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GUIDELINE ON A ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF CATEGORY D MEDICINES

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

Document History

Final Version	Reason for Amendment	Effective Date
1	Version 1 – Implementation in accordance with Government Gazette Notice R.870 in *Government Gazette* 37032 of 15 November 2013	15 November 2013
2	Version 2 – Implementation in accordance with Government Gazette Notice R.859 in *Government Gazette* 41064 of 25 August 2017	September 2019
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3	Version 3 – Amendments published for public comment	17 July 2023

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Glossary

Abbreviation/ Term	Meaning
Category D medicines	Established in terms of regulation 9 of the General Regulations.
CM	Complementary medicines which are Category D medicines.
DS	Discipline-specific medicines, which are a sub-category of Category D medicines.
General Regulations	The General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965)
HS	Health supplements, which are a sub-category of Category D medicines.
Medicines Act	The Medicines and Related Substances Act, 1965 (Act 101 of 1965)

1. INTRODUCTION

The General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (hereafter referred to as "the General Regulations"), have established a category of medicines, Category D Medicines thus effectively establishing a regulatory framework for this category. The sub-categories of medicines which fall under this category include Disicpline-specific medicines (DS) and Health Supplements (HS). The classes of DS fall across six (6) major disciplines, namely Aromatherapy, Ayurveda, Homeopathy, Traditional Chinese Medicine, Unani Medicine (Unani-Tibb) and Western Herbal Medicine, as well as combination products. The classes of HS include Amino acids, Aminosaccharides, Animal Extracts, Products and Derivatives, Carotenoids, Enzymes, Fats, Oils and Fatty Acids, Minerals, Polyphenols (including Bioflavonoids), Probiotics, Saccharides (including prebiotics), Vitamins, and Other as well as combinations of HS substances, referred to as "Multiple substance formulations".

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, at minimum, required 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 SAHPRA.

The risk profiles of Category D medicines have been redefined to align with the definition of a "medicine" in terms of the Medicines Act. While only medicines or scheduled substances are subject to regulation, SAHPRA will, when requested or appropriate, also continue to support those products which applicants wish to manufacture or supply according to the minimum standards prescribed for medicines.

1.1 Purpose

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

1.2 Scope

This document establishes the roadmap and general overview for the regulatory pathway of Category D medicines, including licensing in terms of section 22C(1)(*b*) and submission of applications for their registration following the implementation of the General Regulations, and applies to medicinal products for human use (DS and HS).

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.

2. LEGAL PROVISION

Regulation 9 of the General Regulations established a category of medicines referred to as “Category D”. Its sub-categories and classes are further defined therein.

The Medicines Act provides for regulation of “medicines” and “scheduled substances” as defined in section 1 of the Medicines Act, including, but not limited to:

Section 2A - Objects of the Authority

Section 14 - Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration

and are not registered

Section 15 - Registration of medicines, medical devices or IVDs

Section 20 - Publication or distribution of false advertisements concerning medicines, medical devices or IVDs

Section 22A - Control of medicines, Scheduled substances, medical devices and IVDs

Section 22C(1)(*b*) – Licensing

The General Regulations provide for requirements of “medicines” including, but not limited to:

Regulation 10 - Labelling of medicines intended for human use

Regulation 11 - Professional information for medicines for human use

Regulation 12 - Patient information leaflet

Regulation 42 - Advertising of medicines

3. RISK PROFILES OF CATEGORY D MEDICINES

Any substance which is a “medicine” or “scheduled substance” in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) will be expected to comply with the provisions of the Medicines Act.

Table 3.1 summarises the risk profile and regulatory options available to substances which are not “medicines” or “scheduled substances”.

The regulatory requirements for substances which make claims typically conforming to the definition of a “medicine” or are “scheduled substances” as defined in the Medicines Act are summarised in Tables 3.2 and 3.3. The risk profiles (LOW and HIGH) provide for specified types of claims as well as the requisite evidence necessary for substantiation or use of such claims.

Table 3.1: Summary of risk profiles for substances that are not expressly "medicines" or "scheduled substances"

INTENDED USE (USED/SUITABILITY FOR USE/MANUFACTURED OR SOLD FOR USE OF/IN)	LICENCE IN TERMS OF SECTION 22C(1)(*b*) OF THE MEDICINES ACT	REGISTRATION OF MEDICINE	GENERAL COMPLIANCE WITH THE MEDICINES ACT
RISK LEVEL: GENERAL			
Substances not subject to regulation or registration as a "medicine" or are not "scheduled substances", which may include: • Substances that are not used or purporting to be suitable for use or manufactured or sold for use as a medicine; • Substances not making medicinal or therapeutic claims in any way; or • Claims of general health maintenance, including nutritional well-being/status.	**OPTIONAL** where, if the facility is licensed, the products listed are not necessarily automatically subject to registration.	**OPTIONAL** unless subject to registration as a medicine.	**NOT REQUIRED** unless otherwise indicated in terms of the Medicines Act or voluntarily subjected to regulatory control as a medicine (where a facility is intended to be or currently licensed or the product registered) **RECOMMENDED** that reference to existing SAHPRA guidance related to labelling (warnings and intended use) be made. Note: If licensed/registered an additional labelling statement is permitted: "This medicine is subject to regulatory control by SAHPRA."

Table 3.2: Summary of risk profiles and associated regulatory requirements for "low-risk" Category D medicines

INTENDED USE (USED/SUITABILITY FOR USE/MANUFACTURED OR SOLD FOR USE OF/IN)	EVIDENCE REQUIREMENT IN SUPPORT OF THE INTENDED USE	LICENCE IN TERMS OF SECTION 22C(1)(*b*) OF THE MEDICINES ACT	REGISTRATION OF MEDICINE	COMPLIANCE WITH THE MEDICINES ACT
RISK LEVEL: LOW				
HEALTH SUPPLEMENTS Indications as specified in the Annexures to SAHPRA Guideline 7.04 in the doses stated which relate to: • Health restoration or health enhancement [from a compromised state]. • Relief of a "minor symptom" or symptoms of a "minor ailment". • Reduction in frequency of a "minor ailment". • Aids/assists in the management of a "minor ailment". • Reduction of risk/progression of a disease/disorder. **OR** Schedule 0 substance listed for use as a Health Supplement. Note: With respect to HS, a "minor ailment" or "minor symptom" is an ailment or symptom which is self-limiting, mild, does not require medical intervention, and is identified as such in Guideline 7.04.	**For purposes of continued rights of sale:** According to the listing of substances in the annexures to Guideline 7.04; **OR** According to relevant application submitted in terms of Annexure B of Guideline 7.04. **For purposes of registration:** According to annexures to Guideline 7.04, **OR** Clinical data related to equivalent compounds of the specific medicine to be evaluated.	**REQUIRED** As per section 22C(1)(*b*) of the Medicines Act. Also refer to the section on Licensing of Manufacturers, Importers, Exporters, and Wholesalers or Distributors	**REQUIRED** If subject to registration in terms of section 14 of the Medicines Act.	**REQUIRED** Note: If licensed/registered an additional labelling statement is permitted: "This medicine is subject to regulatory control by SAHPRA."

INTENDED USE (USED/SUITABILITY FOR USE/MANUFACTURED OR SOLD FOR USE OF/IN)	EVIDENCE REQUIREMENT IN SUPPORT OF THE INTENDED USE	LICENCE IN TERMS OF SECTION 22C(1)(*b*) OF THE MEDICINES ACT	REGISTRATION OF MEDICINE	COMPLIANCE WITH THE MEDICINES ACT
DISCIPLINE SPECIFIC *Group 1* Indications which relate to: • Health restoration or health enhancement [in/from a compromised state]. • Relief of a "minor symptom" or symptoms of a "minor ailment". **OR** Any Scheduled substance which may be used as part of a formulation emanating from a specific discipline. Note: With respect to DS, typically a "minor ailment" or "minor symptom" is an ailment or symptom which is self-limiting, mild, does not require medical intervention, and where the medicine should not be used for longer than 7-10 days without consulting a relevant health care provider.	**For purposes of continued rights of sale:** Compliance with low-risk indication descriptions. **For purposes of registration:** • Evidence of "traditional use" from the specific discipline (Module 1.5) **AND** • Two of the following four sources that demonstrates adequate support for the indications claimed: 1. Recognised Pharmacopoeia; 2. Recognised Monograph; 3. Three independent written histories of use in the classical or traditional medical literature, or 4. Citations from other in vivo, in vitro studies, case reports or others.	**REQUIRED** Refer to the section on Licensing of Manufacturers, Importers, Exporters, and Wholesalers or Distributors	**REQUIRED** If subject to registration in terms of section 14 of the Medicines Act.	**REQUIRED** Note: If licensed/registered an additional labelling statement is permitted: "This medicine is subject to regulatory control by SAHPRA."

INTENDED USE (USED/SUITABILITY FOR USE/MANUFACTURED OR SOLD FOR USE OF/IN)	EVIDENCE REQUIREMENT IN SUPPORT OF THE INTENDED USE	LICENCE IN TERMS OF SECTION 22C(1)(*b*) OF THE MEDICINES ACT	REGISTRATION OF MEDICINE	COMPLIANCE WITH THE MEDICINES ACT
Group 2 Indications which relate to: • Reduction in frequency of a "minor ailment". • Aids/assists in the management of a "minor ailment". • Reduction of risk/progression of a disease/disorder. **OR** Any Scheduled substance which may be used as part of a formulation emanating from a specific discipline. Note: With respect to DS, typically a a "minor ailment" or "minor symptom" is an ailment or symptom which is self-limiting, mild, does not require medical intervention, and where the medicine should not be used for longer than 7-10 days without consulting a relevant health care provider.	**For purposes of registration:** • Evidence of "traditional use" from the specific discipline (Module 1.5) **AND** • Two of the following four sources that demonstrates adequate support for the indications claimed: 1. Recognised Pharmacopoeia; 2. Recognised Monograph; 3. Three independent written histories of use in the classical or traditional medical literature; or 4. Citations from other in vivo, in vitro studies, case reports or others. **AND** • Clinical references for related, similar, or equivalent single or combinations of active pharmaceutical ingredient(s)/substance(s) for the specific medicine.	**REQUIRED** As per section 22C(1)(*b*) of the Medicines Act. Also refer to the section on Licensing of Manufacturers, Importers, Exporters, and Wholesalers or Distributors.	**REQUIRED** If subject to registration in terms of section 14 of the Medicines Act.	**REQUIRED** Note: If licensed/registered an additional labelling statement is permitted: "This medicine is subject to regulatory control by SAHPRA."

Table 3.3: Summary of risk profiles and associated regulatory requirements for "high-risk" Category D medicines

INTENDED USE (USED/SUITABILITY FOR USE/MANUFACTURED OR SOLD FOR USE OF/IN)	EVIDENCE REQUIREMENT IN SUPPORT OF THE INTENDED USE	LICENCE IN TERMS OF SECTION 22C(1)(*b*) OF THE MEDICINES ACT	REGISTRATION OF MEDICINE	COMPLIANCE WITH THE MEDICINES ACT
RISK LEVEL: HIGH				
DISCIPLINE SPECIFIC Indications which relate to: • Where not otherwise included under low-risk: changes made (restores, corrects or modifies) to somatic, psychic or organic function. • Pathognomonic signs and symptoms. • Treats/cures/manages any "disease or disorder". • Prevention of any "disease or disorder". • Aids/assists in the management of a named "disease or disorder" or sign/symptom of a named "disease or disorder". • Relief of symptoms of a named "disease or disorder". • Treatment of proven vitamin or mineral deficiency disease(s). **AND/OR** Any Scheduled substance which may be used as part of a formulation emanating from a specific discipline.	**For purposes of registration:** • Evidence of traditional use from the specific discipline (Module 1.5) **AND** • Two of the following four sources that demonstrates adequate support for the indications claimed: 1. Recognised Pharmacopoeia; 2. Recognised Monograph; 3. Three independent written histories of use in the classical or traditional medical literature, or 4. Citations from other in vivo, in vitro studies, case reports or others. **AND** • Clinical data or references specific to the product to be evaluated.	**REQUIRED** Refer to the section on Licensing of Manufacturers, Importers, Exporters, and Wholesalers or Distributors	**REQUIRED** If subject to registration in terms of section 14 of the Medicines Act.	**REQUIRED** Note: If licensed/registered an additional labelling statement is permitted: "This medicine is subject to regulatory control by SAHPRA."

4. REGULATORY PRIORITIES ASSOCIATED WITH CATEGORY D MEDICINES

4.1 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 *(Licence Application Type DL01)*; ii) import or export *(Licence Application Type DL02)*; or iii) act as a wholesaler of or distribute *(Licence Application Type DL03)* Category D medicines, commenced by way of an electronic application made available on **17 February 2020** by the Authority (www.sahpracm.org.za). 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 appropriateness and any queries of immediate concern are intended to be referred to the applicant within 5 working days of receipt of the application by the Authority.

Once all correct documentation has been received in the correct format, the Authority aims to refer the application for its initial evaluation within 15 working days of its receipt. Licence applications and responses are evaluated according to licence type and the order in which they are received.

Responses are generally requested to be undertaken by applicants within 15 working days. Any requests for extension may be submitted to the SAHPRA CM unit with a suitable motivation and a reasonable proposed time frame.

4.1.1 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 Category D 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. Minimum standards include either compliance with GMP / a valid GMP certificate, or provision of all the necessary and correct information required in the application including all the information listed in **Annexure C**.

For easy reference to the documents required, an extract from the online application is provided below. Refer to the online application for the latest version.

"5. Guidance for completion of the application:

5.1 Applicants are encouraged to utilise the application as a developmental tool for guidance on and compliance with principles of Good Manufacturing Practice (GMP) as determined by SAHPRA. Dependent on the time available, should any Standard Operating Procedures (SOPs) not be in place, the application should prompt the development of SOPs and implementation thereof in order to improve quality systems. Any answers of "No" should prompt development or solutions in order to address that area of minimum compliance.

5.2 A list of SOPs (titles and numbers) is requested for all questions indicated in the Quality Assurance Report (QAR) Attestation. These SOPs may combine various factors queried by the QAR Attestation. It is important that while these SOPs may not be immediately available, applicants initiate processes to develop any SOPs or other documentation that may be required during the period of the licence.

5.3 Complete SOPs must be provided for:

3C.4.4: Quality assurance product release

3C.7.3: Recall

3C.8.5: Finished product specifications and testing

3C.9.5: Determination of shelf life (expiry date)

3C.12.3:Product sterilisation (if applicable)

5.4 For certain statements/questions, the applicant is required to provide supporting records to demonstrate that the SOP listed and/or provided are being followed on a regular basis. Complete records are required to support:

3C.4.5: Quality assurance product release

3C.8.6: Finished product specifications and testing

3C.9.6: Determination of shelf life (expiry date)

If any activities have not commenced, the supply of SOPs along with templates, is acceptable. Once the activities have commenced, completed records from within at least the last 12 months must be maintained."

Certification of an applicant to any relevant standard is subject to the inspection of compliance with the relevant standard. Guidance for completion of the relevant application is integrated into the licence application process.

As part of the online licence application, all Category D medicines sold by the applicant (whether manufactured, imported, exported or distributed) are to be listed. The listed medicines will be confirmed

against the prescribed description of Category D medicines and its sub-categories/classes. Confirmed section 3D lists will be appended to the relevant licence numbers and will be available online to enable public/stakeholder verification of the medicines allowed for sale.

Other alternatives to the section 3D itemised product list are available from the SAHPRA CM portal (https://sahpracm.org.za/catd/3d-product-list-options/), including:

> Instead of providing the itemised product lists, **contracted manufacturers** may refer to the itemised product list and applicable line item numbers of those licence holder companies with whom they have written technical agreements.
>
> **Wholesalers or distributors** of products for third parties only, may similarly list those companies with which the wholesaler or distributor has written technical agreements, or may provide the applicable lists of products.

Provided that products are not yet subject to registration, new products may be launched if the regulatory requirements applicable to medicines, as well the as the guidance provided herein, are complied with.

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.

4.1.2 Issuing of licences

Licences will be issued to successful applicants based on 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 (see 4.1.1) 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 (represented by the owner [Reg 23(1)(*c*)(i)], Responsible Pharmacist [Reg 23(2)(*a*)] and person responsible for compliance with the Act [Reg 23(2)(*b*)]) 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.

All licences issued will be valid for a period of five (5) years, during which the holder of the licence should 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.

4.1.3 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 are intended 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.

4.1.4 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 medicine.

Category A licence holders need not apply for a separate Category D licence.

4.1.5 Amendment and renewal of licences

The prescribed fees for amendment or renewal are payable.

A. Amendment applications

An electronic form is available for the amendment of any existing licence pertaining only to Category D medicines (*Licence Application Type DA01*).

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 (*Licence Application Type DA02*). Any subsequent change to appended product lists will thereafter be considered as an amendment (*Licence Application Type DA01*).

Fees for desktop reviews, as prescribed, relating to these products lists (as a primary overview of compliance with quality, safety and efficacy) are applicable at the point of application and are indicated in the application.

B. Renewal applications

Any application for renewal of a licence *(Licence Application Types DR01, DR02, and DR03)* will require information as prescribed in regulation 24, read together with regulation 23 of the General Regulations.

The renewal of a licence will be considered where full compliance of the attested/minimum standard has not been demonstrated provided appropriate corrective and preventive action(s) (CAPA(s)) are in place. GMP/GDP compliance is foreseen by the time the third licensing period is initiated (after 10 years of having been licensed).

4.1.6 Licence Fees

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

Previously, 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 had pertained only to Category D medicines that were not yet finalised, were eligible to have been transferred to the electronic application system by August 2020, provided that:

- no service had been rendered on the application;
- the fee prescribed at the time of application had been paid; and
- reference for such payment had been provided as part of the electronic application.

Where no fee had yet been paid, the application was required to be re-submitted as a new licence application.

4.1.7 Licensing Periods

Only holders of a valid licence issued in terms of section 22C(1)(*b*) of the Medicines Act are entitled to

manufacture, import, export or act as a wholesaler of or distribute medicines or Scheduled substances.

Period 1 – Priority licensing period

A priority licensing period from **17 February 2020** to **28 February 2022** (see section 5) was 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.

Period 2 – Secondary licensing period

From **01 March 2022** to **28 February 2025** 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.

Period 3

From **01 March 2025** new applicants must submit outcomes of GPP desktop reviews as part of the SAHPRA Category D licensing applications. Attestation inspections to be conducted prior to issuing a licence.

After the publication of call-up notices associated with Category D medicines, any new manufacturers, importers, exporters, or wholesalers or distributors must either hold a licence prior to manufacturing, importing, exporting, wholesaling or distributing any Category D medicines which are subject to registration, or have submitted a Category D licensing application on or before **28 February 2024** which is 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.

4.2 Product Compliance

4.2.1 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 with "minimum legibility", i.e. a printing in 6 -point Helvetica, typeface in black ink on white cartridge paper or the equivalent thereof, 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 has not been made 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 a *Patient Information Leaflets* (regulation 12) that is in English and at least one other official language, with minimum legibility;
- All active ingredients for Category D medicines should be named or referenced on the label, PI or PIL in accordance with *Annex B* of *Guideline 7.05 – Guideline for Category D Medicines – Registration Application ZA-CTD – Quality*. In line with past directives, all Category D medicines are expected to have complied 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 Category D 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;
- All Category D 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; and
- In terms of regulation 10(4) of the General Regulations, where the intended holder of certificate of registration (manufacturer or importer) is appropriately licensed and a product appears on an accompanying finalised product list, the product label may include the wording "This medicine is subject to regulatory control by SAHPRA.".

4.2.2 Rights of sale

4.2.2.1 All Category D medicines, as defined, will be permitted continued rights of sale, provided that:

(a) an application is submitted for their registration by the prescribed deadlines of the applicable call-up notice;

(b) 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 within the applicable time frame specified herein;

(c) 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;

(d) they are indicated based on LOW RISK (or GENERAL RISK) claims; and

(e) they are Discipline-specific medicines indicated based on HIGH RISK provided that they may be subject to individual call up for registration by SAHPRA.

4.2.2.2 Unregistered Category D 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.

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

4.2.3 Advertising and Marketing

Medicines may be advertised, taking into account section 20 (Publication or distribution of false advertisements concerning medicines, medical devices or IVDs) of the Medicines Act and regulation 42 (advertising) of the General Regulations. Unregistered Category D 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.

4.2.4 Certificates of Free Sale

4.2.4.1 Introduction

A Certificate of Free Sale for Category D medicines (Complementary Medicines) issued by SAHPRA, serves as confirmation that the medicine meets the regulatory requirements of South Africa at the time of issue and that the product is freely available for purchase in South Africa.

A Certificate of Free Sale for Category D medicines may confirm whether the medicine is registered but it is otherwise not an indication of quality, safety or efficacy of the medicine and may not be used for any other purpose than those stated above.

Certificates of Free Sale aim to meet the needs of the importing country. Before applying for a certificate, SAHPRA recommends that the applicant contact the relevant foreign government through their Consulate to ascertain what information must be supplied to facilitate the export of the medicine to their country.

A Certificate of Free Sale for Category D medicines may be issued to a holder of a licence in terms of section 22C(1)(*b*) of the Medicines Act to manufacture and/or export Category D medicines as identified on the appended Category D product lists.

The application for a Certificate of Free Sale may include more than one Category D medicine and more than one recipient country.

Only Category D medicines in the sub-categories of either DS or HS may be included in an application for a Certificate of Free Sale for Category D medicines.

The Certificate of Free Sale will be valid for a maximum period of one year (following which a new application may be made if necessary) and will be void should a medicine not be submitted for registration by the date specified in terms of any declaration made in terms of section 14(2) of the Medicines Act that a medicine is subject to registration.

4.2.4.2 Required information

The following documents must be submitted as part of the application for a Certificate of Free Sale:

(a) The completed Certificate of Free Sale for Category D Medicines online application form;

(b) A copy of the manufacturer's valid SAHPRA licence in terms of section 22C(1)(*b*) of the Medicines Act to manufacture Category D medicines;

(c) A copy of the exporter's valid SAHPRA licence in terms of section 22C(1)(*b*) of the Medicines Act to export Category D medicines;

(d) Cover letter on a company letterhead signed by the Responsible Pharmacist of the applicant confirming the application for a Certificate of Free Sale;

(e) Cover letter on a company letterhead of the prospective holder of certificate of registration of the medicine(s) in respect of which the application is being made, consenting to and confirming the application for a Certificate of Free Sale;

(f) Where applicable, the accompanying certificate of Good Manufacturing Practice (GMP);

(g) Details of the medicines to be exported including reference to any approved product listings and the relevant line items appended to the relevant SAHPRA licence; and

(h) Proof of payment.

4.2.4.3 Submission of application and timelines

Applications must be submitted online at www.sahpracm.org.za.

The fee for a Certificate of Free Sale is payable upon application and proof of payment must be submitted together with the completed application.

***Note*:** Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fee structures, as published in the Government Gazette.

Payments should be made in accordance with SAHPRA Guideline on the payment of fees to SAHPRA which describes the direct payment of fees into the bank account of SAHPRA.

The applicant for a Category D Medicine Certificate of Free Sale application should receive a response from SAHPRA within fifteen (15) working days from the date of submission of the application, provided that the application submitted is complete and meets the requirements.

4.2.4.4 Information appearing on a certificate of free sale

The following information will be included on the Certificate of Free Sale:

- Name, site address and licence number of the manufacturer and the exporter concerned;
- Details of medicine/s intended for export and listed in this application including
  - Medicine Name
  - Pack size (where relevant)
  - Category, Sub-category and class of medicine
  - Indication and associated SA risk classification
  - Registration status
- Recipient Country/ies
- Name and contact details of the Responsible Pharmacist
- Any additional particulars required to facilitate the export of the listed Category D medicine to the relevant foreign government.

4.2.5 Products detained at ports of entry

Customs and Port Health Service (PHS) in SA, is the first line of defence to protect the citizens of the Republic of South Africa against the health risks associated with cross-border movement of people, conveyances,

baggage, cargo and imported consignments. Among the imported consignments are medicines in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

Customs officers and Port Health officials, as applicable, are legally capacitated to detain the importation of any goods for their verification of compliance with applicable legislation. This may be for verification of the product as a foodstuff or as a medicine, each of which may hold a different tax implication for the importer.

Following the progression of the regulatory roadmap for Category D medicines (CM), allowing for their continued sale while the importer may not yet hold a licence issued in terms of section 22C of the Medicines Act or certificate of registration for an individual product, considerable referrals to SAHPRA have continued to take place in an unstructured manner. This has resulted in delays in trying to address referrals with deficient information and the issuing of any opinions provided by SAHPRA.

To address the above-mentioned challenges, and following engagements with both Port Health and the National Department of Health, SAHPRA provided input to the development of a single form to be used by Port Health and importers to refer products that are detained for the review by SAHPRA or the National Department of Health, as may be required.

Further to this, SAHPRA developed and implemented an electronic referral mechanism on the SAHPRA CM portal which allows importers to request SAHPRA to review a detained product at the port of entry and issue an opinion concerning its status as a Category D medicine (CM) and to determine whether the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), have been complied with.

SAHPRA, therefore, advises all importers of *bona fide* Category D Medicines to visit **www.sahpracm.org.za – Applications – Medicines – Request: Review of detained product at Port of Entry** and utilise the form issued for the referral of such detained product(s) to SAHPRA.

The request sent from the SAHPRA CM portal is intended to be processed within five (5) working days from the date of submission, provided that the information submitted is complete and meets the requirements. Incomplete requests cannot be reviewed and will be rejected at the point of receipt. All requests submitted must ensure that all relevant fields are completed and all supporting documentation has been supplied. This request form is not intended to facilitate the importation of medicines for personal use.

4.2.6 Post-importation testing

It is the responsibility of the Applicant to have robust quality management systems in place to ensure that the integrity of imported medicines is not compromised during transit from the source site to the patient, and to

confirm the integrity of imported medicines prior to their release for sale in South Africa.

Refer to the guideline SAHPGL-INSP-01 (Post Importation Testing) which includes a risk-based and pro-active approach under validated control and surveillance systems.

4.3 Medicines registration process

All applications for registration that have already been submitted will continue to be processed and will be finalised in due course. 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 recognised 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. SAHPRA 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 be resubmitted in substitution of the previous application without prejudice to the application review. This process took account of the existing progress made on the application and the reasons for upliftment. SAHPRA has provided a separate detailed communication on this option (see SAHPRA Communication to Stakeholders *REQUESTS: Existing Category D Medicines Registration Applications* on 07 October 2021).

SAHPRA will in due course provide online mechanisms for the submission of applications for registration of Category D Medicines, which will continue to make use of the CTD format but will provide for significant guidance specific to the requirements of Category D Medicines and their risk profile.

5. SUMMARY OF LEGISLATIVE CONTROL OF CATEGORY D MEDICINES

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

(i) 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, importers, exporters, and wholesalers or distributors of Category D medicines must be licensed. Specified time frames allowing for progressive compliance with the minimum standard associated with licensing are stated in section 4.1.7.

(ii) Labelling of Category D 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 pertaining to the product label, the Professional Information and the Patient Information Leaflet with minimum legibility as defined in the General Regulations.

Active ingredients must be named according to ***Annex B*** of ***Guideline 7.05 – Guideline for Category D Medicines – Registration Application ZA-CTD – Quality***.

(iii) Advertising and Marketing of Category D Medicines

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

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

(v) All other requirements in terms of the guidance provided herein as well as the Medicines Act, generally or specifically applicable to Category D 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.

6. SUMMARY OF GENERAL TIMELINES

Feb 2020 - Feb 2022	•*Licensing period 1:* A priority period that provides time for current suppliers to apply for licences to manufacture, import, export or wholesale or distribute Category D medicines. SAHPRA CM portal applications available from February 2020.
Mar 2022 - Feb 2025	•*Licensing period 2:* A period in which 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.
>01 Mar 2023	•Compliance of labelling (product label, PI and PIL) of active ingredients with Annex B of Guideline 7.05 (01 March 2023).
>01 Mar 2025	•*Licensing period 3:* New applicants must submit outcomes of GPP desktop reviews as part of the SAHPRA Category D licensing applications. Attestation inspection to be conducted prior to issuing licence.
GENERAL	•Existing applications for medicine registrations which are pending finalisation of licensing status will be finalised once licences are issued •Publication of call-up notices (in terms of section 14 of the Medicines Act) for Category D medicines. •After the publication of call-up notices associated with Category D medicines, any manufacturers, importers, exporters, or wholesalers or distributors must either hold a licence prior to manufacturing, importing, exporting, wholesaling or distributing any Category D medicines which are subject to registration, or have submitted a Category D licensing application on or before 28 February 2024 which is pending its finalisation.

7. VALIDITY

This guideline will be valid for a period of 5 years from the effective date of implementation and will replace SAHPRA Guideline 7.02 – Roadmap and Transitional Process for the Regulation of Category D (Version 2.3) when implemented. It will be reviewed on this timeframe or as and when required.

8. GENERAL ADVICE TO BE CONVEYED TO CONSUMERS

It is important for consumers to know and appreciate that all Category D medicines (also referred to as complementary medicines) are medicines. As with any other medicine they should be used with care. When intending to use a Category D medicine, you may make sure it is the correct product for you by seeking professional advice. “Natural” does not necessarily mean safe. Plants and other natural compounds have the capacity to cause adverse effects, illness or even death in humans. The quality, safety and efficacy of Category D medicines in South Africa cannot be assured unless they have been evaluated and registered by SAHPRA.

Complementary medicines, while generally regarded as safe, can interact with other medicines. This could result in either of the medicines having reduced or enhanced effects, including side-effects. When consulted, relevant health care providers should always be told of any complementary medicines being taken. During pregnancy or breastfeeding the relevant health care provider should be consulted for advice before taking these medicines. As with all medicines, complementary medicines must be kept 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 navigating to www.sahpra.org.za – e-services – Adverse Drug Reaction Reporting.

8.1 Complaints

Other than reports of adverse events, consumers are able to report or lodge anonymous complaints related to the non-compliance of 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.

9. 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: Time frames 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: Time frames 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: • Time frame adjustments with guidance. • Amended time frames for labelling requirements in terms of Annex B of Guideline 7.05. Annexure C: Licensing process narrative added.	v2_3 December 2021
July 2023	Amendments to SAHPRA Guideline 7.02 published for public comment.	V3 July 2023

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 Category D Medicines on the South African market, for which quality, safety and efficacy have not yet been evaluated or verified, may inappropriately be 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” .

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 SAHPRA and such claims are only affirmed by its registration after having determined that the claim is valid and demonstrated, and appropriate based on the available evidence relied upon and submitted.
2. As SAHPRA has not yet evaluated and approved any scientific evidence to support the use of the words “clinically proven” or similar expression (as indicated above), the use of such expression may be potentially misleading, constituting 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) (the “Medicines Act”).
3. 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 “General Regulations”).

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

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

EXAMPLE OF LOW-RISK INDICATION

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

System/Type	Indication
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 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 Category D medicines.

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 the 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.

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 Category D 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, is provided below.

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: During licensing periods 1 and 2, licence applications may be submitted 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. They may be provided 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 Category D 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 Category D Medicines [manufacturers only]
   - Type DL02 - Licence to import or export Category D Medicines [holders of certificate of registration]
   - Type DL03 - Licence to act as a wholesaler of or distribute Category D Medicines [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 time frame 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.org.za, 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.

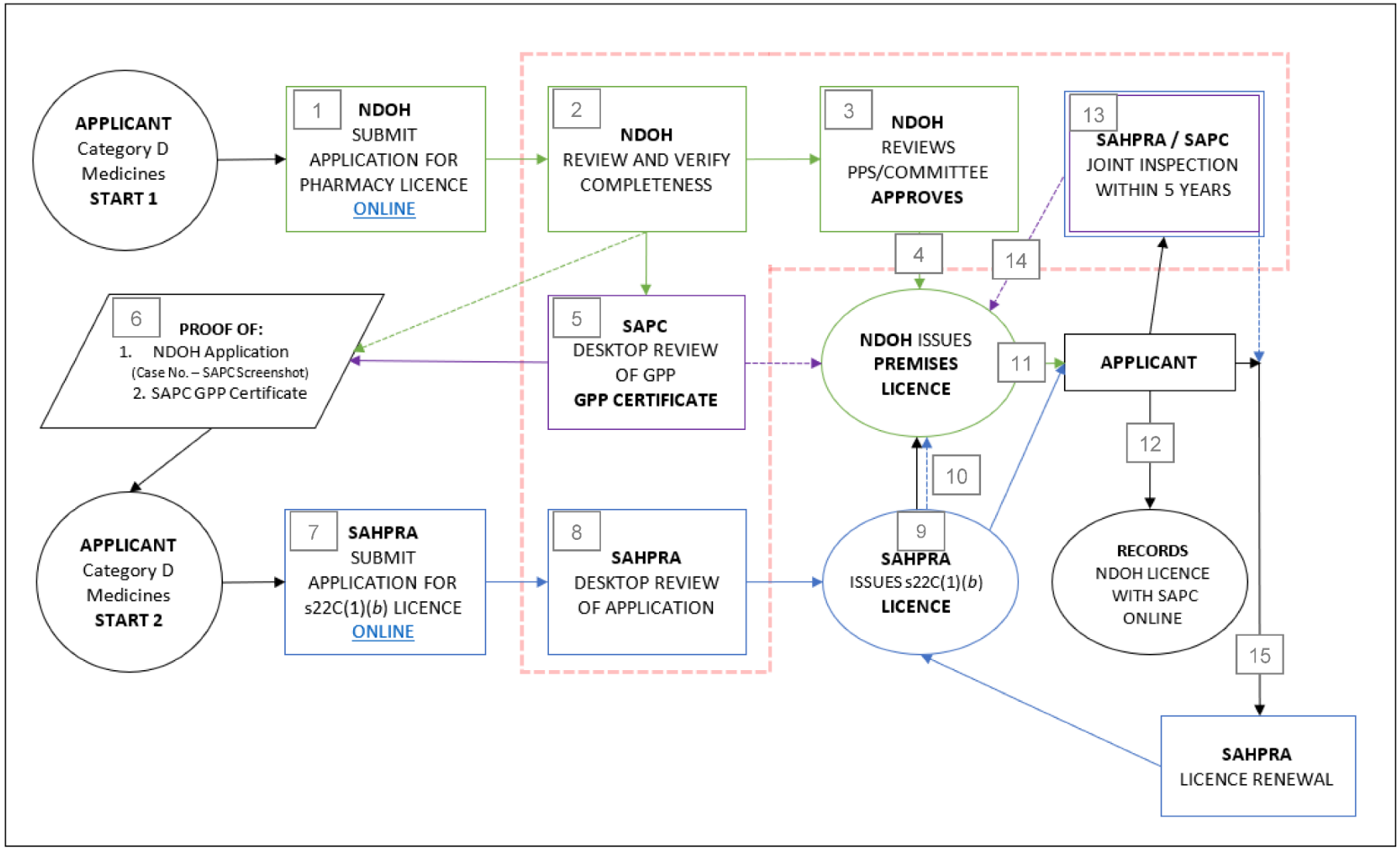

FIGURE 1: PROCESS FLOW FOR NEW APPLICATIONS FOR LICENCES LIMITED TO CATEGORY D MEDICINES