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ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF COMPLEMENTARY MEDICINES

This document has been prepared to serve as guidance to stakeholders regarding the regulation pathway of complementary medicines (CMs) for which claims of safety, quality and efficacy and which may be called up for registration. It represents the South African Health Products Regulatory Authority's current thinking on the appropriate assurance of safety, quality and efficacy of CMs and the intention of the Authority over the described period of time.

Version 1 – Implementation in accordance with Government Gazette Notice R. 870 in *Government Gazette* 37032 of 15 November 2013	15 November 2013
Version 2 – Implementation in accordance with Government Gazette Notice R. 859 in *Government Gazette* 41064 of 25 August 2017	September 2019
Version 2_1 – Guideline format, process update and minor amendments	June 2020
Version 2_2 – Updated of timelines, inclusion of process flow for new application for SAHPRA licences limited to Category D medicines	March 2021

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1. Introduction

On the 15th November 2013 the Minister of Health published amendments to the General Regulations made in terms of the Medicines and Related Substance Act, 1965 (Act 101 of 1965) (hereafter referred to as "the General Regulations"), which established a category of medicines, Complementary Medicines (Category D) and effectively established a regulatory framework for this category. The medicines which fall under this definition originate from the six (6) major disciplines recognised by the South African Health Products Regulatory Authority (SAHPRA) namely Aromatherapy, Ayurveda, Homeopathy, Traditional Chinese Medicine, Unani Medicine (Unani-Tibb) and Western Herbal Medicine [1], as well as combination products identified in the accompanying Guideline for Complementary Medicines (Quality, Safety and Efficacy) published in the same year.

Following further interaction with various stakeholders, the category of Complementary Medicines was broadened to establish two sub-categories of Category D (Complementary medicines), reflected in the General Regulations published and implemented as per Government Notice 859 in *Government Gazette* 41064 on 25 August 2017. This resulted in the inclusion of new sub-categories of Category D, including those traditional disciplines that are not indigenous to South Africa (discipline-specific medicines) but also the more modern supplement-type of medicines (health supplements).

The original deadlines for submission of applications for registration prescribed by regulation 48C of the General Regulations in 2013 were deleted by the General Regulations in 2017. A new timeline will be established by way of the publication of declarations that categories, sub-categories or classes of Category D medicines (Complementary Medicines) shall be subject to registration ("call-up notices") in terms of section 14 of the Medicines and Related Substance Act, 1965 (Act 101 of 1965) (hereafter referred to as "the Medicines Act").

The registration and availability of complementary medicines will consider their quality, safety and efficacy as per section 1(2) of the Medicines Act and in line with their relative risk. Discipline-specific medicines are considered either as being of HIGH RISK (clinical evidence required in justification of safety and efficacy) or LOW RISK (traditional evidence may be submitted in justification of safety and efficacy) based primarily on indication but also on composition and dosage form. Health supplements allow only LOW RISK indications and substances, in accordance with lists of substances, dosage ranges and indications stipulated in the guidelines issued by the SAHPRA.

This document is intended to provide guidance to all stakeholders on the intended future regulatory pathway, including licensing of activities associated with the supply as well as the registration of complementary medicines in order to best harmonise activities of the industry and regulator.

2. Scope of the Document

This document establishes the roadmap and general overview for the regulatory pathway of complementary medicines including licensing in terms of section 22C(1)(*b*) and submission of applications for their registration following the implementation of the General Regulations in 2017 and applies to products for human (discipline-specific medicines and health supplements).

With respect to licensing of facilities (section 3.1), this Guideline is not applicable to any product associated with the cultivation or manufacture of Cannabis-related pharmaceutical products containing Tetrahydrocannabinol greater than 0,001 percent. Intended licence holders must instead refer to the

[1] Anthroposophical, Gemmotherapeutic, Spagyric Substances and Flower Essences are provided for. See Guideline 7.01 - item 1.4.5.

SAHPRA *Guideline 2.44* – *Cultivation of Cannabis and Manufacture of Cannabis-related pharmaceutical products for medicinal and research purposes* on www.sahpra.org.za.

3. Guidance for Regulatory Priorities associated with Complementary Medicines

3.1 Licensing of Manufacturers, Importers, Exporters, and Wholesalers or Distributors

In terms of the provisions of section 22C(1)(*b*) of the Medicines Act, all manufacturers, wholesalers or distributors of complementary medicine must be licensed, as the case may be, to manufacture, import, export or act as a wholesaler of or distribute complementary medicines.

A process to license all relevant entities to: i) manufacture, import or export; ii) import or export; or iii) act as a wholesaler of or distribute, complementary medicines will commence by way of an electronic application made available by the Authority: www.sahpracm.org.za. The electronic platform is intended to provide ease of use for all potential licensees and will provide an efficient means of tracking and processing any licence application by the Authority. All applications will be reviewed for appropriate categorisation with any queries relating to the application raised by the Authority, being referred to the applicant within 15 working days of receipt of the application by the Authority.

This licensing process is intended to be made available at least twelve (12) months prior to any new call-up notices being published.

3.1.1 Information Required

The information to be provided by an applicant for the licence is stipulated in regulation 23 of the General Regulations and includes information specific to the requirements of the various classes of complementary medicines. The minimum information required shall be guided by the application process which is meant to provide a developmental basis for the achievement of minimum standards.

Guidance for completion of the relevant application will be integrated into the licence application process and may also be accompanied by the relevant licence application guideline.

As part of the application, all complementary medicines sold by the applicant (whether manufactured, imported, exported or distributed) are to be listed. The listed medicines will be confirmed against the prescribed definitions of complementary medicines and its sub-categories / classes. Confirmed lists will be appended to the relevant licence numbers and will be available online for verification of what medicines would be allowed for sale, prior to any relevant call-up notice deadline expiring.

Any medicine that has not been submitted for registration by any relevant prescribed deadline associated with a call-up notice issued in terms of section 14 of the Medicines Act will be removed from the relevant licence and will be indicated as being non-compliant.

3.1.2 Issuing of Licences

Licences will be issued to successful applicants based on the SAHPRA's acceptance of the applicant's attestation of compliance with minimum requirements at the time of application and the payment of the required licence application and desktop evaluation fees. The nature of the licensing process is developmental and compliance with minimum standards will allow the successful licensee time and space to develop compliance in the field prior to the renewal application. Following successful application for a licence, annual licence retention fees are also payable.

Applicants will be notified of the result of the evaluation of their application by e-mail and licences may then be collected from the offices of the SAHPRA as indicated by such communication. No electronic versions of licences will be made available to applicants.

All licences issued will be valid for a period of five (5) years during which the holder of the licence must be inspected for verification of the attestation of compliance with minimum requirements, included with the application received and/or accepted by the Authority, at least once. Attestation verification failure may result in the suspension or withdrawal of the licence. Licences may be renewed in line with the prescripts of the Medicines Act.

3.1.3 Inspections of Licensed Sites

Authority inspections of sites will be conducted for verification of compliance with the minimum requirements as attested. Inspections of local sites will take place at least once every five years. The Authority will rely upon relevant/appropriate GMP inspection reports by PIC/S members for the issuing of the licence but will consider conducting individual inspections as merited by the risk or other reasons associated with products manufactured or managed by any international site. The licensee is responsible for the payment of any fees to the SAHPRA that may be associated with the verification inspection. The SAHPRA may, at its discretion, elect to undertake an inspection of any premises prior to the issuing of any licence.

3.1.4 Specificity of Licences for Category D Medicines

Licences issued by way of attestation shall be specific to complementary medicines only. The normal licensing procedure applies to the manufacture, import, export or wholesale or distribution of any other medicines.

Existing licence holders need not re-apply using this process for current licences linked to other Categories of medicine as well as Category D medicines, that do not require any amendment or alteration.

3.1.5 Renewals and Amendment of Licences

An electronic form will also be made available for the renewal or amendment of any existing licence pertaining only to Category D medicines. The prescribed fees for renewal or amendment will be payable.

Any application for renewal of a licence will require information as prescribed in regulation 24 read together with regulation 23 of the General Regulations.

An application for an amendment to a licence must be submitted when any of the following changes take place:

(a) Name of the licence holder;
(b) responsible pharmacist;
(c) responsible person;
(d) site address;
(e) activities provided for by the licence; or
(f) the medicines or Scheduled substances to be manufactured, imported, exported or distributed and sold.

Any existing licences which pertain to or include Categories of medicines other than Category D and which require amendment of their existing product list by adding/removing Category D medicines only, may apply on the SAHPRA CM website for a product list amendment by use of the dedicated link provided. Fees for desktop reviews, as prescribed, relating to these products lists (as a primary overview of compliance with quality, safety and efficacy) may be applicable at the point of application. Any subsequent change to appended product lists will thereafter be considered as an amendment.

3.1.6 Licence Fees

Applications for licences submitted to the regulator (either the Medicines Control Council or the South African Health Products Regulatory Authority) prior to 17 February 2020, and which pertain only to Category D medicines and have not yet finalised, may be transferred to the electronic application, provided that:

- the fee prescribed at the time of application has been paid; and
- reference for such payment is provided as part of the electronic application.

If no fee has yet been paid, the application must be re-submitted as a new licence application.

New licence applications are subject to payment of the licence fee as prescribed at the time of application.

3.2 Licensing Periods

Only holders of a valid licence issued in terms of section 22C(1)(*b*) of the Medicines Act shall be permitted to manufacture, import, export or act as a wholesaler or distribute complementary medicines. A transitional period from 01 July 2020 to 31 January 2022 (see item 5) will be provided for licence applications of existing complementary medicine manufacturers, importers, exporters, wholesalers or distributors prior to the publication of new call-up notices issued in terms of section 14 of the Medicines Act.

After the priority licensing period and publication of call-up notices associated with Category D, any new manufacturers, importers, exporters, or wholesalers or distributors must hold a licence prior to manufacturing, importing, exporting, wholesaling or distributing any Category D (complementary) medicines.

3.3 Product Compliance

3.3.1 Labelling

All medicines identifiable as Complementary Medicines in terms of the Medicines Act and General Regulations must be compliant with regulations 10 (labelling of medicines intended for human use), 11 (professional information for medicines for human use) and 12 (patient information leaflet).

In terms of the General Regulations made in terms of the Medicines Act:

- The immediate container of any medicine must be labelled in compliance with regulation 10;
- All medicines must be accompanied by *Professional Information* (regulation 11) which must at least be in English and may be accessed electronically provided that the manner in which the professional information may be accessed is stated on the patient information leaflet as contemplated in regulation 12(2)(*p*). If the Professional Information is not available electronically, then it must be supplied in hard copy or as an integral part of the package with the supply of the medicine;
- All medicines are required to be supplied with *Patient Information Leaflets* (regulation 12) that are in English and at least one other official language;
- All active ingredients for complementary medicines should be named or referenced on the label, PI or PIL in accordance with **Annex B** of **Guideline 7.05 – Guideline for Complementary Medicines – Registration Application ZA-CTD – Quality.** Medicines available for sale prior to the date of publication of this notice are expected to comply by 01 July 2021. All new applications for registration must be submitted in compliance with this requirement;
- All unregistered complementary medicines must state the disclaimer on all labelling, exactly as prescribed by the General Regulations made in terms of the Medicines Act: "***This unregistered***

medicine has not been evaluated by the SAHPRA for its quality, safety or intended use." Only once registered, may this disclaimer be removed; and

- All complementary medicines must be identified as such, the relevant discipline must be clearly stated, and all general or specific regulatory requirements adhered to relevant to the specific product.

3.3.2 Rights of sale

All complementary medicines, as defined, will be permitted continued rights of sale, provided that:

- An application is submitted for their registration by the prescribed deadlines of the applicable call-up notice;
- they are manufactured, imported, exported, wholesaled or distributed by a holder of a relevant licence contemplated in section 22C(1)(*b*) of the Medicines Act at the end of the timeframe specified herein;
- they are specifically compliant with the requirements of section 20 and regulations 10, 11, 12 and 42 as prescribed, and are compliant with any other relevant provisions of the Medicines Act and its regulations; and
- they are indicated based on LOW RISK, which includes:
  i. General health enhancement without any reference to specific diseases;
  ii. Health maintenance; or
  iii. Relief of minor symptoms (not related to a disease or disorder).

Complementary medicines on sale indicated for use deemed to be of HIGH RISK without amendment of their indication as above may be called up individually for registration by the SAHPRA. HIGH RISK indications include:

i. Treats/cures/manages any disease/disorder;
ii. Prevention of any disease or disorder;
iii. Reduction of risk of a disease/disorder;
iv. Aids/assists in the management of a named disease/disorder or sign/symptom of a named disease;
v. Relief of symptoms of a named disease or disorder; or
vi. Treatment of proven vitamin or mineral deficiency diseases.

Unregistered complementary medicines making use of the terms "Clinically proven" or any similar expression (as per **Annexure A**) shall also be considered to be HIGH RISK and may be subject to individual call-up in terms of section 14(2) of the Medicines Act.

Examples of low-risk indications are provided in **Annexure B**.

Any call-up notice issued for individual products on the basis of HIGH RISK classification may be associated with the immediate cessation of its sale pending registration of the medicine by the SAHPRA in terms of section 14(1) of the Medicines Act.

3.3.3 Advertising and Marketing

Medicines may be advertised, taking into account section 20 of the Medicines Act and regulation 42 of the General Regulations. Unregistered complementary medicines should consider LOW RISK advertising while bearing in mind the rights of members of the public to receive information that is transparent, fair, honest, accurate, truthful and empowering.

3.4 Medicines Registration Process

All applications for registration that have already been submitted will continue to be processed and will be finalised as soon as possible. For those applicants with products not associated with valid licences this

may occur only once the relevant licence in terms of section 22C(1)(*b*) of the Medicines Act has been issued.

The Authority recognises that applications already submitted up until June 2020 may have undergone fundamental changes due to a variety of reasons including, but not limited to, updated quality data, amended clinical evidence or updated indications. As such, the SAHPRA will provide for a process by which applicants may, at their choosing, request that such applications be temporarily "uplifted", effectively suspending the relevant review, for such amendment and may be resubmitted in substitution of the previous application without prejudice to the application review. This process will take into account the existing progress made on the application and the reasons for upliftment. The SAHPRA will provide a separate detailed communication on this option.

In future, the Authority will provide online mechanisms for the submission of applications for registration of Complementary Medicines, which will continue to make use of the CTD format but will provide for significant guidance specific to the requirements of Complementary Medicines and their risk profile. This mechanism of application for registration will be prioritised for LOW RISK applications that consist of single substances and will be progressively expanded to multiple substance formulations, combination products and medicines of HIGH RISK.

All applications for registration of a medicine, where an electronic mechanism is not provided, must comply with the current requirements for such application.

4. Summary of legislative control of Complementary medicines

In terms of the legislative provisions aimed at the regulation of complementary medicines, the following regulatory requirements should be adhered to:

(i) Licensing of Manufacturers, Importers, Exporters and Wholesalers:

In terms of the provisions of section 22C(1)(*b*) of the Medicines Act, all manufacturers, importers, exported and wholesalers or distributors of complementary medicines must be licensed.

(ii) Labelling of Complementary medicines

In terms of the provisions of regulations 10, 11 and 12 of the General Regulations, all medicines falling in Category D must comply with the labelling requirements in so far as the product label, the Professional Information and the Patient Information Leaflet are concerned. Active ingredients must be named according to **Annex B** of **Guideline 7.05 – Guideline for Complementary Medicines – Registration Application ZA-CTD – Quality**.

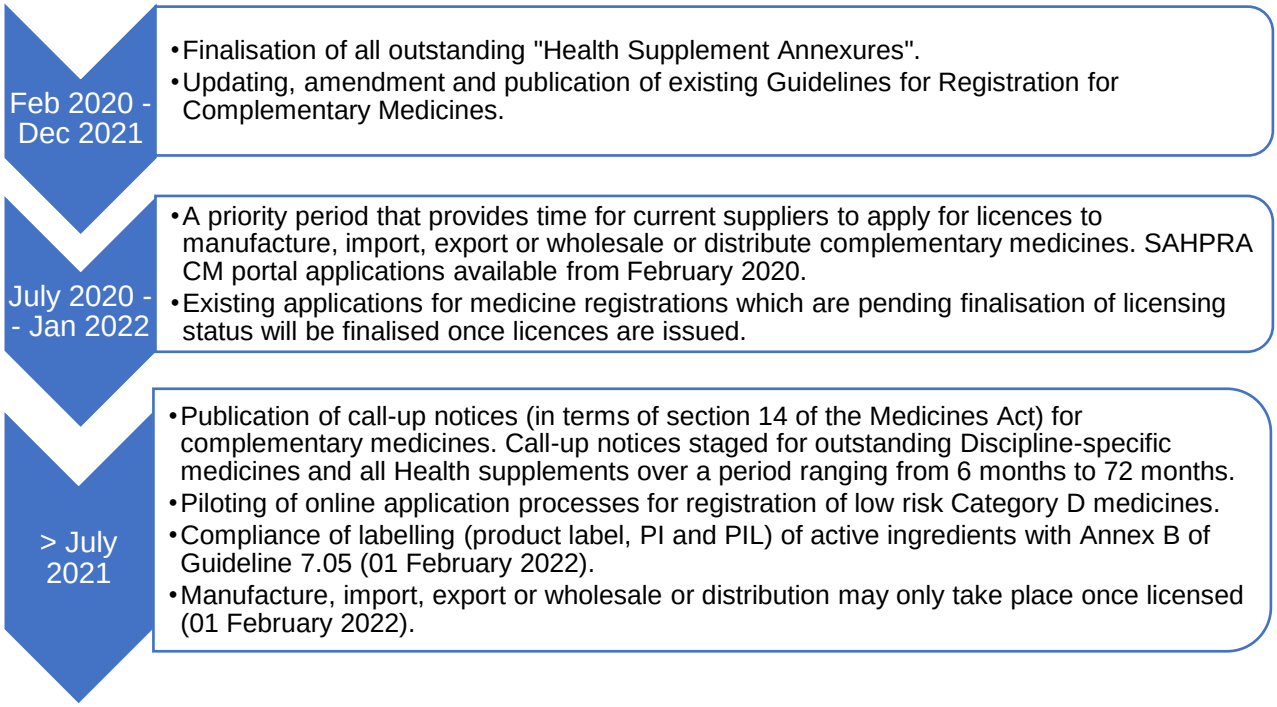
(iii) Advertising and Marketing of Complementary Medicines

Section 20 of the Medicines Act and regulation 42 of the General Regulations.

(iv) Submission of applications of applicable medicines for registration as complementary medicines by deadlines prescribed by relevant call-up notices issued in terms of section 14 of the Medicines Act.

(iv) All other requirements in terms of the guidance provided herein as well as the Medicines Act, generally or specifically applicable to complementary medicines that would permit continued rights of sale. Offences and penalties as prescribed by the Medicines Act and the General Regulations apply equally in cases related to Category D medicines.

5. Summary of General Timelines



6. General advice to consumers

Consumers must remember that all complementary medicines are medicines. As with any other medicine they should be used with care. When intending to use a complementary medicine, make sure it is the correct product for you by seeking professional advice. Consumers must remember that "natural" does not necessarily mean safe. Many plants and other natural compounds can be poisonous to humans. Many pharmaceutical medicines have been developed from plants because of the powerful compounds they contain. The quality, safety and efficacy of complementary medicines in South Africa cannot be ascertained unless they have been evaluated and registered by the SAHPRA.

Complementary medicines can interact with other medicines. This could result in other medicines having reduced or enhanced effects, including side-effects. When consulting your relevant health care providers about your health always tell them about any complementary medicines you are taking. If you are pregnant or breastfeeding your baby, please consult your relevant health care provider for advice before taking these medicines. As with all medicines, keep complementary medicines out of the sight and reach of children.

Adverse reactions can occur as a result of taking complementary medicines as for any other form of medicine. Consumers and prescribers are encouraged to notify the Authority of any adverse event (including therapeutic ineffectiveness) that may be experienced, by using the SAHPRA Adverse Drug Reactions and Quality Problem Reporting Form

Other than reports of adverse events, consumers will soon be able to report or lodge anonymous complaints of non-compliance against any complementary medicine through a dedicated website: www.sahpracm.org.za or consumers are welcome to report complaints of non-compliance with the SAHPRA directly.

7. Update History

Date	Reason for update	Version & publication
Nov 2013	Publication for implementation	v1 November 2013
Sep 2019	Amended publication in accordance with amended regulation.	v2 September 2019
June 2020	SAHPRA Branding Amendments: Section 2: CBD products and licensing Sections 3.1, 3.1.5, 3.2, 3.3.1, 5: Timeframes Section 3.1: Hyperlink correction Section 3.1.3: Discretionary inspection guidance Section 3.1.5: Clarification of fees Section 3.3.2: Clarification of high risk bullet *iv* (see also Guideline 7.01 amendment) Section 3.3.2: Introduction to Annexure B Section 3.4: Reference to upliftment of medicine registration applications Section 6: Pregnant / breastfeeding reference Annexure B: Examples of low risk indications	v2_1 June 2020
March 2021	Sections 3.2, 5: Timeframes Annexure C: Process flow for new application for licences limited to complementary medicines	v2_2 March 2021

ANNEXURE A

GUIDANCE ON THE USE OF PARTICULAR EXPRESSIONS IN ADVERTISING OF UNREGISTERED MEDICINES

It has come to the attention of the South African Health Products Regulatory Authority (SAHPRA) that various companies selling unregistered Complementary Medicines on the South African market, for which quality, safety and efficacy have not yet been evaluated or verified, may be inappropriately making use of advertising or marketing strategies which include use of the words “clinically proven” or similar descriptions including, but not limited to: “clinically”, “expertly” or “scientifically”, “formulated”, “developed” or “tested” .

The SAHPRA has resolved and hereby advises that:

1. Any clinical or other evidence related to unregistered medicines purported to be in substantiation of any claim about the quality, safety or efficacy of a medicine must be evaluated by the SAHPRA and such claims may only be confirmed by its registration. This is in order to ensure that the claim is valid in terms of the evidence relied upon and reflects the relative weight of all available evidence related to the medicine.
2. As there has not yet been any scientific evidence evaluated and approved by the SAHPRA to support the use of the words “clinically proven” or similar expression (as indicated above), the use of such expression may be potentially misleading and constitutes a risk to the public. Such expression may also prove to be a contravention of section 20(1), paragraphs (*a*) and (*b*) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (hereafter referred to as “the Medicines Act”).
3. The SAHPRA considers the use of the words “clinically proven” or other similar claims that may suggest the product to be of substantiated or accepted clinical efficacy without specific approval from the SAHPRA to potentially be a contravention of regulation 42(4) of the General Regulations made in terms of the Medicines Act.

The SAHPRA hereby notifies all stakeholders that a contravention of section 20(1) of the Medicines Act or regulation 42(4) of the General Regulations made in terms of the Medicines Act may constitute an offence in terms of the Medicines Act or General Regulations made in terms of the Medicines Act, respectively.

The SAHPRA therefore strongly recommends to all stakeholders to be mindful of the protection of public health and all relevant legislation which may impact upon such claims described herein and to refrain from the use of such terms which may prove misleading to consumers. It is recommended that all processes relevant to the registration of medicines and the control thereof are considered in the best interest of all members of the public.

ANNEXURE B

EXAMPLES OF LOW-RISK INDICATIONS

The following examples of indications are guides as to how various low-risk indications may be phrased in compliance with guidance provided by SAHPRA in Guidelines 7.01 and 7.04.

System/Type	Indication
GENERAL	Helps maintain /support energy production in body cells
GENERAL	Helps maintain /support cell membrane structure
GENERAL	Helps maintain /support cell structure
GENERAL	Helps maintain /support body cell uptake of (state vitamin/mineral/nutrient)
GENERAL	Helps enhance/promote collagen formation
GENERAL	Maintain/support collagen formation
EAR	Maintain/support ear health
EAR	Maintain/support healthy ear function
EAR	Maintain/support healthy hearing
EYE	Helps maintain/support healthy eye development
EYE	Maintain/support healthy eye function
EYE	Maintain/support eye health
JOINT	Helps enhance/promote joint health
JOINTS	Maintain/support joint health
JOINTS	Maintain/support joint mobility/flexibility
NAILS	Maintain/support nail health
MOUTH	Maintain/support oral health
BONE	Helps enhance/promote bone health
BONE	Maintain/support bone health
NUTRITION	Enhance/improve/promote/increase nutrient uptake
NUTRITION	Enhance the assimilation/transportation of nutrients
GIT	Decrease/reduce/relieve abdominal feeling of fullness
GIT	Decrease/reduce/relieve abdominal pain/discomfort
GIT	Maintain/support stomach function
GIT	Helps enhance/promote stomach health
GIT	Maintain/support stomach health
NERVOUS	Maintain/support brain health
NERVOUS	Nourish the brain
NERVOUS	Brain tonic/Enhance brain health
NERVOUS	Maintain /support nerve cell health
NERVOUS	Maintain/support refreshing sleep
NERVOUS	Decrease/reduce/relieve sleeplessness
FEMALE	Maintain/support female reproductive system health
IMMUNE	Helps enhance/improve/promote immune system function
IMMUNE	Maintain/support immune system health
MUSCLE	Maintain/support muscle health
MUSCLE	Maintain/support healthy muscle contraction function
MUSCLE	Helps enhance/promote healthy muscle function
MUSCLE	Maintain/support muscle function

System/Type	Indication
NUTRITION	Maintain/support (state vitamin/mineral) within normal range
NUTRITION	Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
RESPIRATORY	Helps enhance/improve nose breathing
RESPIRATORY	Maintain/support lung health
SKIN	Helps enhance/promote skin health
SKIN	Maintain/support skin health
SKIN	Maintain/support skin elasticity
SKIN	Maintain/support healthy skin flora
SKIN	Helps enhance/improve skin internal structure
URINARY	Maintain/support urinary tract health
URINARY	Maintain/support urinary tract function
WEIGHT / SLIMMING	Prior to evaluation and registration, preparations indicated for slimming will be regarded as being of low risk with the following combination of indications/labelling: **1. Low-risk indication:** May assist with weight loss when used with increased physical activity and an energy-reduced diet in healthy individuals. **2. Time limit of use recommended:** Do not use continuously for more than two (2) months without consulting your relevant health care provider. **3. As a boxed warning:** This product is not intended to prevent or treat obesity.

ANNEXURE C

LICENSING OF MANUFACTURERS, WHOLESALERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF CATEGORY D (COMPLEMENTARY) MEDICINES IN TERMS OF THE PHARMACY ACT AND THE MEDICINES ACT

"Pharmacy Act" refers to the Pharmacy Act, 1974 (Act 53 of 1974)
"Medicines Act" refers to the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Effective 17 February 2020, SAHPRA provided for a means of electronic application for licences related to:

i) the manufacture, import or export;

ii) the import or export; or

iii) acting as a wholesaler or distribution,

of Category D medicines.

The application portal is available at www.sahpracm.org.za and includes new applications, renewal applications as well as applications for amendments to existing licences. With respect to the application for any of the licences to be issued in terms of the Medicines Act, information to be submitted includes that which is stipulated in regulation 23 of the General Regulations as well as information specific to the requirements of the various classes of complementary medicines (Category D).

As prescribed, licences issued will be valid for a period of five (5) years during which the holder of the licence must be inspected for verification of the attestation of compliance with minimum requirements included with the application submitted to the Authority. This inspection is required prior to the renewal of any licence issued and will be based on the submission of the application as attested to by the Responsible Pharmacist. While a licence may be issued on the basis of attestation, a Good Manufacturing Practice (GMP) Certificate would only be issued to applicants following a successful GMP inspection and a positive recommendation from such inspection.

In design of the licensing process, SAHPRA took note that new applicants for SAHPRA licences must first be in the possession of pharmacy premises licences, responsible pharmacist certificates and recording of the pharmacy owner. The SAHPRA further noted that both the National Department of Health (NDOH) and South African Pharmacy Council (SAPC) rely upon the outcomes of the SAHPRA licensing process before any of these applications are finalised. A key challenge to the licensing process in general, was therefore the different processes outlined by all three entities (SAHPRA, NDOH and SAPC) and the lack of coordinated and streamlined processes between these entities in outlining the steps to be taken when licensing the applicants.

The SAHPRA, having noted and acknowledged the challenge mentioned above and in an effort to assist in coordinating the various steps required by potential applicants, consulted the SAPC and NDOH and all entities have subsequently developed a draft process flow (Figure 1) that will guide the process for new applications for licences limited to Complementary Medicines. This process considers the nature of the application type related to Category D medicines, and further provides for the establishment of clear points of communication between NDOH, SAHPRA and SAPC which will assist with the efficient finalisation of applications.

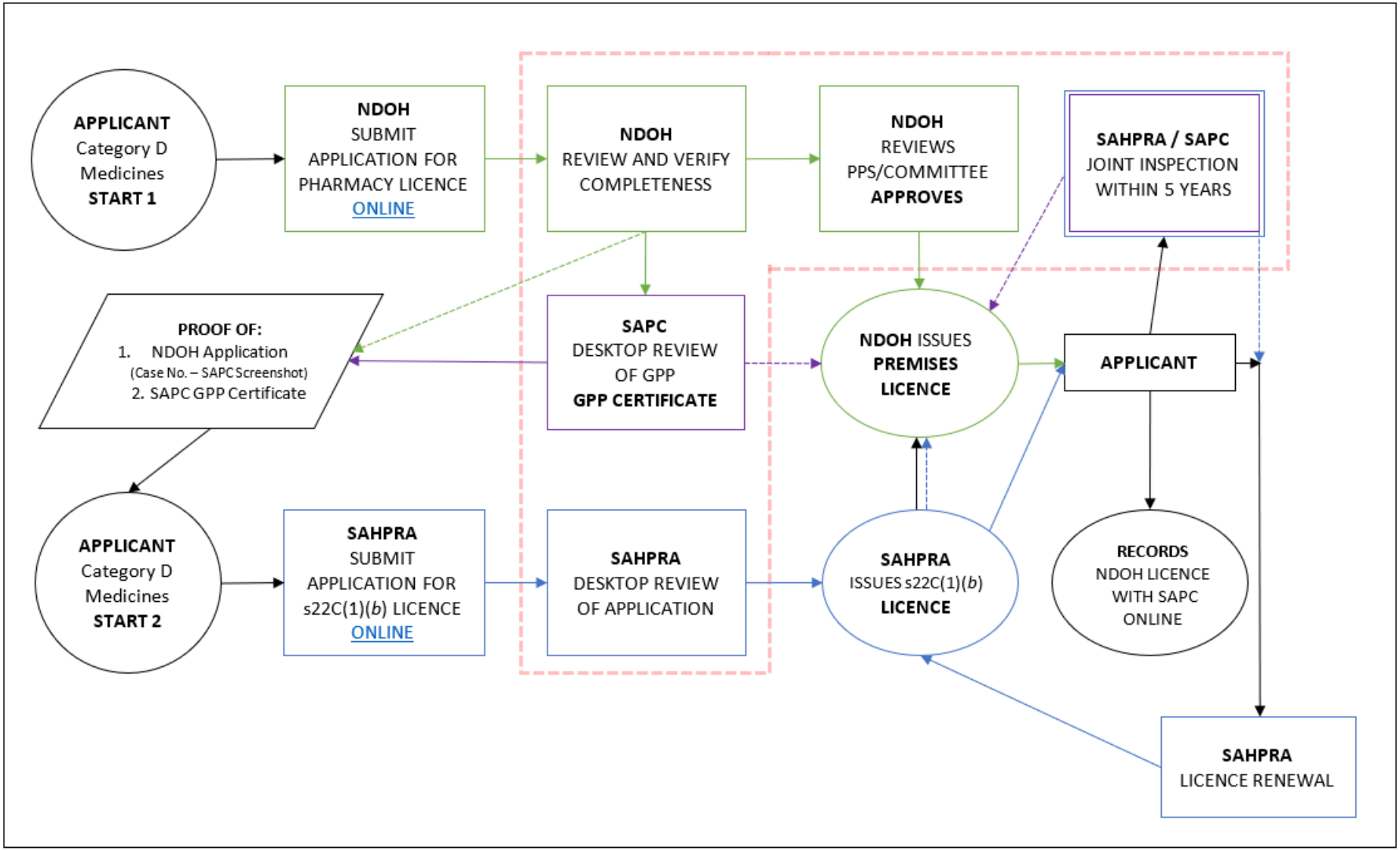


FIGURE 1: PROCESS FLOW FOR NEW APPLICATIONS FOR LICENCES LIMITED TO COMLEMENTARY MEDICINES