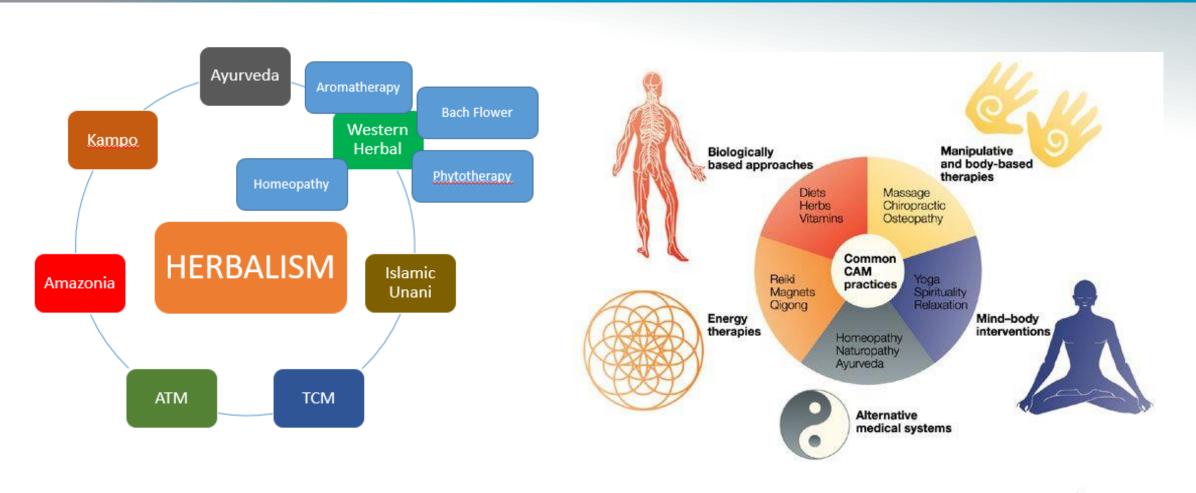


Current Trend: Integrated medicine

Affords patients and prescribers more choice, but little appreciation of clashes



CAMS vs Herbalism vs Alternative Medicine





CAMS Overview

CAMS market share is substantial:

- 1996: approx. R900 million
- 2003: approx. R1.35 billion
- 2010: approx. R7.8 billion = 0.7 % global market
- 2015: R8 billion with a growth rate of 13.5 % (Health Eye)

Definition and Scope

- CAMS = groups of diverse treatment systems, practices and products which have historic origins outside mainstream medicine
- Alternative: parallel, independent system: a substitute for orthodox medicine. Not based on evidence-based scientific method
- Complementary: also alternative but complements i.e. possibility for use with orthodox medicine

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WHO Definitions

Traditional Medicine (TM):

It is the sum total of the knowledge, skill, 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 Medicine (CM):

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



International Trends

Dietary Supplements













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SAHPRA CAMS - Definitions

Discipline Specific CAMS

i) The definition of a complementary medicine (CM) is provided as:

"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 Council, and
- (b) is used or purporting to be suitable for use or manufactured or sold for use—
 - in maintaining, complementing, or assisting the innate healing power or 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 Council, or
- (d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine.



SAHPRA CAMS - Definitions

Health Supplements

- ii) The definition of a health supplement (HS) is provided as:
 - "Health supplement" means any substance, extract or mixture of substances that—
 - a) may
 - i) supplement the diet;
 - ii) have a nutritional physiological effect; or
 - iii) include pre- and probiotics classified as schedule 0; and
 - b) are sold in pharmaceutical dosage forms not usually associated with a foodstuff and excludes injectables or substances schedule 1 or higher.

Combination Products

iii) The definition of a combination product is provided as:

Combination product means a single product that contains:

- a mixture of substances of different discipline-specific origins or philosophies;
- a mixture of at least one substance of discipline-specific origin and one or more health supplements; or
- a mixture of at least one substance of discipline-specific origin and one or more of its isolated constituents.



SAHPRA CAMS Disciplines

Disciplines Identified as "the CAMS that will be subject to these guidelines" (CAMS Discipline Specific Safety & Efficacy)

- 1. Homeopathy
- 2. Western Herbal Medicine
- 3. Traditional Chinese Medicine
- 4. Unani
- Aromatherapy
- 6. Additional: Combination products; Other herbals
- 7. Ayurveda??? → Is this still valid or meant to be put as "Other"

AND Health Supplements



Category D Medicines

	DISICIPLINE SPECIFIC (DS)	HEALTH SUPPLEMENTS (HS)
Types	Aromatherapy	Probiotics
	Ayurveda	Prebiotics
	Homoeopathy	Vitamins
	Traditional Chinese Medicine	Minerals
	Unani (Unani-Tibb)	Amino Acids
	Western Herbal Medicine	Animal Extracts, Products and
	Other Herbal	Derivatives
		Fats, Oils and Fatty Acids
	Combination Products	Carotenoids
	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]	Polyphenols (including
		Bioflavonoids)
r		Aminosaccharides
i		Saccharides
		Enzymes
		Other
1		
		Single substance formulations
1	RATIONALE PART OF THE COMPLEX]	Multiple substance formulations

High Risk

Table 1. Risk Level, type of claim and evidence required

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 disorder² 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: Recognised Pharmacopoeia ⁴; Recognised Monograph ⁴; Three independent written histories of use in the classical or traditional medical literature, or Citations from other <i>in vivo</i>, <i>in vitro</i> studies, case reports or others.

¹ Health enhancement claims apply to enhancement of normal health. They do not relate to enhancement of health from a

² All claims relating to symptoms must be accompanied by the advice "If symptoms persist consult your healthcare practitioner".

³ Refer to section 5.1 i) - vi)

⁴ Refer to section 5.1 vii) - ix) and ANNEXURE D

⁵ In cultures where an oral tradition is clearly documented, evidence of use from an oral tradition would be considered acceptable provided the history of use is authenticated. Modern texts that accurately report or confirm the classical or traditional literature may be used to support claims. Traditional claims should refer to corresponding traditional descriptions of the condition(s).

⁶ Terms used must be in accordance with the practice of the associated discipline.

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Low Risk

Risk Level	Type of Claim	Evidence required to support claim
LOW RISK	General health enhancement without any reference to specific diseases 1	Clinical data to be evaluated ³ AND/OR:
	 Health maintenance, including nutritional support. Relief of minor symptoms (not related to 	Two of the following four sources that demonstrates adequate support for the indications claimed:
	a disease or disorder) ²	 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.

¹ Health enhancement claims apply to enhancement of normal health. They do not relate to enhancement of health from a compromised state.

² All claims relating to symptoms must be accompanied by the advice "If symptoms persist consult your healthcare practitioner".

³ Refer to section 5.1 i) - vi)

⁴ Refer to section 5.1 vii) - ix) and ANNEXURE D

⁵ In cultures where an oral tradition is clearly documented, evidence of use from an oral tradition would be considered acceptable provided the history of use is authenticated. Modern texts that accurately report or confirm the classical or traditional literature may be used to support claims. Traditional claims should refer to corresponding traditional descriptions of the condition(s).

⁶ Terms used must be in accordance with the practice of the associated discipline.



2017 Government Gazettes

On 24 Feb 2017 the MCC published GG No 40637:

20 No. 40637

GOVERNMENT GAZETTE, 24 FEBRUARY 2017

DEPARTMENT OF HEALTH

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

The Medicines Control Council by virtue of the powers vested in it by section 14(2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), has by resolution approved by the Minister of Health, resolved to rescind the call-up notice for medicines frequently referred to as complementary medicines as published in the Government Notice R.204, Gazette No 23128 of 22 February 2002.

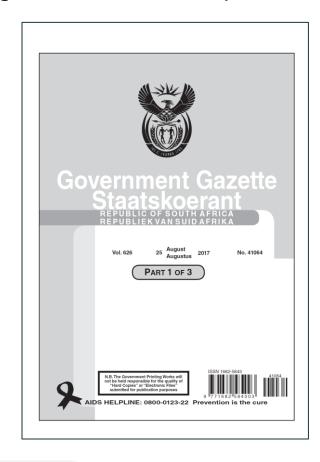
DR JC GOUWS
REGISTRAR OF MEDICINES

This understandably caused confusion and concern in the industry, especially for importers



2017 Regulations

On August 2017 the MCC published GG41064 No 859:



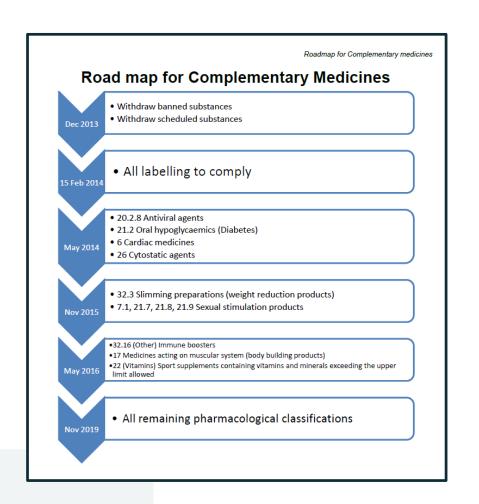


This "created" SAHPRA and also regulated Health Supplements as CAMS.



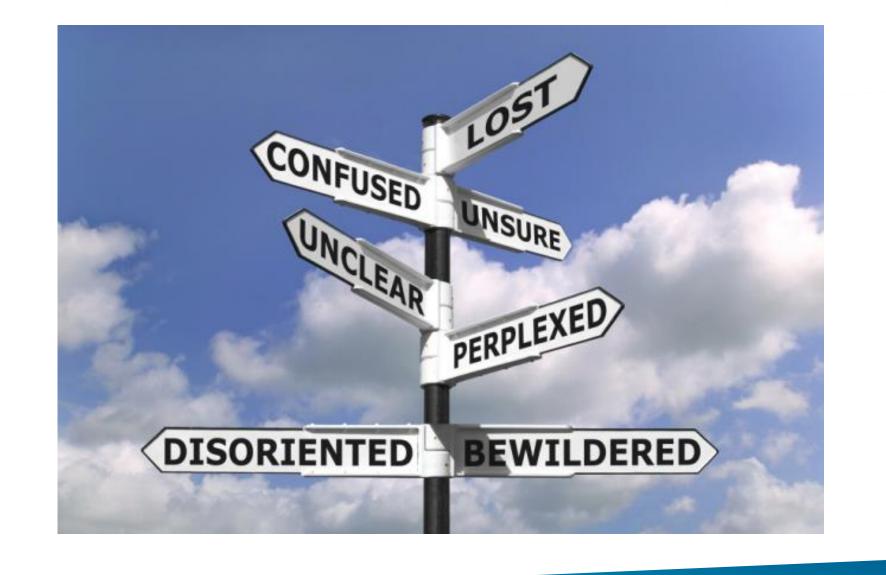
Section 48C - CAMS Road Map

SAHPRA Roadmap vs Current situation



vs **???**

No. 859 General
Regulations - Medicines and
Related Substances Act,
1965 (GG41064) on 25
August 2017 resulted in
previous roadmap being
rescinded or DELETED.
This has left the industry in a
grey area regarding the callups on Discipline Specific
CAMS and Health
Supplements



Which Way forward



SAHPRA Meeting with CAMS CEOs

- SAHPRA hosted a meeting with the CAMS CEOs on 12 June 2018.
- At this meeting the Acting CEO, Mrs Portia Nkambule, gave an update on SAHPRA.
- Dr Neil Gower also gave a presentation on Complementary Medicines:

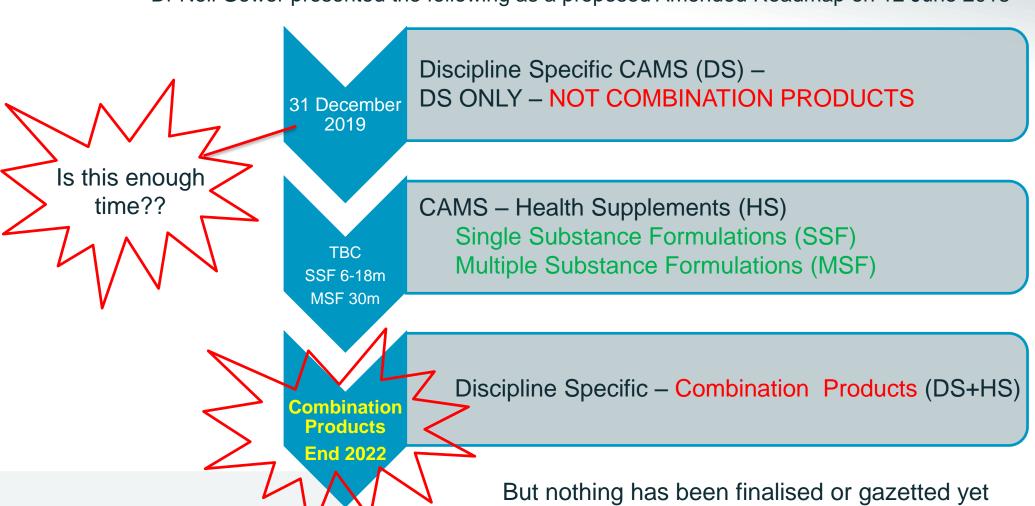


- This presentation highlighted a number of things to industry:
 - There is currently no Roadmap for Discipline Specific CAMS & Health Supplements
 - Health Supplements can still be launched in SA
 - SAHPRA have received approx. 246 dossiers which are being evaluated
 - However, there still has not been any CAMS product that has been registered thus far



SAHPRA Amended Roadmap

Dr Neil Gower presented the following as a proposed Amended Roadmap on 12 June 2018





SAHPRA's view on New Products

- Discipline Specific CAMS:
 - According to SAHPRA NO new Discipline Specific CAMS can be launched in the market as a result of the 15 November 2013 Regulations
- Health Supplements:
 - SAHPRA have confirmed that HS are not subjected to the 15 November 2013 Regulations
 - As a result there is no cut-off date that is formally prescribed (yet)
 - NOTE there are only 4 Annexures that have been finalised:
 - Annex C Probiotics
 - Annex D Prebiotics
 - Annex E Vitamins
 - Annex F Minerals
 - This would be applied to SSF, MSF and Combination (DS+HS) products
 - Risk: need to look at the HS Annexures before finalizing the formulation. If falls outside substance, limit and claims then could be considered a Category A medicine.



Health Supplement Annexures



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Probiotics	ANNEXURE C
Prebiotics	ANNEXURE D
Vitamins	ANNEXURE E
Minerals	ANNEXURE F
Amino Acids	To Follow
Animal Extracts, Products and Derivatives	To Follow
Fats, Oils and Fatty Acids	To Follow
Carotenoids	To Follow
Bioflavonoids	To Follow
Aminosaccharides	To Follow
Saccharides	To Follow
Enzymes	To Follow
Other	To Follow



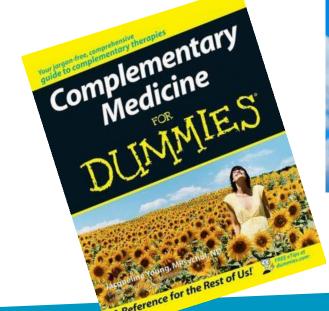
SAHPRA's Application Process

- SAHPRA is meant to be doing things differently to achieve greater results
- Being a Schedule 3A Public Entity, SAHPRA is meant to have more flexibility
- SAHPRA is investigating an electronically guided application process / dossier formulation for LOW RISK CAMS
 - HS: SSF → MSF
 - DS CAMS: Low Risk ----→ Progress to High Risk
- NB: for Tracking and evaluation of applications
- SAHPRA application process is a risk-based approach system
- Aim to minimise the HIGH RISK Claims (or substantiate):
 - Consideration of more efficient review of LOW RISK
 - Guidance on LOW RISK Clinical Info
 - Guidance on LOW RISK Quality Info
 - DS Medicine: Low risk vs High Risk
- Health Supplements: de facto listing system with application requirements focussed on quality

Industry has proposed:

- Interim Licencing System
- Appropriate GMP
- Abbreviated / Expedited HS submission
- Notification / Listing System





A Practical Approach

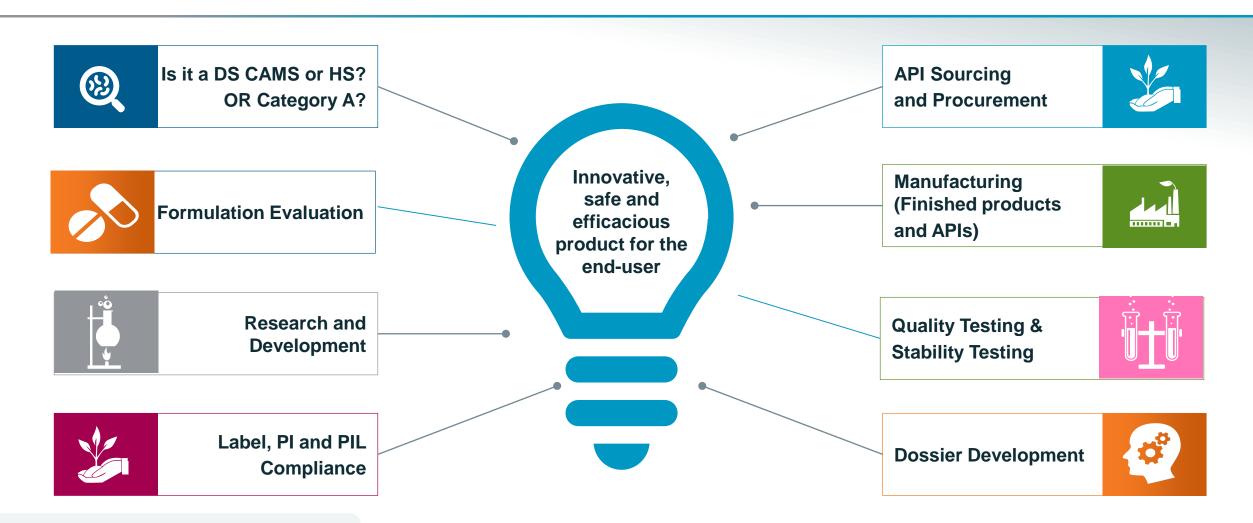


Medicine Regulation Core Principles





Practical Approach to Product Evaluation

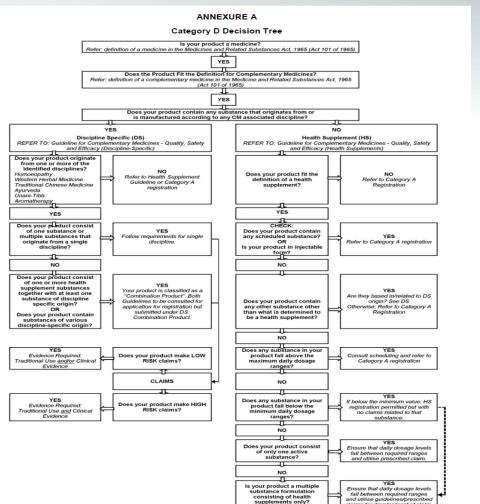








- Make sure it's a CAMS or a HS!
- Use the Category D Decision Tree
- If it is not a Health Supplement it must be DISCIPLINE-SPECIFIC CAMS (or Category A)
- Choose a discipline 6 + 1 are recognised:
 - Homeopathy
 - Western Herbal Medicine
 - Unani Medicine
 - Traditional Chinese Medicine
 - Aromatherapy
 - Combination Products / Other Herbal
 - Ayurveda??





Product / Formulation Evaluation

- Complementary Medicine Category D medicines
- Discipline-specific CAMS's versus Health Supplements
- The importance of determining and demonstrating a discipline
 - Is this formula congruent with the discipline?
 - Is the formulation within API limits
- Is the dosage form suitable and stable?
- Low Risk versus High Risk claims burden of proof
 - Modules 1.5.1 & 2.5 [& Modules 1.3; 5]



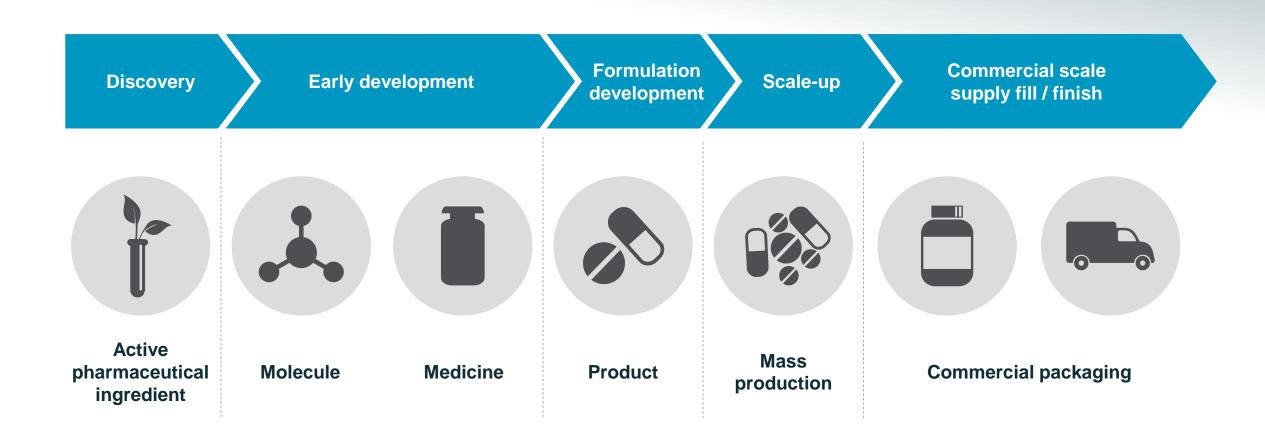


SAHPRA's Application Process

Low Risk	High Risk
Module 1 Including Application Form, PI, PIL, Label	Module 1 Including Application Form, PI, PIL, Label
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



Innovation & Formulation Importance





Using the Health Supplement Annexures available



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Probiotics	ANNEXURE C
Prebiotics	ANNEXURE D
Vitamins	ANNEXURE E
Minerals	ANNEXURE F
Amino Acids	To Follow
Animal Extracts, Products and Derivatives	To Follow
Fats, Oils and Fatty Acids	To Follow
Carotenoids	To Follow
Bioflavonoids	To Follow
Aminosaccharides	To Follow
Saccharides	To Follow
Enzymes	To Follow
Other	To Follow

Ensure your limits are within the API levels if HS



Research and Development



- Now is the time to ensure your formulation has USP benefits
- Ensure dosage form is suitable
- Check your OOS, deviations and customer complaints to improve product formulation
- Use R&D staff to evaluate formulation, dosage, API and design





Use the SAHPRA Guidelines

Comple	mentary [6]								
Туре	Doc#	Title	Version	SubVersion	PublishDate	Size	Select			
<u>}</u>	7.01	Complementary Medicines - Discipline Specific Safety and Efficacy	V3		13-Jun-2016	1 MB				
) PO	7.02	Road map for complementary medicines	V1		03-Dec-2013	262 KB				
٨	7.03	Complementary Medicines - Use of the ZA-CTD format in the Preparation of a Registration Application	V3		13-Jun-2016	355 KB		2.242.25	Guidance General PA CTD	and Module 1
100	7.04	Complementary Medicines - Health Supplements Safety & Efficacy	V2		13-Jun-2016	966 KB		2.052.01	Stability General Information	on
NO.	7.05	Complementary Medicines Registration Application ZA-CTD - Quality	V1		13-Jun-2016	1 MB		• 4.01	SA Guide to GMP	Herbal Annex 7
1	9.72	Complementary Medicines submitted for registration - right to sale	V1		24-Apr-2016	155 KB				



API Sourcing and Procurement

Sourcing Ingredients / APIs

- What can be in a CAMS? Combination Products?
- Extracts, concentrated extracts, standardised extracts & isolates?
- Is there a 3.2.S section? If not what next?
- GMP Status of API manufacturer vs ISO accreditation
- Does the API have monographs?

Procuring APIs

- Ensure it is from the SITE you approved
- Ensure it is the correct grade (esp botanical extractions)
- Test the incoming APIs
- Justify the sampling model you use
- Keep reccords





API







Initialization Road Map

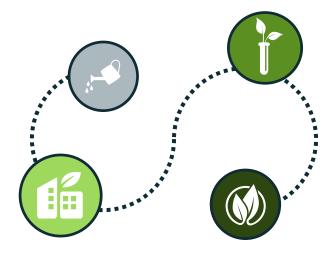
Fully-integrated product solutions

Plant Cultivation & Procurement

With a strong emphasis on reliable quality and sustainability, Our high-quality raw materials are harvested from sustainable resources and transformed into a range of innovative, industry specific active ingredients

Comprehensive Quality Control & Assurance

All incoming components undergo vigorous testing to eliminate possible quality issues early on in the process, which ultimately ensures a uncompromised final product.



State of the art facility and processes

Our manufacturing activities are supported by our integrated Material Resource Planning (MRP) system, allowing direct access to real-time data concerning stock availability, product requirements and progress

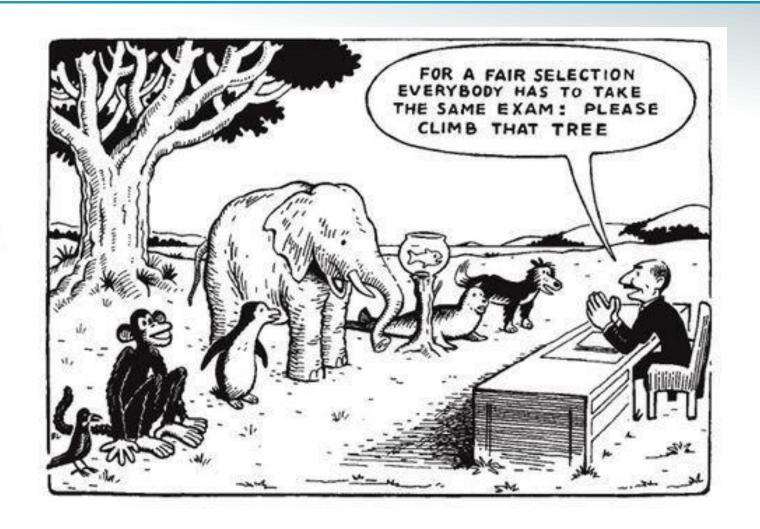
Standardised Botanical Extracts

Our portfolio includes a range of Botanical extracts (Liquid and Powder), Plant material and Oils. By utilising our research and development capabilities, we also ventured into Active Pharmaceutical Ingredient (API) development and supporting API master files



What is Quality?







Using GMP Manufacturing Sites

Good Manufacturing Practices

SA Guide to GMP

MEDICINES CONTROL COUNCIL





SA GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINES

This document is intended to serve as guidance on the requirements for Good Manufacturing Practice in South Africa. This guideline is not intended as an exclusive approach. The MCC reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine. The MCC may make amendments in keeping with the knowledge which is current at the time of consideration of data accompanying applications for registration of medicines. Alternative approaches may be used but these must be scientifically and technically justified. The MCC is committed to ensure that all medicines gaining market approaches mit of the required quality, safety and efficacy standards.

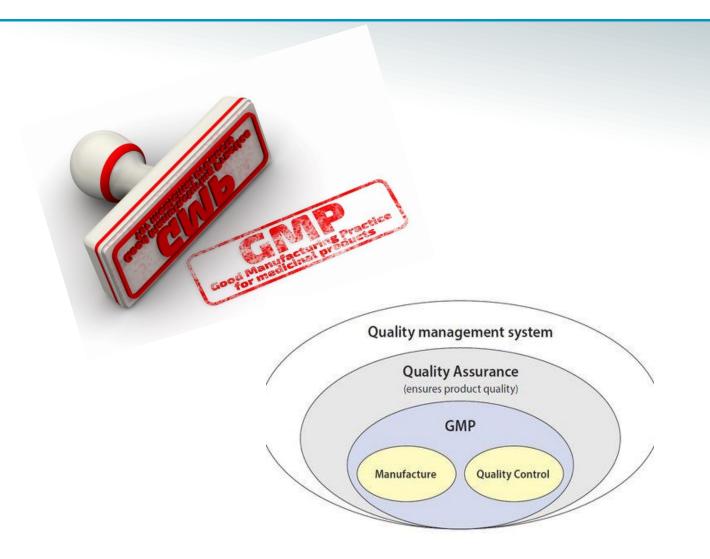
Version 1	Implementation	1997
Version 1	Chapter 9 (Validation) reformatted	January 2004
Version 2	Adoption of PIC/S GMP Guide of July 2004	January 2006
Version 3	Updates to Sections in line with PIC/S Guide updates	September 2008
	Released for comment	31 January 2009
Version 4	Amendments to Annexes 3 & 7	March 2009
	Released for comment	30 June 2009
Version 5	Consolidation of comments on versions 3 & 4	November 2010
Version 6	Adoption and acknowledgement of future adaptations of the PIC/S Guide to GMP	December 2017

DR JC GOUWS REGISTRAR OF MEDICINES

4.01_SA_Guide_to_GMP_Dec17_v6

December 2017

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The 4 P's of GMP





People

Procedures &



Premises Equipment



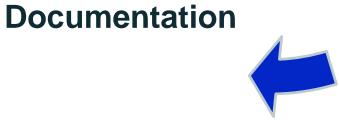






Process

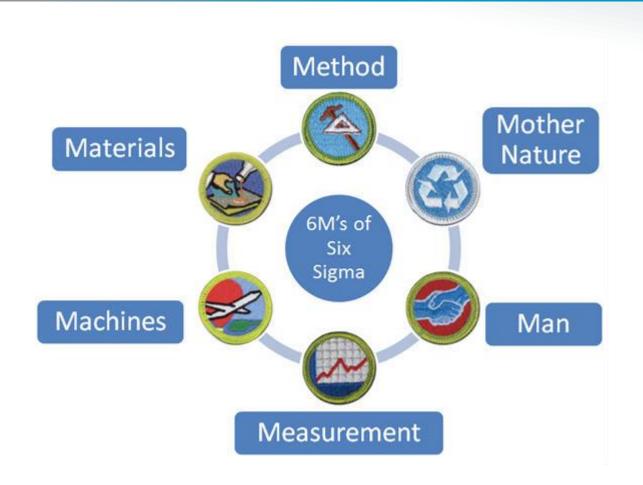








6 M'S of Six Sigma







Manufacturing - Processing Facilities

Specialised equipment for manufacturing finished products

Bulk liquid manufacturing



- Bulk batches (1,000,000 litres per annum) of plant extracts, tinctures and other medicinal liquids – (largest tank being 6,340 litres)
- AtEx (explosive atmospheres) rated area

Bulk liquid storage



- After bulk liquid manufacturing the product is placed on hold, sampled and sent to Quality Control for testing, approval and releasing
- 6 x 5,000 litres stainless steel tanks continuous stirring ability with each tank mounted on three weight load cells so as to control and reconcile bulk liquid batches

Liquid filling and packing



- State of the art liquid filling carousals for a diverse range of applications, e.g. varying viscosity and filling size
- There are three liquid filling and packing lines
- Total capacity 8,000,000 units per annum ranging from 20 ml 1000 ml per unit



Manufacturing - Processing Facilities

Specialised equipment for manufacturing final products

Oral solid dosage (OSD) manufacturing



 These manufacturing areas are equipped to fill gelatin capsules (size "0" & "00") or compress tablets in various shapes and mass, complimented by 3 primary OSD counting and 3 OSD secondary packing lines

Temperature / humidity controlled warehousing



- The latest technology / energy efficient fully integrated and real time controlled
- HVAC systems
- An integrated Material Resource Planning (MRP) system ensures on-time delivery to our client base

Water treatment



- Reverse Osmosis (RO) treatment plant capable of supplying 2,000 liters of purified water per hour
- Circulated closed loop supply to 11 take-off points



Labelling, PI & PIL Requirements

Requirements for Continued Right of Sale

- Labelling / Advertising
 - Regulation 10 "Labelling of medicines intended for human use"
 - Regulation 11 "Professional information for medicines for human use"
 - Regulation 12 "Patients information leaflet"
 - Regulation 13 "Labelling of veterinary medicines"
 - Regulation 14 "Professional information for veterinary medicines"
 - Regulation 42 "Advertising of medicines"
- Prescribed levels / indications
- No scheduled substances > S0
- Low risk indications as defined by SAHPRA
 - Complementing health
 - Supplementing the diet or
 - A nutritional effect

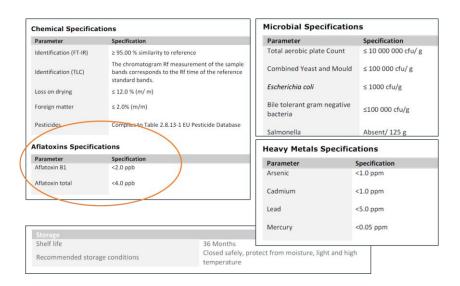




Quality Assurance



Quality control systems should be in line with cGMP. To keep pace with the current ZACTD regulatory requirements, some companies have invested in the necessary equipment and expanded our quality control system.





Specialized QC Testing









General Chemistry Lab

- FT/IR identification
- Viscosity
- pH
- Conductivity
- SG
- Loss on drying
- Dissolution, Solubility
- Disintegration of capsules and tablets



Instrument Lab

- High-performance liquid chromatography
- Thin layer chromatography and fingerprinting
- Gas chromatography





Specialized QC Testing







Microbial Lab

- Total plate count
- Yeast & Moulds
- E.coli (quantitative analyses)
- Salmonella (quantitative analyses)
- Bile-tolerance estimations



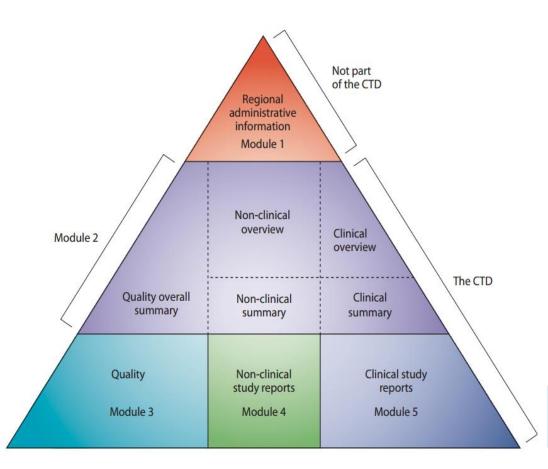
Stability Room

- Long term stability chambers
- Short term stability chambers
- Accelerated stability chambers



5

Dossier: Common Technical Document Format-Multisource products



"Registration Dossier" – Common Technical Document (CTD) is the document that contains all the technical data (administrative, quality, nonclinical and clinical) of a pharmaceutical product to be approved / registered / marketed in a country

- DMF: Drug Master File DATA proving; Quality, Efficacy, Safety
- 3.2S: Active Ingredient (Active Pharmaceutical Ingredient)
- 3.2P: Final pharmaceutical product
- Extensive technical documents for CAMS regulations <



CTD value-adding capabilities











Module 1

- Administrative information
- Completion of application documentation

Module 2

- Overview of application
- Formulation
- PI/PIL

Module 3

- Stability data
- Raw material information
- Pharmaceutical and analytical

Module 4

- Pre-clinical studies
- Data analysis
- Result publication

Module 5

- Clinical studies
- Data analysis
- Results publication



CAMS Future

SAHPRA Relocation to CSIR





our future through science

Communication to all stakeholders

SAHPRA

SOUTH AFRICAN
HEALTH PRODUCTS
RESULATORY AUTHORITY

25 January 2019

INTERIM RELOCATION OF SAHPRA TO CSIR

To all Stakeholders

Further to our communication of 31 October 2018 regarding the protest action at the Civitas Building, and the instruction from the Director-General Health regarding the vacating of the building, we can now confirm that interim new premises have been rented on the CSIR campus. Brummeria. Pretorial

This is an interim relocation due to the emergency situation, while the process to procure new premises for SAHPRA is in progress.

SAHPRA is located in the following buildings on the CSIR campus:

Accessed from the Visitor's Centre, North Gate (opposite the Sasol garage):

- Building 10f
- Building 16

Accessed from the Visitor's Centre, South Gate:

- Building 41
- Building 42

Outside, to the left of the gate to the Convention Centre (South Gate):

Building 38a – Reception

Please note that telephone landlines are not currently available. The cellphone contact numbers under Key Contacts on the website should be used.

Reception in building 38a will open on Friday, 01 February 2019.

Please note the following regarding deliveries to SAHPRA:

The trading hours will be as follows:

Deliveries: Monday to Thursday: 08h30 – 15h15
 Friday: 08h30 – 12h00

Collection of certificates, permits, licences: Tuesday & Thursday 10h00 – 12h00

- Applicants will be contacted when certificates, permits, and licences are ready for collection. These should then be collected at the next designated time, as indicated above.
- Please refer to the communication 9.113 for the submission procedure for Section 21 authorisations (orthodox medicines for human use only), and

communication 9.114 regarding the submission of post-marketing pharmacovigilance correspondence. Both documents are available on the SAHPRA website under Publications, Communications.

Please note that access to the other buildings is by appointment only. The relevant official to be visited will advise which building when the appointment is made. The visitor then has to report to the CSIR Visitor's Centre at the closest gate, as indicated above. The visitor's driver's licence or ID document will be required, otherwise the visitor will not be allowed onto the campus. Assets such as laptops taken into the CSIR will also have to be declared.

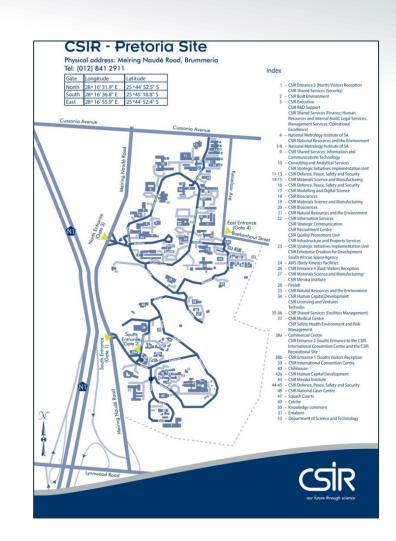
Ms P Nkambule Acting Chief Executive Officer

9.120_SAHPRA_Relocation_Jan19_v1

Jan 2019

Page 1 of 1

Relocation of SAHPRA





Recent Guidelines for Review



SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Private Bag X828, PRETORIA, 0001 Tel 012 395 8000

Fax 012 395

Subject: Request for comment on draft Variations Addendum for Orthodox Medicines, eCTD and eSubmission Guidelines, and New Registration Validation Template Date: 10 May 2019

Comment period: 10 May – 10 June 2019 Comment submissions: backlog@sahpra.org.za

Subject line for email: [Industry comments] Organisation name

One of the critical priorities of the South African Health Products Regulatory Authority (SAHPRA) is to clear its inherited backlog of new medicine registration and variation applications. SAHPRA's Board has committed to achieving this objective within 2 years. In addition, SAHPRA also needs to ensure that such a crisis does not arise again. It is thus imperative that SAHPRA designs and implements new evaluation policies and models for evaluation.

SAHPRA has a mandate to ensure the safety, quality, and efficacy of medicines available in South Africa. Part of this responsibility is revising its guidelines to reflect global regulatory best practices and to appropriately manage the regulatory burden on our industry partners to ensure access to quality, affordable medicines for all South Africans.

After consultation with our industry partners, the SAHPRA management team has decided to harmonise certain SAHPRA human medicine policies and procedures with those of the European Medicines Agency (EMA). Harmonisation will align South Africa with global best practices and enable increased collaboration with foreign regulators.

The following documents were published for comment mid-April; please note that the window for comment closes on 10 May 2019:

- 1. Professional Information (PI) and Patient Information Leaflet (PIL) guidelines
- Clinical guideline
- Clinical cover letter
- 4. Pharmaceutical and Analytical (P&A) guideline
- 5. Summary of Critical Regulatory Elements (SCoRE) document

SAHPRA is now releasing for industry comment:

- Variations Addendum for Orthodox Medicines
- 7. eCTD and eSubmission Guidelines
- 8. New Registration Validation Templates (eCTD and eSubmission)

These documents are DRAFT documents. SAHPRA may refine components of these documents prior to the industry comment period ending.

6. Variations Addendum for Orthodox Medicines

SAHPRA is adopting the <u>EU variations guideline for orthodox human and veterinary medicines</u>. To aid its application and interpretation in South Africa, SAHPRA has developed a Variations Addendum, which should be read in conjunction with the EU guideline. The Variations Addendum details specific classification and procedural deviations to the adoption of the EU

Registration of Medicines eCTD Submission in South Africa



GUIDANCE FOR THE SUBMISSION OF REGULATORY INFORMATION IN eCTD FORMAT

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medicines in eCTD format. It reflects the current situation and wilb the regularly updated with changes in legislation and experience gained. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of amplications.

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

First publication released for pilot implementation and comment	March 2013
Version 2 published for implementation	September 2016
Version 2.1 published due to administrative corrections	April 2017
Version 3 change from MCC to SAHPRA (draft for public comment)	May 2019

Registration of Medicines

Guideline for Professional Information for Human Medicines

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GUIDELINE FOR PROFESSIONAL INFORMATION FOR HUMAN MEDICINES

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medicines and variations. It represents the Authority's current thinking on the safety, efficacy and quality of medicines. It is not intended as an exclusive approach. SAHPRA reserves the right to request any additional information to establish the safety, efficacy and quality 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. The Authority is committed to ensure that all registered medicines will be of the required safety, efficacy and quality. 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 Chief Executive Officer and the website.

Version 1 - Publication for comment	15 April 2019
Due date for comment	15 May 2019

2.23 SAHPRA cCTD Guideline 2019 05 06vF Page 1 of 13

PI Guideline 2019_04_12vF

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Page 1 of 2



Recent Guidelines for Review

Registration of Medicines

Guideline for Patient Information Leaflet for Human Medicines

Page 1 of 8



GUIDELINE FOR PATIENT INFORMATION LEAFLET FOR HUMAN MEDICINES

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medicines and variations. It represents the Authority's current thinking on the safety, efficacy and quality of medicines. It is not intended as an exclusive approach. SAHPRA reserves the right to request any additional information to establish the safety, efficacy and quality 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. The Authority is committed to ensure that all registered medicines will be of the required safety, efficacy and quality. 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 Chief Executive Officer and the website.

Version 1 - Publication for comment	15 April 2019
Due date for comment	15 May 2019

Registration of Medicines

Health Supplements



COMPLEMENTARY MEDICINES - HEALTH SUPPLEMENTS SAFETY AND EFFICACY

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Complementary Medicines containing specified substances. In addition to this guideline, SAHPRA reserves the right to request any additional information to establish the safety, qualify and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. SAHPRA is committed to ensure that all registered medicines will be of the required quality, safety and efficacy.

Guidelines and application forms are available from the office of the Chief Executive Officer and the website.

First publication released for comment	November 2014
· · · · · · · · · · · · · · · · · · ·	11010111201 2011
Version 2 – deletion of quality aspects for inclusion in separate guideline	June 2016
Version 3 - addition of Annexures G and I for comment	April 2017
Deadline for comment	31 May 2017
Version 3_1 – addition of Annexure J for comment	May 2017
Deadline for comment	30 June 2017
Version 3_2 – addition of Annexures H, K and L for Comment	April 2019
Deadline for comment	15 June 2019

Use the Guideline Comments Form¹ available on the SAHPRA website when submitting comments. Submit comments by e-mail to Dr Kaizer Thembo at kaizer.thembo@sahpra.org.za.

¹ 6.13 Guideline Comments Form

7.04_SE_Health_Supplements_Apr19_v3_2_for_comment

May 2019

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Registration of medicines

Access to unregistered medicines



ACCESS TO UNREGISTERED MEDICINES

This document provides guidance on access to unregistered medicine for human use through the provisions of Section 21 of the Medicines and Related Substances Act. 1956. Act 101 of 1953 and califies the mandate, intert and scope of this section and Regulation 29 of the General Regulations published in terms of the Act. It outlines the process to be followed when requesting a medicine through Section 21, as well as the information required to comply with the provisions of the Act and Regulations. ASHPRA reserves the right to request any additional information to establish the safety, qualify and efficacy of a medicine and may make amendments to this document in keeping with knowledge which is current at the time of consideration of the data accompanying applications for access to and use of unregistered medicines. Alternative approaches may be used but these must be scientifically and technically justifiable. The Authority is committed to ensuring that all medicines granted approval will be of the required quality, safety and efficacy.

Version 1: First publication released for comment	April 2019
Deadline for comment	31 May 2019

2.52 Section 21 Access to Unregistered Medicines Dec17 v1 for comment April 2019

Page 1 of 13



SAHPRA Job Adverts

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ONCETTORS IN POST SEP: SAMPRA 024/2019	Must have demonstrable experience in a management position of phyrmosotical evolution and employee. Hanager: Christa Evolution (Prof. Bog) CANTEL PATOOIA.	CENTRACE	regard text, registration with the Health Proteocorals Council of South Johns (HPCSA) as Medical Physiciat. By years appropriate experience after registration with the HPCSA as a Health Physicial.	1X POST REF: SAMPRA 050/2019	3-Say tropedor (Reflative Scientist) Cantino Posttoma CSD TCL Reflation Scientist Grade 1
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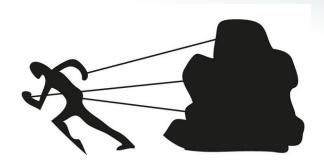
State of the last	EDICINES REGULATION (17 posts)	TEP SAMPER DED/2019	Copydy Manager: Supply Chair. Covres Petromia	3 x POSTS BER: SAMPINA 084/2019 DOSA CONNENT LINE	Assistant Manager: Project Office Manager CENTRE: PRETORIA (Full-time, 2-year Fixed Terro)
EX POST BEF: SAMPRA 052/2019	Legal Regulatory Advisor Course-sections	DESIGNATION DESIGNATION MINI QUALIFICATION	CENTRE PRETORIA PSAF TCI, ONIO OSSI SI Supply Cham & Asset Management	OPER Equipaint Lines OFTELL/COMPONENT MIN GUIL FICATION	MUNICIPAL SACREDO DE SECURITA
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	Further Conditions (CHEST PRINCE Conditions) (In Case Conditions)	SED SAVERA DES/2006		CONDITIONS	and evaluating bodgets, creating and implementing work plans, and mentioring both project and staff performance.
OFFICE/COMPONENT MIN GUALIFICATION	Health Product Project Office Appropriate A way Starbeing of Sharmon's Dealers of Star In A Sharmon's	DIFFA EQUIVARIE LOWE DIFFICE/COMPONENT MIN QUALIFICATION DIFFENCE	IPSAFTIC Non-OSCI Chef Executive Officer 2 year degree in Commence, Finance or Factori-Resource. Pleatour I years minuted experience superstany or middle management.		Support the courance of the medical drug application backing their. The project management of assigned modules.
CHRISTON	Science or opposited, Registration with SAPC or HPCSA. Grade In Chartester Science, Vi. 1992. Ill Blanch Decree. Ill service.	OPERING	2 year degree in comments, includes or recircle resources. Phintum 1 years miserant experience supervisory or middle management.	TX POST BEP: SAMPRA DES/2018	Deputy Manager: PMO Lead CENTRE: PRETORIE (Fell-time, 2-year Food Term)
	Registration as Pharmacist - name Grade 3. Chemistry Degree - Brussus, B. Pharm degree - Ni year.	CONDITIONS	Assistant Manager: Asset Management Calving: Pegrosia USAN 17: Pegrosia	OPSA Equivalent Level	PSAP TCE (Non-OSS)
CONDITIONS		BEF: SAMPEA DES/2019	CENTRE PRETORIA	OFFES/COMPONENT HIN GUAL FICATION	PSAP TCE Bloin-OSE) HISIOCHES BLOILOS PROJECT An apprepriate 5-year qualification. National certificatio-frobtonal Diploma/freid Graduate certificatio/ freid graduate Diploma/facilists
1 x POSTS BEF: SAMPEA 054/2019	Inspector (Fharmacouttical)	OFFICE/COMPONENT MIN GUAL PICATION	Supply Chain & Asset Management. An accessorate Nation couldn't show makeup contracted Aparticipal	- Company	Degree / Rinch.
OPSA Equipment Level	OSD TO Medicine Control Officer St 1-5 B		opena/not coolate orbicate/ Foil godiale options /backers begree /ithich.	- Committee	(e.g., consulting, treed treed banking, or striker environments). A successful track second of assessing as more banking in the property line.
OFFICE/COMPONENT MEN QUALIFICATION	Appropriate 4 year Sucheior of Pharmacy Degree, Segistration as a	CONDITIONS	PRIAD TOC (then 0000 Biggly Claim & Alexi Management An appropriate is year qualification, notices a certificate National Importation of Godule: estimate/ and godules ceptural (Isochesias (Ingres) (Isracia) — a para in Francia (Isochesias (Isochesia) — a para in Francia (Isochesia)		Equinnel Vivol. Collabolis infollation Find, graduate Openina / Racches langers / Richol. I years work superment in high precisive roses requiring decidibility org., consulting, investment baseling, or smoke resistancewish. A successful hand record or engaging in cross a certificate polyvior. Their amongement inspersival including a managing lateral, acceptance and evaluating badyloris, resulting and impairmenting earls plant and evaluating badyloris. Including professional consistency and evaluating badyloris. Including professional consistency and evaluating badyloris. Including professional consistency and the professional consistency of the professional consistency and the professional consistency and and the professional consistency and the professional consistency and the professional consi
COPERENCE	Crade T No experience heeded Crade 2 Chernolly disease. To usins 8 Pharm Charms - 8 years.	FEET SAMPER GPO/2010	be at advantage.	T CONDITIONS	monitoring both project and staff performance. Support the countries of the medical drug application backing at
	Claritie Mattolie On Dis Medicine cultiful critics of 1-5 Appropriate is your State from or 1-5 Appropriate is your State from Only 1-5 Appropriate is your State from Only 1-5 Control Control State (1-5 Control C	BEF: SANPRA 070/2019	Ser Systems Engineer CENTRE PRETORIA		Support the descrace of the medical drug application backing at SalatRIA through the oversight of the project management from
conomons	Registration as a Pharmacod - 6 years Previous reporterce in pharmacodical evaluation would be an advantage.	DPIA EQUIPMENT DPICE/COMPONENT MIN QUALFICATION	HAM TOO JOHN O'GO: ### TOO JOHN O'GO: ### TOO JOHN O'GO: ### TOO JOHN O'GO: ### TOO JOHN O'GO: #### TOO JOHN O'GO: #### TOO JOHN O'GO: ###################################	Z X POSTS REF: SAMPRA 096/2019	Ser Administrative Officer: Evaluator Coordinator CENTRS: PRETORIA (Full-time, 3-year Fixed Term)
REF: SAMPRA 055/2019	Imperior (GNP)(Scientist)		graduate Diptoma Nachwiers degree 13 fech degree. Studies in Computer Science.	OFFICE CONTROL LINE OFFICE COMPONENT MIN GUAL PICKTON	PSAP (Non-OSD) MEDICINES BACKLOG PREJECT
OPER EQUICATION CHARLEST CONTROLLOCATION CONTR	Personal registers in profitational constitution would be at according to the profit of the profit o	CONDITIONS	Science. 5 years appropriate eigeneisse.	DOEBONG	Sacheto's degree in related or health sciences, or SPturm
MN QUILLEE AT ION	Inspections. Sic in a Biological Science, or equivalent, Appropriate Gualification that allows registration with the Health Professionals Council of Gualification that allows registration with the Health Professional Council of Gualification (HPCSG) in reference profession (HeALT Gualification of Gualification of HeALT Gualification of Indicated professions after registrations with HPCSA orders approximate	Tai POST	ICT Analysi Programmer Calvinia: Historia	1	MIDICANS SACIO-OS HIGACI A Appropriate times year National Diploma-Cloques, invelocibly a Saciolos's degree in statular or health sciences, or Siftson's 3 years registered. Analytical sides, report withing sides, correlations sides, controlations sides, propriet management sides, poople management sides and extreme personal sizes. Analytical sides of reducine applications by assigning resources.
CHARRACE	(APCSA) in relevant profession (where applicable). Merman 1 years appropriate redesence in relevant promissor, after	DPSA Equipment Lover	PLAP (Non-CSC) 10	concimons	Harage worklow of medicine applications by assigning resources to applications, issue knowledge of medicines control and regulation.
congrions		DESA Equipment Lovel DESCLACOMPENENT MIN GUALIFICATION EXPERENCE	CANTER: PRETORIA PERO (NEC. PERO	7 x POSTS REF: SAMPRA 060/2019	Technical Screener CONTROL PORTOGRA (Full-time, 2-year Road Term) Streenersh Assistant (South Source)
TX POST MEET: SAMPRA OSE/DOTO	Hedicine Registration Officer (Grade III) Blood and Blood Products (ENTRI: PRETORIA	ECHOTONS	Lighted Kong II C. Jugita	OFFICIAL OFFI	CENTRE: PRETORIE (Fall-time; 2-year Fixed Term) Plannacid Amintani (Fod Rasic)
CPSA Equivalent Level		REF: SAMPRA GF2/2010	ICT Security Specialist CENTRE PRETORIA	MIN GUAL FICATION	Appropriate 3 year degree in Chemistry or Bachelor of Pharmacy Do or Birc in a Brokegical Science or equivalent, Registration with SAPC
OFFICE/COMPONENT MIN GUILLIFICATION	Appropriate 3 year degree in Chemotry or Sachelor of Pharmacy Degree or Sic in a Biological Science or equivalent, Registration with SAPC or ASYCA.	DEFICE/COMPONENT	MULEY (Non-Osc) ICT intrastruction & Operations	DEFENCE	HPCSA. I wan operators after teaching with PCSA.
CAPERENCE	HPCSA. Gade 1 No experience needed	MIN QUALIFICATION EXPERENCE	ICT Security Questation Copyright Profession PLAP Organ CSCS (If Polysthochies A Operations IDE, Degree or Material Operations IDE, Degree or Material Operations IDE, September September Ingelennes Working IDEC September Ingelennes Working IDEC September Ingelennes Working IDEC September ID	CONDITIONS	INFICIA. Il years expenses or after negatration with PCSA. Returns assuming of the lastnessal content of neutrons registration applications. Exposure to medicines regulatory environment is an ad-
22.000	HPCSA. Gade 1 to experience needed. Gade 2 Chemistry degree - 10 years, 3 Pearn Degree - 5 years, Registrates as Pearnteeth - new Gade 3 Chemistry Degree - 16 years, 6 Morn degree - 16 years.	CONDITIONS 1 K POST BEET SAMPER 075/2019	ADDITATE RECORDS CONTRE PRETORIA	1	
	Grade 5 Chemidity Degree - W years, B Pharm degree - W year, Regultration as a Marmachill - B years	SEF: SAMPEA 075/2016 DRIA Equivalent Lovel		FA POSTS REF: SAMPRA DIRE/2019 DPSA Exposited Lavel	Administration Clark CENTRE: PRETORIA (Full-time, 2-year Fland Terre)
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ESF: SAMPRA 053/2019	Hedicine Registration Officer (Grade III) Vaccines and other Biologicals CSHTISE PASTORIA. OSD TCL Medicine Registration Officer Gr 5 12	CONDITIONS	I years in it or related field. Studies in Computer Science would be an adventions.	MIN GUAL FICATION	MIDDOWS BOOK OF PROJECT Ceals D reviewer An appropriate I year qualification, Notional certificate/National Diploma/Post Graduate certificate/ Fost gradual Diploma /Bachelors Degree (G-Tech to an advantage.
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- Contractor Contractor	Appropriate 3 year degree in Cheredity or Bachelor or Pfurmacy Degree or BSc in a Bological Science or equivalent, legislation with SAPC or EPCSA.	BEF: SAMPEA CIN/2019 (IFDA E-QUANIERI LEME) DEFICE/COMPGNENT MIN QUALIFICATION	PSAP (Non-ciscs 7	- CARONICAE	Optime (Nachelors Degree (Id-Tech Is an advantage. I years registeries. Support the proceds narrang or the Sucking project. Organise and so applications, willind administration gueries and address responses, smallels (Opticia.
EMPERENCE	Age and any part of year to committee or experience, disperience with Charles PACCAL. Grade Time depression amended Heritage Regulation amend	MIN QUALIFICATION	is: I intramentate it operations. An appropriate 5 year qualification flushman unfillicate/flushman Dipsons/froit colodulae unfillicate/froit graduate Options /flusheron Depol //flittol. 3 years organized or indicated froit graduate Options /flusheron Depol /flittol. 3 years organized or indicated froit Statelin in Forestell transportment or accounting would be an advantage.	OFFIN POSTS BEF: SAMPRA 089/2019	Medicines Enstandor Level 1-Foundation
	Regulation as Pharmacht - name Grade S Chemistry Degree - 10 years, Ill Pharm degree - 16 year.	ESPERIENCE	Degree /Effects 3 years experience in resourt field	DES SAMPRA 089/2019 DPSA Equivalent Level	Medicine Entitlator Level Fooddation CERTEL ANY (Feet-time, Warriy Bales) DESA CONSISTENT SAIDS MEDICINES BADDLOOF POLICE IS Desturation for Registration Appropriate 5 year degree in Chemistry or Soldeer of Harmons D or Sto. in a Boxingual Science of equivalent, Registration with SAPC METCSA.
CONOTIONS	regenson as a Mamadid - 8 years		Studies in Francial management or accounting would be an advantage.	OFFICE/COMPONENT MIN GOAL PICATION	MEDICINES BADILOG PROJECT & Debution for Registration Appropriate 5 year degree in Chemistry or Sachelor of Marriago D
	Medicine Regisfration Officer - Clinical finals CENTRIC PRETORIA	TEPOST BEF: SAMPRA 075/2019 1075 A Chapter I and	Marian Securities Fractitioner CENTRE: PRETORNA PEAP (Non-OSC) 6	Designo	or too, to a trionigical Science or organization, Registration with SAPC HPCSA.
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MIN GLIESFICATION	CENTRIC PRETORIA OID TIC Medicine Confess Officer GL 1-5 TO Concer Swapping on the Registration occiti Appropriate 3 year degree in Chemistry or Bacterior of Pharmacy Degree or Bic on a Biological Science or equivalent, Registration with SAPC or HPCSA.		Appropriate II year qualification National Certificate/National Diploma ,/frait graduate certificate/ Post graduate Opioma/Sacheism degree/ Ellock	CONDITIONS	generics, supervised by Level 2 or 3 ministrative. Registration with DI or HPCSA. Province expension is plantacountrial restablish would be an advan-
EMPERENCE	of list in a disciplinal foliation or equivalent, Registration with SAPC or HCCLA. Clade 1 to experimen revokulo. Clade 1 to experimen revokulo. Clade 2 Conventing Register 1 to years, is Plearn Degree—8 sylvars, September 4 to years, 1 in Plearn Degree—8 sylvars, September 4 in Plearn Degree—15 years, September 3 is 1 therefold to year 1 in years, III in Plearn Degree—15 years, Registration 3 is 1 therefold 1 in years.	CONDITIONS	Typics expenses in released field studies in internal fresource Management would be an advantage.	OPEN POSTS BEE SAMPRA DRO/2019	Medicines Exaluator: Level 2-Specialisation
	Grade 2: Chemistry disgree - 10 years, Ill Pharm Degree - Ill years, Registration as Pharmacol - none	T x POST BEP: SAMPEA SPS/2009 SPSA E-gangiert Level	Human Resources Practitioner / 10P	DPSA Equivalent Lines	DPSA CONSULTANT PARES
controls	Registration as a Pharmactist - 5 years	BBF: SAMPBE DIN/2019 DPSA E-QUIGHT LOVEL DEFICE/COMPONENT MIN GUALE KARDN	PSAP (Non-OSC) Harsen Demonstr	DPSA Equivalent Lives OFFICUCOMPONENT MIN GUAL FICATION	CENTRE ANY (Plat-Time, mounty Ballet) DPGA CONCENTATION FAILS MEDICINES BACKLOS PRESECT & Equipation for Registration Appropriate 3 year degree in Chemistry or Rachelor of Phormacy Or or Sill in a Biological Science or equipalent, Registration with SAPC HPCSA.
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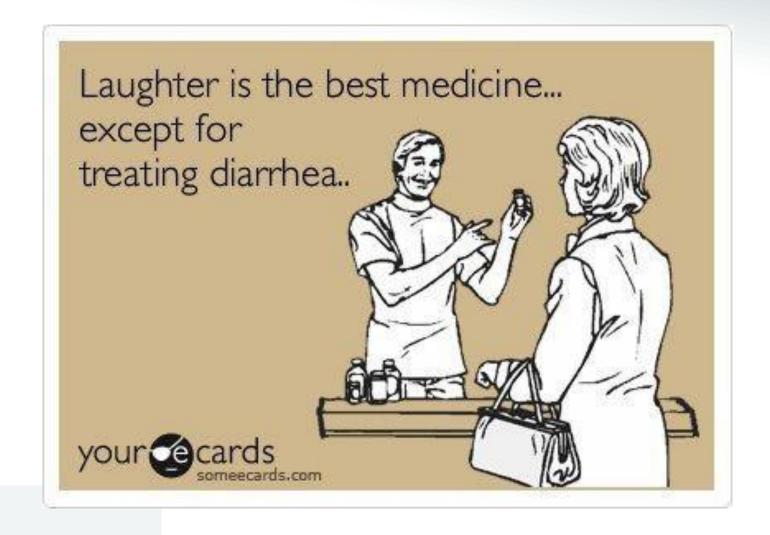
SAHPRA Challenges

- SAHPRA will need to overcome the following challenges in order to be successful:
 - Communication & Interaction with Stakeholders
 - National Health Insurance seen as a priority
 - National Drug Policy
 - Antimicrobial Resistance National Strategy Framework
 - Regulatory Pipeline or Backlog Project for Category A Medicines
 - Resource Constraints
 - Database & Infrastructure
 - Organizational culture recent strikes and fires
 - Timing and Result Driven
- Although SAHPRA is made up of the same people from DoH/MCC, it is important to remember that it is still very new and thus will likely experience "teething" issues during the next few months.
- I believe it is the CAMS Industries responsibility to work with SAHPRA to ensure we have a regulatory framework that is appropriate and adds value not only to the public but also to all the stakeholders.





Remember ...





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Closing remarks

Afriples African African African Policy Cource to Shelf

Wayne Robinson

Director: Business Development



+27 84 232 7961



WayneR@afriplex.co.za

