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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 Category D medicines (complementary medicines) 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 timelines, inclusion of process flow for new application for SAHPRA licences limited to Category D medicines	March 2021
Version 2_3 – Process update; Updated timeline, Updated labelling compliance timeline (Annex B of Guideline 7.05); Addition of narrative on process flow for new licences.	December 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 Category D 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 Category D 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 use (discipline-specific medicines and health supplements).

With respect to licensing of facilities (section 3.1), this Guideline does not apply 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 SAHPRA *Guideline 2.44 – Cultivation of Cannabis and Manufacture of Cannabis-related pharmaceutical products for medicinal and research purposes* on www.sahpra.org.za.

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

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 medicines or Scheduled substances must be licensed, as the case may be, to manufacture, import, export, or act as a wholesaler of or distribute medicines, inclusive of Category D 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, commenced by way of an electronic application made available by the Authority: www.sahpracm.org.za on **17 February 2020**. The electronic platform is intended to provide ease of use for all potential licensees and provides 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 provided that all correct documentation has been supplied and in the correct format.

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.

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.

In the case of the wholesale or distribution of products for third parties only, licence applicants may list those companies with which the wholesaler or distributor has technical agreements, or may provide lists of products as stated above.

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 a 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 may 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 Category D 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 is available for the renewal or amendment of any existing licence pertaining only to Category D medicines (*Licence Application Type DA01*). The prescribed fees for renewal or amendment are 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 (*Licence Application Type DA02*). 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 and are indicated in the application. Any subsequent change to appended product lists will thereafter be considered as an amendment (*Licence Application Type DA01*).

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:

- no service has been rendered on the application;
- 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 medicines or Scheduled substances.

A transitional priority licensing period from **17 February 2020** to **28 February 2022** (see item 5) is provided for licence applications of existing Category D 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.

In compliance with section 22C(1)(*b*) of the Medicines Act, the manufacture, import, export, wholesale or distribution of medicines or Scheduled substances may only take place once licensed.

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 or have submitted a Category D licensing application on or before **28 February 2022**, pending its finalisation.

The online licensing application process will continue to be available after the priority licensing period for all new, amendment and renewal applications specific to Category D medicines.

From **01 March 2022** to **28 February 2023** new applicants may continue to submit licence applications to SAHPRA with either a copy of NDoH premises licence or proof of application to NDoH without confirmation of compliance with GPP for their NDOH/SAPC applications provided that an undertaking is made to supply these when received. From **01 March 2023** new applicants must submit outcomes of GPP desktop reviews as part of the SAHPRA Category D licensing applications.

3.3 Product Compliance

3.3.1 Labelling

All medicines identifiable as Category D 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 with Annex B of Guideline 7.05 by **28 February 2023**. 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 Category D medicines (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 or applicant for 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 has provided 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 has provided a separate detailed communication on this option (see SAHPRA Communication to Stakeholders *REQUESTS: Existing Category D (Complementary Medicines) Registration Applications* on 07 October 2021).

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***.

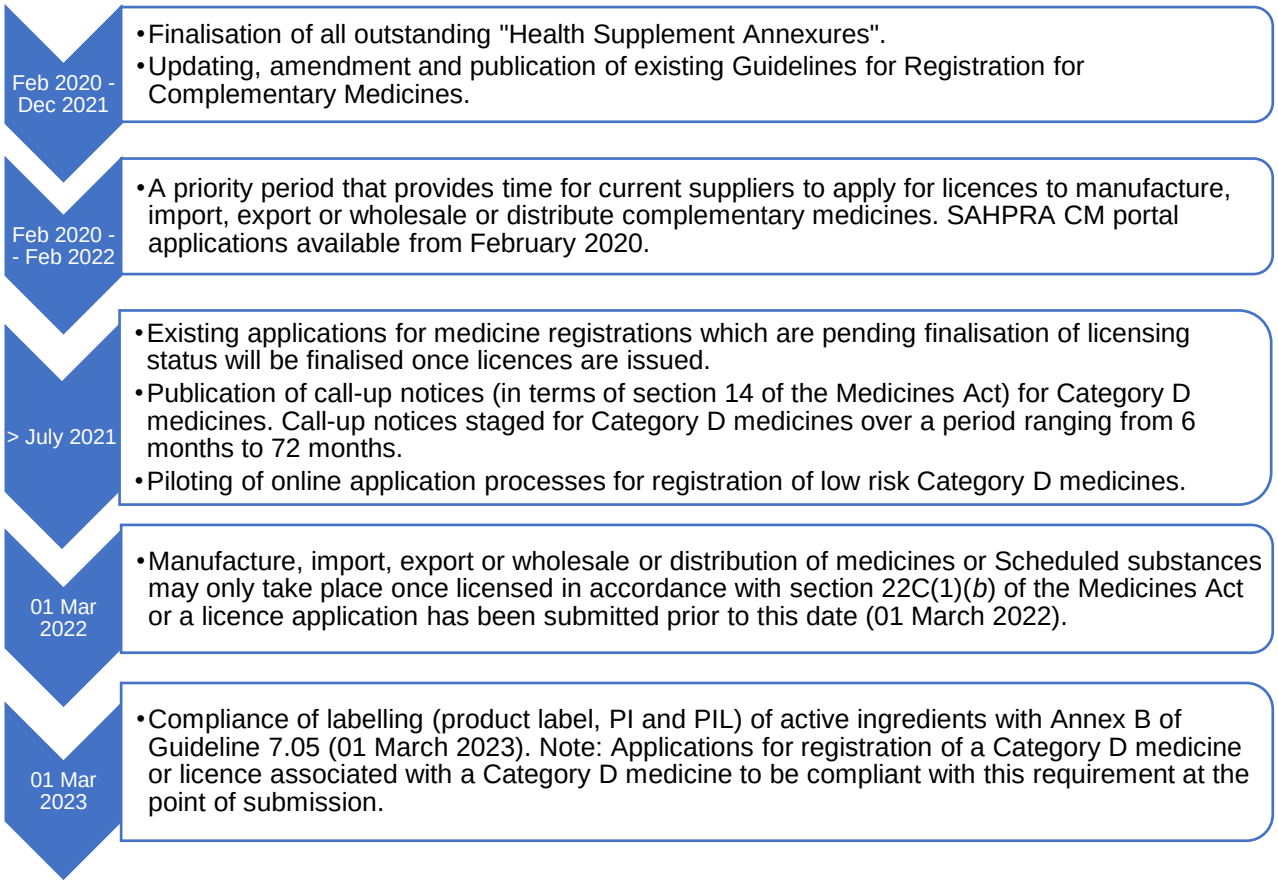
(iii) Advertising and Marketing of Complementary Medicines

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 are 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
Jun 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
Mar 2021	Sections 3.2, 5: Timeframes Annexure C: Process flow for new application for licences limited to complementary medicines	v2_2 March 2021
Dec 2021	General amendments for process update. Sections 3.2, 3.3.1, 5: Timeframe adjustments with guidance. Amended timeframes for labelling requirements in terms of Annex B of Guideline 7.05. Annexure C: Licensing process narrative added.	v2_3 December 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
NUTRITION	Maintain/support (state vitamin/mineral) within normal range
NUTRITION	Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
RESPIRATORY	Helps enhance/improve nose breathing

System/Type	Indication
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.

An explanation of the flow chart (Figure 1) tracking the process of a successful application for new licences limited to Category D medicines (complementary medicines), is provided on the next page.

START 1:

1. The process of licensing should be initiated by an applicant applying for a Pharmacy Premises Licence to the National Department of Health (NDOH). This may be submitted via the South African Pharmacy Council (SAPC) website. [a, b, c]
2. The NDOH reviews and verifies the completeness of the application.
3. The application is forwarded for further review to the relevant NDOH committees and SAPC.
4. The NDOH committees will provide a recommendation concerning their review.
5. The SAPC will undertake a desktop review of Good Pharmacy Practice (GPP) and may issue a recommendation of apparent GPP compliance based on the desktop review undertaken to the applicant and will notify the NDOH of such.
6. The applicant, in possession of the proof of the NDOH application made in step 1 (such as a screenshot of the application case number confirmation) as well as the confirmation of compliance with GPP from SAPC may proceed to **START 2** and utilise these documents for the initiation of an application for the relevant Category D licence.

   NOTE: Prior to 01 March 2023 applicants may submit licence applications to SAHPRA with either a copy of the NDoH premises licence or proof of application to NDoH without confirmation of compliance with GPP for their NDOH/SAPC applications provided that an undertaking is made to supply these when received. Their supply may be during or after the SAHPRA application review process.

START 2:

7. An applicant may, once the documents in step 6 are available, apply to the South African Health Products Regulatory Authority (SAHPRA) for the appropriate Category D medicine licence via the online SAHPRA CM complementary medicines portal available at www.sahpracm.org.za. An applicant must first be registered as a SAHPRA CM website user and then log in to access the applications by navigating to "Applications" – "Licensing" – "APPLY" – "1. New Applications" which provide options for new licences including:
   - Type DL01 - Licence to manufacture, import or export Complementary Medicines (Category D) [manufacturers only]
   - Type DL02 - Licence to import or export Complementary Medicines (Category D) [holders of certificate of registration]
   - Type DL03 - Licence to act as a wholesaler of or distribute Complementary Medicines (Category D) [wholesalers or distributors]

   Required information is stated in the preamble of every application to which applicants must refer. Documents necessary for new applications are listed below [d].
8. SAHPRA will undertake a desktop review of the application submitted in step 7 concerning apparent compliance with Good Manufacturing Practice (GMP), Good Distribution Practices (GDP) or Good Wholesaling Practices (GWP), as may be applicable, based on the attestation and documents provided. SAHPRA will also verify that the list of products supplied in the section 3D product list includes only *bona fide* Category D medicines. [e]
9. Following successful review of the application, including review of any replies from the applicant, SAHPRA may then recommend the issuing of a licence in terms of section 22C(1)(*b*) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) to the applicant who, in turn, may provide this to the NDOH. [f]
10. SAHPRA notifies the NDOH of the issuing of the section 22C(1)(*b*) licence specific to Category D medicines to the applicant.
11. The NDOH may, following satisfaction of all application criteria, issue a premises licence to the applicant.
12. The applicant may proceed to record the NDOH licence with the SAPC online in the manner and timeframe prescribed. The SAPC issues the certificate of recording for the pharmacy and pharmacy owner, and a certificate of registration for the responsible pharmacist. [g, h]

13. Within five (5) years from the date of issue, the holder of the licence must be inspected by SAHPRA against the applicable standards. In the case of GPP certificates issued without an inspection by the SAPC (desktop review only) then a joint inspection by SAHPRA and SAPC must take place. [i]
14. The NDOH may be notified of the SAPC inspection outcome.
15. Following a successful SAHPRA inspection, an application for the renewal of the Category D licence issued in terms of section 22C(1)(*b*) may take place including the outcomes of steps 9, 11, 12, 13.

Notes:

a. For guidance on the process and requirements of this application, applicants may refer to the:

- SAPC website www.sapc.za.org, navigate to "Registered Organisations" and "Licensing and Recording". This includes a user Manual for applicants wishing to apply for a new pharmacy licence.
- NDOH application form ("Application for Pharmacy Premises licence in terms of Section 22 of the Pharmacy Act 53 of 1974") for guidance on the requirements.

b. The appointment of a Responsible Pharmacist is required for submission of an application for a pharmacy premises licence.

c. Applications for Category D medicines with SAHPRA run independently from the pharmacy licensing process with the NDOH and the SAPC.

d. Documents required for a new licence application include:

1 SAPC certificate of recording of the pharmacy or proof of submission of the application to the SAPC
2 Letter of authorisation of the responsible pharmacist to communicate with SAHPRA
3 Latest CV of the Responsible Pharmacist
4 Copy of proof of SAPC registration of the Responsible Pharmacist (RP)
5 Letter of authorisation of the responsible person to communicate with SAHPRA (if not the RP)
6 CV of the responsible person
7 Copy of NDoH premises licence or proof of application to NDoH
Copy SAPC certificate of recording of the pharmacy for the site
8 Copy of SAPC certificate of recording of the pharmacy owner for the site
9 Site Master File (SMF) or the attestation and documentation as part of this application, and acknowledgement of responsibility to prepare and submit the SMF
10 Local area plan
11 Building floor plan
12 Layout
13 Equipment inventory
14 Quality manual or Quality Assurance report (minimum SOPs and documentary evidence as required in the application preamble)
15 Additional site copy of pharmacy premises licence, SAPC certificate of recording, and others as for primary site.
16 Quality assurance report including complete SOPs for:
Quality assurance product release
Recall
Finished product specifications and testing
Determination of shelf-life
Product sterilisation (if applicable)
Records of Quality assurance product release
Finished product specifications and testing
Determination of shelf life (expiry date)
List of SOPs (titles and numbers related to Quality management system)
17 List of products
18 Confirmation of understanding of responsibilities
19 Proof of payment

e. Completion of a licence product list (section 3D product list) is required as part of the SAHPRA licence application. A tutorial video for guidance on the completion of the section 3D product list is available online for registered users at www.sahpracm.org.za – Cat. D Medicines - Media.

f. Retention of a SAHPRA category D licence is subject to the payment of an annual fee as determined by the SAHPRA and specified in the Regulations Regarding Fees Payable in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

g. The pharmacy premises licence, certificates of recording for the pharmacy and pharmacy owner, and responsible pharmacist registration certificate must be forwarded to the SAHPRA as final confirmation of meeting the licensing requirements.

h. Retention of the recording of a pharmacy with the SAPC is subject to the payment of an annual fee as determined by the SAPC and specified in the Fees Payable to the Council under the Pharmacy Act, 1974 (Act 53 of 1974).

i. Concerning the SAHPRA inspection, the holder of the licence is inspected for verification of compliance to the minimum requirements as included in the attestation when the application was submitted to SAHPRA.

j. A licensing application in terms of either process may be recommended for refusal or rejection at or because of any information obtained by any of steps 2, 3, 5, 8 and 13.

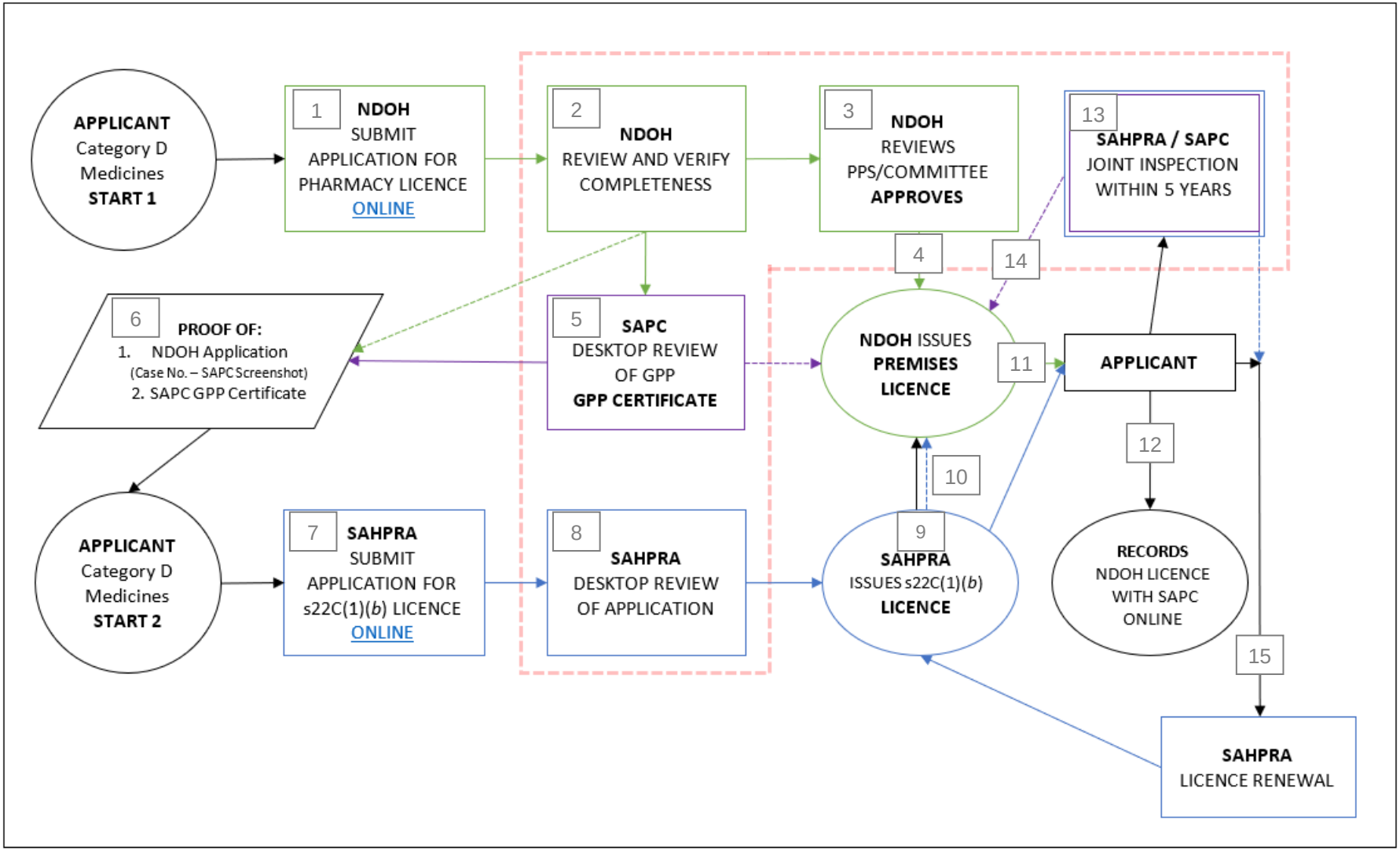


FIGURE 1: PROCESS FLOW FOR NEW APPLICATIONS FOR LICENCES LIMITED TO COMPLEMENTARY MEDICINES