

MAY 2022

SAHPGL-CEM-NS-04_v3_SCHEDULING OF SUBSTANCES FOR PRESCRIBING BY AUTHORISED PRESCRIBERS OTHER THAN MEDICAL PRACTITIONERS OR DENTISTS

This document provides guidance on the process for amending the Schedules to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) to allow prescription rights to authorised health professionals, other than medical practitioners or dentists, in accordance with the provisions of section 22A of the Act. It also covers the process for providing input to the Director-General of Health in relation to applications for exceptional access by means of section 22A(15) permits. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of their applications. Guidelines and application forms are available from the office of the Chief Executive Officer of SAHPRA and on the SAHPRA website.

DOCUMENT HISTORY

Final Version	Reason for Amendment	Effective Date
1	First version: date of implementation	14 March 2014
2	Second version: date of implementation	06 November 2019
3	Third version: date of implementation	30 May 2022

BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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1. INTRODUCTION

1.1. Scope

This document is intended to provide applicants with information and guidance on the criteria and policies applied by the South African Health Products Regulatory Authority (SAHPRA) when evaluating applications for amendments to the Schedules with the objective of specifying substances to be made available for prescription by designated categories of health professionals, other than medical practitioners or dentists, as provided for by section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

This document also provides guidance on the way SAHPRA would provide an input to the Director-General of Health in relation to applications for exceptional access permits, as provided for in section 22A(15) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

However, the designation of medicines to be listed for the purposes of prescribing by practitioners registered with the Allied Health Practitioners Council of South Africa is outside of the scope of this guideline.

2. STATUTORY CONTEXT

- 2.1. Amongst the proposals advanced in the National Drug Policy (1996) was the stated intention to facilitate broader access to prescription medicines by the establishment of a wider range of competent prescribers, thereby advancing access and improving efficiency. One of the basic health care objectives of the National Drug Policy was “to ensure good dispensing and prescribing practices”. However, the document continues, “[the prescribing] of drugs above schedule 2 by pharmacists, except as provided for in the regulations of the Medicines and Related Substances Control Act (101 of 1965), will not be permitted.
- 2.2. Similarly, the policy documents states that prescribing by nurses will only be permitted in accordance with the provisions of Act 101 of 1965. While the broad-based authorisation of prescribing rights for pharmacists was not signalled, the policy document did indicate a preference for the adoption of competency-based measures as criteria for access to expanded prescribing privileges: “At primary level prescribing will be competency, not occupation, based”.
- 2.3. Broadly, the development envisaged in the National Drug Policy (1996) and structurally enabled in the Medicines and Related Substances Act, 1965 (Act 101 of 1965) is consistent with the World Health Organization’s promotion of task-shifting as a means to advancing access to medicines and improving efficiency in health systems (*World Health Organization. Task shifting: global recommendations and guidelines. 2008 - <http://www.who.int/healthsystems/TTR-TaskShifting.pdf>*)

Similar principles were outlined in the United Kingdom Department of Health report “Review of Prescribing, Supply & Administration of Medicines. Final Report, March 1999.
(http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4077153.pdf).
- 2.4. The legal basis for the inclusion of medicines or substances in the Schedules specifically for prescribing by authorised prescribers registered in terms of the Health Professions Act (Act 56 of 1974), other than medical practitioners or dentists, or in terms of the Nursing Act (Act 33 of 2005) is provided for in section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

Sub-section 4 provides that:

Section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

“(4) Any Schedule 1 substance shall not be sold-

- (a) by any person other than-*
 - (i) a pharmacist, or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist;*
 - (ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;*
 - (iii) a medical practitioner or dentist, who may-*
 - (aa) prescribe such substance;*
 - (bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);*
 - (iv) a veterinarian who may prescribe, compound or dispense such substance;*
 - (v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-*
 - (aa) prescribe only the Scheduled substances identified in the Schedule for that purpose;*
 - (bb) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C (1) (a);*
- (b) to any person apparently under the age of 14 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 14 years;*
- (c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.”*

Sub-section (5) then applies the same construct to Schedule 2 to 6 substances:

- (5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than-*
 - (a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;*
 - (b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;*
 - (c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;*

- (d) a medical practitioner or dentist, who may-
 - (i) prescribe such substance;
 - (ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
- (e) a veterinarian who may prescribe, compound or dispense such substance;
- (f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-
 - (i) prescribe only the Scheduled substances identified in the Schedule for that purpose;
 - (ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a);

In addition, notice needs to be taken of sub-section 22A(14)(b) and sub-section 22A(17)(a), which read as follows:

“(14) Notwithstanding anything to the contrary contained in this section-

- (b) *no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned.”*

“(17) For the purposes of this section-

- (a) *‘authorised prescriber’ means a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974;”*

Specifically, it should be noted that there is no mention of pharmacists in sub-sections 4(a)(v) or 5(f). It is therefore not possible for a list of Scheduled substances, apart from Schedule 1 and 2, to be identified in the Schedules for prescribing by pharmacists. The only enabling provision which can be used to authorise Primary Care Drug Therapy (PCDT) pharmacists is therefore section 22A(15). This reads as follows:

“(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act No. 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.”

2.5. Taking into consideration the aforementioned, section 22A(15) enables an exceptional circumstance, which is to be determined on a case-by-case basis. In responding to such applications, the Director-General can look to the South African Health Products Regulatory Authority for advice on the matter. Such input should not in any way restrict the ability of the Director-General to make individual determinations for specific circumstances.

2.6. As outlined in the National Drug Policy, expansion of prescribing rights to nurses and authorised persons, other than medical practitioners and dentists, who are registered with the Health Professions Council of South Africa, is intended to improve access and efficiency at Primary Health Care level.

Any application for the scheduling of medicines for this purpose or for access in terms of section 22A(15) of the Act should therefore use the most recent set of Standard Treatment Guidelines/Essential Drugs List (STG/EDL) for Primary Health Care (PHC) issued by the National Department of Health as a starting point, wherever appropriate. However, the application of the changes to the Schedules would occur both in the public and private sectors, so the medicines selection choices made in the public sector are indicative and not prescriptive. The PHC STG/EML is intended to guide the practice of medical practitioners and nurses at PHC facilities in the public sector, including mobile clinics, fixed clinics, community health centres and the out-

patient departments of district (level 1) hospitals.

Critically, although the STG/EDL does not specify the prescriber level for each of the medicines, the list is intended to cover medicines that can be initiated by medical practitioners only, as well as those that can be continued or initiated by nurses holding a permit issued in terms of section 56(6) of the Nursing Act (Act 33 of 2005). The exact line of demarcation between these categories is determined by each province, based on local circumstances and the availability of staff. There is therefore no official designation of any of the medicines listed in the STG/EDL as being nurse-initiated. However, there will be specific circumstances where the PHC STG/EML will not cover the intended area of practice. Examples would include the provision of emergency services outside of clinics as well as the provision of services which are poorly covered by the public sector (e.g. eye care, podiatry).

3. POLICIES FOR EVALUATING PROPOSED CHANGES TO THE SCHEDULES

- 3.1 Any application for amending the Schedules in order to designate specific substances to be prescribed by selected health professionals, other than medical practitioners or dentists, in accordance with section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), must provide at least the following information:
- 3.1.1 clear identification of the category of holders of registration in that particular category of nurses or persons registered with the Health Professions Council of South Africa, other than medical practitioners or dentists, who will be considered by the statutory council concerned as being “authorised prescribers” as outlined in section 22A(14)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
- This category may be defined as having gained registration after a specified point in time (after a change in curriculum which provided for such competence) or as holders of a specific registration on the basis of having completed a designated supplementary course or post-graduate qualification.
- This course or qualification must be accredited for this purpose by the statutory council concerned, as enabled in applicable legislation. The provider of such a course or qualification must also be accredited by the statutory council concerned, as provided for in the applicable legislation.
- 3.1.2 a clear explanation of the competencies held by such holders of registration, indicating the clinical conditions which would be appropriate to be diagnosed and managed by such persons.
- 3.1.3 a clear explanation, with justification, of the means of ensuring the competence of such holders of registration to manage the clinical conditions listed. This would entail a detailed description of the curriculum, the nature of the practical clinical training provided, as well as the approach to assessment of clinical competence.
- 3.1.4 a clear and justified listing of the substances to be included in Schedules 1 to 6 (as appropriate), linked to the list of conditions to be managed by such holders of registration. While the most current PHC STG/EML may be used as a reference in determining this list, consideration may need to be given to the inclusion of additional examples of pharmacological classes that are of comparable efficacy and safety, where the STG/EML lists only one example from that class.
- 3.2 In addition to the information listed above, the applicant should provide evidence of close liaison with the Health Professions Council of South Africa regarding the design of any training programme which deals with diagnosis and prescribing. Where the applicant is a particular Professional Board of the Health Professions Council of South Africa, input should be sought from the Professional Board most appropriate to the area of clinical practice as well as the Council itself.

This requirement would also apply to the situation where the applicant is the Nursing Council of South Africa. Although an application by a person or a body other than a statutory council is not precluded, clear support from the statutory council concerned would be critical.

- 3.1 The South African Health Products Regulatory Authority will consider a complete and comprehensive application for an amendment to the Schedules to allow a specific authorised prescriber access to prescription rights. Once the Authority has resolved to recommend such a list, a draft set of proposed changes to the Schedules will be published to allow for comment by interested persons and institutions. Thereafter, a final set of recommended changes will be submitted to the Minister of Health for publication in the Government Gazette, in terms of section 37A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

4. POLICIES FOR EVALUATION OF APPLICATION IN TERMS OF SECTION 22A(15)

- 4.1 The requirements listed in points 3.1 and 3.2 above would apply, *mutatis mutandis*, to any application submitted to the Director-General in terms of section 22A(15), on which the input of the South African Health Products Regulatory Authority was requested.
- 4.2 Although the end point of such a request would be the designation of medicines for the authorised prescriber, not a listing in the Schedules, the same process as outlined in section 3.3 would apply.

5. SUBMITTING AN APPLICATION

- 5.1 Applications for the amendment of scheduling of substances for prescribing by authorised prescribers other than medical practitioners or dentists must be submitted via the File Transfer Protocol (FTP).
- 5.2 Applicants are requested to adhere to the below file naming convention. This will assist SAHPRA to route the application to the relevant technical unit. The applicant is to ensure that the file is correctly named. Incorrectly named files may lead to a delay in the evaluation of the application.

<u>FTP file naming convention</u>	<u>Example</u>
BAU(n&s)-PRES	BAU(n&s)-PRES

6. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces 2.37_Scheduling for prescribing by authorized prescribers other than medical practitioners or dentists_Nov2019_v2. It will be reviewed on this timeframe or as and when required.