INTERN AND TUTOR MANUAL FOR THE PRE-REGISTRATION EXPERIENCE OF PHARMACIST INTERNS

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1. Introduction

The practical training year is extremely important to the pharmacy graduate. The pre-registration programme, developed by the South African Pharmacy Council (Council), lays the foundation for the internship year and provides the pharmacy graduate with an opportunity to gain practical experience and knowledge in a practice setting. It is also the year in which the tutor nurtures and guides the intern towards adopting a specific approach and attitude towards the practice of the pharmacy profession.

Internship for pharmacy graduates extends over a **minimum period of twelve months**, or a period of not less than twelve months in the aggregate, as determined in the Pharmacy Act, 53 of 1974 (the Act). In terms of the Act, **internship can only commence after registration with Council**. Prior to registration of the intern, Council must approve the tutor as well as the pharmacy or institution as a training site. At the end of the internship period, the intern should have had exposure to the practice of pharmacy and be able to practise as a competent professional.

The pre-registration programme is based on a set of exit level outcomes (ELO) which describe the knowledge, skills and attitudes required of an entry-level pharmacist. During the year the intern should gain the technical skills to augment the knowledge they acquired during their undergraduate study periods.

This manual is designed to assist interns, in a structured manner, in their preparation for a career as professional pharmacists and equip them to:

- apply legal and ethical principles in their activities;
- demonstrate an holistic approach to and accept responsibility for professional actions;
- obtain knowledge and expertise in conducting a patient-orientated health service;
- develop communication skills to enable them to interact with patients and members of a healthcare team;
- gain knowledge of the general aspects of healthcare, with particular emphasis on the South African situation, and the role of the pharmacist in the promotion of health and prevention of illness;
- make sound decisions relating to drug-related problems;
- apply the principles of pharmaceutical care to achieve definite therapeutic outcomes for the health and quality of life of a patient;
- plan and manage personal programmes in terms of workflow and tasks;
- apply knowledge of products used in pharmacist initiated care and maintain the same diligence required for the dispensing of prescribed medicines; and
- manage personnel and work as part of a team, both within the pharmacy and with members of a healthcare team.

The objectives of this manual are to:

- clarify requirements for the pre-registration year;
- emphasise the responsibilities and the role of both the intern and the tutor;

- provide a timetable with the most important dates for the year;
- explain the manner of assessment of the progress and performance of the intern;
- inform interns of the relevant application forms and online procedures that are required during internship; and
- provide information regarding the various professional organisations and other pertinent information.

The fifth year of the education and training of a pharmacist is of such a hands-on nature that the responsibility for training lies, to a large extent, with the tutor. Council endeavours to assist both the intern and the tutor through this manual, which offers a structured training programme and methods of assessment to measure the progress of the pharmacist intern.

2. Guidelines for the pre-registration year

This manual is a guide for pharmacist interns and tutors to ensure a successful pre-registration experience. Its aim is to explain the purpose and the contents of the internship programme, the role of the tutor and the intern, as well as the assessment of an intern's performance.

In terms of the programme for the pre-registration year, the following should be noted:

- the practical training site should allow an **introduction (orientation) period** of two weeks for the intern;
- Council will organise an **information session (intern/tutor workshop)** which must be attended by both tutors and interns. The workshops will take place in each province between Feb and May 2019. Interns and tutors must RSVP online on Council's website for the event. Please note that **all registered active interns and their tutors should attend the workshops annually** as guidelines, assessment criteria and timetables may change;
- the list of **competence standards (CS)** should be used as a guideline for training (refer to Annexure A);
- **progress reports** (see section 3.3) on the skills and knowledge obtained by the intern, as well as their personal development, must be submitted **during the year** as reflected online;
- **online submission of a continuing professional development (CPD) portfolio is required** (see section 3.2);
- the intern should attend at least **two continuing education** sessions;
- the tutor is responsible for confirming that the practical training of an intern was conducted to their satisfaction at the **end of the internship;**
- all interns must successfully complete **the pre-registration examination** (see section 3.1); and
- to **qualify for a pre-registration examination for the first time**, interns should have completed at least **six months** of internship, submitted at least six CPD entries, and had three progress reports submitted by the tutor (i.e. the 12 weeks personal and professional development report, and the 24 weeks personal and professional development report and sectoral experience checklist).

It is strongly recommended that <u>exposure to other sectors of pharmacy</u> takes place during the internship period. For example, community pharmacy interns be exposed to hospital pharmacy and vice versa. Interns should also be exposed to different aspects within the practical training facility. Pharmacist interns should thus spend time on a rotational basis in various areas of an approved hospital, community or manufacturing pharmacy where they are placed. The approved tutor remains responsible for the training of the intern during such rotations.

2.1 GENERAL REQUIREMENTS AND CONDITIONS FOR INTERNSHIP

The period of internship for all sectors extends over a period of **at least 12 months**. Leave may be taken in accordance with the Basic Conditions of Employment Act, 75

of 1997. Allowance is made for sick leave and other types of leave as applicable. Legislation pertaining to the internship is found in the Pharmacy Act, 53 of 1974, and in the *Regulations relating to pharmacy education and training* and the *Regulations relating to the registration of persons and the maintenance of registers*.

No person may commence internship unless:

- **they are duly registered with the SAPC as a pharmacist intern;**
- **a contract has been entered into between the tutor and the prospective pharmacist intern at the pharmacy or institution registered as a provider of a qualification in pharmacy (academic institution) at which the internship will take place; and**
- **the tutor and the practical training premises have been approved by the SAPC.**

2.2 PROFESSIONAL CONDUCT

The intern must always act in accordance with all relevant legislation and the *Code of Conduct for pharmacists* which is available on the SAPC website at www.sapc.za.org under *Legislation_Rules.* This code should be used to support the intern (and all pharmacists) in the challenging task of providing good healthcare and fulfilling their professional roles as well as providing a framework to help guide professional judgement.

2.3 THE ROLE OF THE TUTOR

One of the most important responsibilities of the tutor is to be a **role model** and **mentor** in all aspects of practice, with emphasis on the values and attributes of a pharmacist. Pharmacists should not only be competent to perform certain functions and tasks but be able to perform these tasks with a specific attitude and set of values. Tutors must take particular care to observe the requirements of the Act, including the applicable rules and regulations, the code of conduct of the profession, and other applicable legislation.

In being aware of the responsibility to educate and train the new graduate in an appropriate and responsible manner, the tutor should supply the required equipment, materials, programmes, access to information systems and literature as necessary. Tutors should also participate in CPD on a regular basis and attend continuing education courses as well as the intern/tutor workshops conducted by Council. It should be kept in mind that the intern will be in possession of theoretical knowledge and will require the assistance in the application thereof. The CPD will assist in ensuring that tutors practise competently and in a manner that will provide an effective role model for the intern.

The tutor should furthermore be available to assist the intern in the performance of day-to-day tasks and to provide guidance in the development of an independent, responsible decision-maker on matters affecting the health of the public. It is assumed that all tutors can benefit from exposure to courses on, for example, communication and counselling skills.

The ultimate responsibility for passing the competency evaluation lies with the pharmacist intern. The tutor should, however, also realise that a specific standard should be maintained. The assessments that must be conducted throughout the year are thus of importance as a measure of the progress being made by the intern.

The benefits of being a tutor include:

- supporting the future of the pharmacy profession;
- diversifying skills;
- strengthening pharmacy practice;
- maintaining knowledge; and
- the potential for future recruitment of a newly qualified pharmacist.

(a) Internship conducted in academic institutions and manufacturing pharmacies

The internship must include a period of not less than 400 hours of practical training at a community or institutional (hospital) pharmacy approved by Council for such training. The tutor at the academic institution or manufacturing pharmacy must make the necessary arrangements for and keep a record of the 400 hours of practical training. **The 400 hours of practical training must be done over periods of at least five consecutive (eight hour) days.**

The pharmacist supervising the 400 hours of practical training must complete the *Declaration of completion of 400 hours* online.

(b) Internship programme in hospital complexes (public sector hospital complexes)

Interns may be rotated in hospital complexes (i.e. where hospitals have been grouped together in healthcare complexes and/or provide healthcare services in collaboration with community healthcare centres or primary healthcare clinics) under the following conditions:

- there must be at least one approved tutor responsible for the effective practical training of the pharmacist intern concerned;
- facilities (hospital pharmacies) where the intern would be rotating must be approved and recorded by Council and each facility must have a pharmacist to supervise the intern;
- the facility (hospital pharmacy) where such rotation would take place for purposes of practical training, the period(s) that such services would be provided, as well as the name of the pharmacist under whose supervision the intern would work, must be clearly indicated/described in the contract to be approved by Council before the internship commences;
- the rotation must be for purposes of practical training only; and
- an approved tutor may not delegate the supervisory function to a community service pharmacist.

2.4 CESSION OF CONTRACT

Section 15 of the *Regulations relating to education and training* contains the requirements for cession of contract between the tutor and the pharmacist intern. According to this section of the regulations, an internship contract may be ceded to

another approved tutor at the same pharmacy/institution or at another approved pharmacy/institution. Such cession may occur in the event of:

- the death of the tutor, the sequestration of their estate, their conviction of a serious offence, their suspension or the removal of their name from the register of pharmacists;
- the discontinuation of practise of the tutor or the resignation of the tutor from the pharmacy or institution approved for an internship;
- the closure of the pharmacy or institution;
- mutual consent between the tutor and the pharmacist intern for a reason which is acceptable to the registrar; or
- any other reason that Council may deem fit.

Only the period of internship undertaken by an intern under the original registered tutor and the new registered tutor will be recognised by Council.

A pharmacist intern who intends to cede a contract to another tutor must, **at least seven days before such cession, submit the applicable documents to Council**. These documents include:

- the application for cession of contract of internship;
- the applicable cession fee; and
- the tutor application (if not approved).

Cession of an internship contract may only occur once the prospective new tutor has been approved by Council as a tutor. Any periods that an intern spends in a pharmacy which was not approved for purposes of training will not be recognised by Council as part of the internship period. The applicable forms, which must be completed in the case of a cession of contract, are available on the SAPC website.

2.5 REMOVAL OF NAME FROM THE REGISTER

In terms of **section 11 of the *Regulations relating to registration of a person and maintenance of registers***, the Registrar may remove from the register of pharmacist interns the name of a pharmacist intern who:

- has completed their internship to the satisfaction of the Council;
- has not completed their internship to the satisfaction of the Council;
- has discontinued their internship with the consent of the Council;
- no longer complies with the requirements and conditions for registration as a pharmacist intern; or
- is deceased.

A person whose name has been removed from the register will be notified thereof and any registration certificate issued shall be deemed to be cancelled.

2.6 RESTORATION OF NAME TO THE REGISTER

A pharmacist intern whose name has been removed from the register may have their name restored to the register by submitting to the Registrar:

- a duly completed application form for restoration of their name to the register;
- acceptable documentary evidence that they comply with the conditions under which they may be registered as a pharmacist intern; and
- acceptable documentary evidence from a tutor to the effect that they have resumed their internship.

2.7 REGISTRATION AS A PHARMACIST IN SOUTH AFRICA

To practise as a pharmacist in the Republic of South Africa, registration as a pharmacist with the South African Pharmacy Council is required. It is an offence to practise as a pharmacist if you are not registered as such. All persons who wish to register as a pharmacist for the first time are obliged to perform one year of pharmaceutical community service in a gazetted public sector institution. This requirement was implemented with effect from 20 November 2000. Further information regarding community service may be obtained from the Department of Health.

All pharmacist interns will be required to have passed the pre-registration evaluation before registering as pharmacists for purposes of performing pharmaceutical community service.

Once a pharmacist intern has submitted the documents and the fees referred to below, they will be registered as a pharmacist and issued with a registration certificate. They will, however, only be able to practise as a pharmacist for purposes of performing pharmaceutical community service and for a maximum period of two years. The Council will revoke the conditions of registration referred to above once the pharmacist has submitted a report from the relevant health authority that they have satisfactorily completed the period of pharmaceutical community service in terms of the Act. No additional fee will be imposed for revoking the conditions of registration.

Application for registration as a pharmacist for purposes of performing pharmaceutical community service could be delayed if Council does not receive all the required documents as well as the prescribed fees.

The contract entered into between the employer and the pharmacist intern should not necessarily be terminated after twelve months from the date of commencement, especially if the pharmacist intern has not successfully completed the pre-registration evaluation. The reason for this is that a pharmacist intern who has not successfully completed the pre-registration evaluation will require the same environment to successfully complete their CPD portfolio and/or the pre-registration examination.

Please note that, unless approved by the Registrar, once the intern has successfully completed all the components of the pre-registration evaluation and the tutor has signed off the intern, the intern may no longer practise as a pharmacist intern, a pharmacist's assistant or as a pharmacist until registered for community service. According to Chapter 2 of the Pharmacy Act, 53 of 1974, *no person shall be entitled to provide the services which form part of the services specially pertaining to the scope of practice of a pharmacist or assist therewith, unless he or she is duly registered in one of the categories prescribed in terms of this Act.* **Noncompliance to this regulation is a contravention of the Pharmacy Act.**

Registration as a community service pharmacist will be effected when all the documentation listed below, correctly certified and completed fully, and the prescribed fees have been received by Council:

- all assessment forms, i.e. progress reports (12, 24, 36 and 45 weeks) and summary of outcomes achieved;

- declaration of completion of 400 hours of practical training (academic interns and interns in manufacturing pharmacy only);
- application form for registration as a pharmacist for the purpose of performing pharmaceutical community service;
- certified copy of the intern's qualification in pharmacy (BPharm degree certificate), or confirmation that the intern holds a qualification in pharmacy, submitted directly to Council by a provider of a qualification in pharmacy;
- certified copy of a master's degree certificate in the study approved by Council, or other documentary evidence acceptable to the Registrar, that the intern has satisfied the requirements of the institution for the awarding of at least a master's degree (academic interns only);
- certified copy of identity document or passport;
- documentary evidence of the name of the public health facility or complex of health facilities where the applicant has been placed to perform pharmaceutical community service and the date on which community service will commence (copy of letter of appointment/employment);
- a work permit to work as a pharmacist obtained from the Department of Home Affairs (non-South Africans only); and
- registration fee and annual fee.

PLEASE NOTE:

The registration date for persons who are eligible to register as pharmacists for purposes of performing pharmaceutical community service, i.e. those who have completed their internship, is as follows:

- The date on which community service will commence is **the date** indicated on the letter of appointment or placement received from the relevant health authority.
- In cases where all the relevant documentation/fees have not been received before this date, **the date on which Council received the last document or fee required** for purposes of registration in terms of the *Regulations relating to the registration of persons and the maintenance of registers***.**
- A pharmacist intern will not be eligible for registration as a pharmacist before a period of at least twelve months has elapsed from the date of registration as a pharmacist intern.

COPIES OF ALL FORMS THAT MAY BE REQUIRED DURING THE INTERNSHIP ARE AVAILABLE ON COUNCIL'S WEBSITE.

All declarations must be signed by a Commissioner of Oaths.

3. Pre-registration evaluation

Persons who wish to register as pharmacists in South Africa are required to complete the pre-registration evaluation to ensure that they are competent to enter practice as generalist pharmacists prior to registration as pharmacists. The pre-registration evaluation for pharmacist interns consists of three components:

- a pre-registration examination written on the online platform;
- a portfolio submitted on the online CPD platform; and
- progress reports submitted online by the tutor.

Competence and exit level outcomes for the BPharm qualification

The evaluation of competence is based on the exit level outcomes (ELOs) developed for the pharmacy profession. **These ELOs form the basis of the BPharm curriculum registered with the South African Qualifications Authority (SAQA) and contain all the knowledge, skills and attitudes required by the entry-level pharmacist.** Although it is not always directly evident how the combination of knowledge, skills and attitudes contribute to the demonstration of competence, an extensive knowledge of the principles of pharmacy is essential to enable the pharmacist to apply their skills in effectively dealing with the demands of pharmacy practice in the various sectors of the profession.

The following ELOs describe the essential knowledge and skills:

ELO 1: Integrate and apply foundational scientific principles and knowledge to pharmaceutical sciences

ELO 2: Apply integrated knowledge of product development and formulation in the compounding, manufacturing, distribution and dispensing of pharmaceutical products

ELO 3: Compound, manipulate and prepare medication in compliance with Good Pharmacy Practice (GPP) rules, Good Manufacturing Practice (GMP) and/or Good Clinical Practice (GCP) guidelines

ELO 4: Manage the manufacture, packaging and registration of pharmaceutical products in compliance with GMP and GCP

ELO 5: Manage the logistics of the selection, procurement, storage, distribution and disposal of pharmaceutical products

ELO 6: Dispense medication and ensure optimal pharmaceutical care for the patient in compliance with GPP and, where applicable, GCP

ELO 7: Apply a pharmaceutical care management approach to ensure rational medicine use

ELO 8: Initiate and/or modify therapy, where appropriate, within the scope of practice of a pharmacist and in accordance with GPP and GCP, where applicable

ELO 9: Promote public health

ELO 10: Integrate and apply management principles in the practice of pharmacy

ELO 11: Participate in research

The associated assessment criteria for the exit level outcomes are:

ELO 1: Integrate and apply foundational scientific principles and knowledge to pharmaceutical sciences

1.1 Physical, chemical and biological principles are integrated and applied in the development, formulation, compounding, manufacturing, drug supply management and dispensing of pharmaceutical products.

1.2 Anatomical, physiological, biochemical and pathophysiological principles and knowledge are integrated and applied in the initiation and/or modification of therapy and provision of pharmaceutical care.

1.3 Social and behavioural principles and knowledge are integrated and applied in the initiation of therapy and provision of pharmaceutical care.

ELO 2: **Apply integrated knowledge of product development and formulation in the compounding, manufacturing, distribution and dispensing of pharmaceutical products**

2.1 Physicochemical and biopharmaceutical principles are applied in the formulation and development of pharmaceutical products.

2.2 Physical, chemical and biological principles are applied in the manufacturing, compounding and quality assurance of pharmaceutical products.

2.3 Physicochemical and biopharmaceutical principles are applied in compounding and dispensing of pharmaceutical products.

2.4 Pharmaceutical product integrity is maintained during storage and distribution according to GPP.

ELO 3: **Compound, manipulate and prepare medication in compliance with Good Pharmacy Practice (GPP) rules, Good Manufacturing Practice (GMP) and/or Good Clinical Practice (GCP) guidelines**

3.1 Standard operating procedures (SOPs) are generated and implemented in compliance with GPP.

3.2 Pharmaceutical preparations are compounded in accordance with GMP.

3.3 Sterile admixtures are produced in accordance with aseptic techniques and principles of GMP and GPP.

3.4 Records are generated for each of the preparations produced according to organisational procedures and legal requirements.

ELO 4: **Manage the manufacture, packaging and registration of pharmaceutical products in compliance with GMP and GCP**

4.1 Medicines registration dossiers for pharmaceutical products using the supplied data and documentation are compiled in accordance with the current relevant legislation.

4.2 Master production documentation for the manufacture of pharmaceutical products is interpreted in terms of GMP.

4.3 The GMP requirements for generation and reconciliation of batch manufacturing documents are described.

4.4 Dosage forms are manufactured on a laboratory scale according to plan and standard operating procedures.

- Range of dosage forms includes, but is not limited to: solid, liquid, semi-solid, sterile and non-sterile.

4.5 Packaging labelling and package inserts are contextualised according to the product, GMP and the current relevant legislation.

4.6 A quality management system (QMS) is critically evaluated in accordance with GMP.

- Range of aspects of QMS includes but not limited to: quality assurance (QA) and quality control procedures, in-process controls, validation, qualification and Good Laboratory Practice (GLP).

ELO 5: **Manage the logistics of the selection, procurement, storage, distribution and disposal of pharmaceutical products**

5.1 The selection of medicines and related products is managed according to rational scientific and evidence-based principles and patient needs.

- Range of selection criteria includes, but is not limited to: morbidity, pharmacoepidemiological data, quality medicine products, bioavailability, therapeutic equivalence, generic equivalence and pharmacoeconomic data and availability.

5.2 The quantity of medicines needed is identified according to standard methods.

- Range of methods includes, but is not limited to: patient morbidity, standard treatment guidelines and the adjusted consumption method.

5.3 The procurement of medicines and related products is managed according to organisational policies and procedures.

- Range of procurement criteria includes, but is not limited to: vendor qualification, reliability and cost effectiveness.

5.4 Pharmacoeconomic knowledge, principles, models and theories are applied in the provision of cost-effective therapy and pharmaceutical services.

5.5 The storage and distribution of medicines and related products is managed according to GPP, Good Distribution Practice (GDP) and Good Wholesaling Practice (GWP).

- Range of storage and distribution considerations includes, but is not limited to: storage conditions, security, pest control and storage space.

5.6 Disposal of expired and unwanted pharmaceutical products is managed according to current relevant legislation and guidelines.

ELO 6: **Dispense medication and ensure optimal pharmaceutical care for the patient in compliance with GPP and, where applicable, GCP**

6.1 The prescription is evaluated in terms of the appropriateness of the prescribed medication according to GPP.

- Range of evaluation criteria includes, but is not limited to: > indications, dosage, safety, possible contraindications, interactions, treatment duplication, legal and economic implications.

6.2 Medicines are prepared and labelled in accordance with GPP and current legislative requirements.

6.3 Appropriate drug information sources and information systems are accessed and the relevant information communicated to the patient and/or carer in order to optimise therapeutic outcomes.

6.4 A pharmaceutical care plan, including design, implementation and monitoring, is developed in collaboration with other healthcare professionals and the patient.

6.5 Records are kept in accordance with the GPP and current legislative requirements.

ELO 7: Apply a pharmaceutical care management approach to ensure rational medicine use

7.1 The philosophy and principles of pharmaceutical care are demonstrated in terms of optimising therapeutic outcomes for a specific patient.
7.2 A pharmaceutical care management approach is applied in collaboration with other healthcare professionals and the patient.
7.3 Rational drug use is facilitated by applying pharmaceutical care, medicine utilisation reviews and the principles of pharmacoeconomics.
7.4 Pharmacovigilance is practised and adverse drug events are reported.

ELO 8: **Initiate and/or modify therapy, where appropriate, within the scope of practice of a pharmacist and in accordance with GPP and GCP, where applicable**

8.1 Relevant clinical information and history is obtained from the patient.
8.2 Appropriate advice, including referral, and/or medicines are supplied for specific symptoms according to GPP and principles of pharmaceutical care.
8.3 In the case of possible medicine interactions, or any other possible contraindications, appropriate modification of therapy is suggested in consultation with the prescriber.
8.4 Appropriate records are kept and therapeutic outcomes monitored in accordance with GPP and principles of pharmaceutical care.

ELO 9: **Promote public health**

9.1 Advice on health promotion, disease prevention and disease management is provided in terms of use of medicinal and non-medicinal options.
9.2 Tools are designed to inform the public on healthcare and lifestyles, health promotion, disease prevention, disease management and medicine usage, in addition to enabling the recognition and management of risk factors.
9.3 Promotive health services are offered in terms of current health policy, epidemiological information and current legislative requirements.
9.4 The public is assisted in recognising and managing health risk factors in terms of medication and disease states.
9.5 Screening tests are used to assist in counselling, therapeutic intervention, referral and early detection of disease.
9.6 Appropriate records are kept and therapeutic outcomes monitored in accordance with GPP and pharmaceutical care principles.

ELO 10: **Integrate and apply management principles in the practice of pharmacy**

10.1 Basic financial management principles are applied in the practice of pharmacy.
10.2 Human resource management principles are applied in the practice of pharmacy.
10.3 Strategic management principles are applied in the practice of pharmacy.
10.4 Marketing management and change management principles are applied in the practice of pharmacy.
10.5 Logistics management principles are applied throughout the medicines supply chain.
10.6 Relationships with patients, caregivers and other healthcare professionals and workers are managed in accordance with professional practice standards.
10.7 Risk management principles are applied in the practice of pharmacy.
10.8 Quality improvement principles and strategies are continuously applied.

ELO 11: **Participate in research**

11.1 The principles of quantitative and qualitative research are explained.
11.2 A research proposal is formulated.
- Range of formulation requirements includes, but is not limited to: delineating the problem selecting the research methodology, conducting literature review and structure.

11.3 Research is conducted ethically in accordance with established research methodology practice.
- Range of research conducted includes, but is not limited to: gathering and processing, capturing, and interpreting information.

11.4 Findings and conclusions are presented in oral and written formats in accordance with established research practice.

The following **competence standards (CS)** were developed by Council in 2006 in line with the BPharm qualification at that point in time and these have been used in the pre-registration examination and portfolio to evaluate the competency of interns:

CS 1: Organise and control the manufacturing, compounding and packaging of pharmaceutical products
CS 2: Organise the procurement, storage and distribution of pharmaceutical materials and products
CS 3: Dispense and ensure the optimal use of medicines prescribed to the patient
CS 4: Provide pharmacist-initiated care to the patient and ensure optimal use of medicine
CS 5: Provide information and education on healthcare and medicine
CS 6: Promote community health and provide related information and advice
CS 7: Participate in research to ensure the optimal use of medicine
CS 8: Facilitate the development of pharmaceutical personnel
CS 9: Practice pharmacy professionally and ethically
CS 10: Manage the pharmacy / pharmaceutical service

Council in 2018, approved the new **competency standards** for pharmacists in South Africa for implementation. The new competency standards were developed in line with the current BPharm qualification and the 2012 FIP global competency framework to encompass the changes and developments in all sectors of pharmacy and practice, including new technologies, work processes, changes in legislation and international trends, primarily to ensure public safety. The new competency standards were published in Board Notice 59 of 2018 which is available on the SAPC website at www.sapc.za.org under *Publications_Legislation*.

Council is in the process of phasing in the use of new competency standards in the pre-registration evaluation of interns.

3.1 WRITTEN PRE-REGISTRATION EXAMINATION

Council, in 2018, developed a new format for the pre-registration examination which is in line with the new competency standards. Council also resolved that, in 2019, the pre-registration examination be conducted three times, i.e. in March, July and October as indicated in the schedule below. The March 2019 examination will be the same format as the 2018 and prior examinations and the new examination format will be implemented from the July 2019 examination onwards.

Council will conduct workshops in May/June 2019 to introduce the new examination format to interns and their tutors. The practice examination paper in the new format will be made available on the secure site of the Council website to assist interns with preparing for the examination.

Pharmacist interns attempting the pre-registration examination for the first time will only be allowed to sit for the examination **after completing the first six months of their internship and submitting online at least six CPD entries and three progress reports submitted by the tutor (i.e. the 12 weeks personal and professional development report, and the 24 weeks personal and professional development report and sectoral experience checklist)**. Interns registered for nine (9) months or more must submit eight (8) CPD entries and their tutor must submit four progress reports (**i.e. the 12 weeks personal and professional development report, the 24 weeks personal and professional development report and sectoral experience checklist, and the 36 weeks personal and professional development report)** to be eligible to write the examination.

Interns are required to **book online** to write the examination. The booking must be done on the SAPC website (www.sapc.za.org) under the secure site for registered people. On booking, interns are required to select the venue where they will be writing the examination and, for the old format, the sector which they will be writing. The examination booking must be completed at least **four weeks prior to the examination date.** A late booking fee determined by Council will be charged for bookings submitted less than four weeks and up to 14 days before the examination date. Bookings submitted less than 14 days before the examination date will not be accepted.

No fee will be charged for the **first and second** attempt at the examination. Interns will, however, be charged a fee for a third and any subsequent attempts at the examination.

The fees are published by Council each year and are available on the Council website.

A pharmacist intern may attempt an examination on any of the scheduled dates. If the intern fails the examination, he/she may rewrite it on the next available examination date.

The pre-registration examination dates* for 2019 are:
02 March (old format)
20 July (new format)
23 October (new format)

***THESE DATES ARE SUBJECT TO CHANGE. Please refer to www.sapc.za.org**

(a) Policy for conducting examinations

The following policy applies when conducting Council examinations:

- The **invigilator is officially in control of the examination** and must be obeyed on all matters pertaining to the examination.
- Candidates must **present in the examination venue at least an hour before the examination and** must be **seated 30 minutes before the examination.**
- **Only candidates whose names appear on the official list of candidates who booked to write the examination** in that venue or who produce the written / electronic confirmation of the examination booking in that venue will be admitted to that examination venue.

- Each candidate must produce proof of their identity such as an **identity document, a valid passport or a driver's license.**
- **Cellular phones, tablets and other electronic gadgets may not be used** during any examination.
- Candidates must **log on to the secure site** of the SAPC website using their login details to access the examination paper.
- Candidates are allowed **15 minutes to read through the paper.**
- Candidates must ensure that their question paper for the examination is correct.
- All questions are the same for that examination but are randomised. Therefore, the **order of questions will not be the same between candidates**.
- There are **four (4) answer options per question**. There is **only one correct answer** per question.
- The candidate must **use the mouse to select an answer option**. The selected option is then the candidate's answer for the question and is auto-saved by the system.
- **Clicking the "Submit" button completes the examination** and candidates cannot go back to the examination questions.
- Candidates will not be allowed to exceed the time limit. If the allocated examination time lapses without the candidate answering all the questions, the completed **answers are automatically submitted** even if the candidate has not clicked the "submit" button.
- **Only textbooks will be allowed** in the examination room and **candidates may share these through the invigilator**. Personal notes are allowed but may not be shared between candidates. Previous examination papers are **not allowed** in the examination room.
- If a candidate attempts to obtain information from another person by any means during the examination, or if any irregularities occur, the invigilator must report this to Council in writing.
- **Candidates may not leave the examination venue during the examination without supervision.**

(b) Format of the examination from July 2019 (see 2018 intern manual for the old format)

(i) The examination will be conducted as an **open book** examination using the SAPC online platform.

	The approach to an open-book examination differs greatly from the traditional closed book examination. The closed book examination assesses the ability to remember the information from the (closed) book, whereas the open book examination primarily assesses the application of information from the book to different situations.

(ii) The examination will be **one paper** comprising of general practice and calculation type questions and a minimum of **120 multiple choice questions** (MCQ).

(iii) The **general practice questions** will amount to not >70% of the paper and **calculations** will amount to not <30% of the paper.

(iv) The paper will be written over **4 hours**.

(v) Each MCQ consists of a stem describing a problem or practice scenario and will have four answer options, one of which will be the most correct/appropriate answer.

	Although the multiple-choice questions are quicker to answer than the response type questions, paging through books in open book examinations may waste time. Interns must, therefore, understand the concepts to apply to given scenarios and know which reference sources contain specific information to remain time efficient in the examination.

(vi) Each question will be worth **one mark** and no negative marking will be applied.

(vii) The **pass mark** for the examination will be 50% and a subminimum of 60% will be applied to the calculation section of the paper.

(c) Exam content

(i) The examination questions will test knowledge and problem solving skills and will include application.

(ii) Each exam question will be set in accordance with the competencies required for entry into practice as described in the 2018 Competency Standards for Pharmacists in South Africa approved by the SAPC.

(iii) The 6 domains in the competency standards are broad categories linked to specific sub-categories of competency. Even though the domains and competencies are gazetted as they are, they should be read in context with the behaviours to be displayed by an entry level pharmacist.

(iv) Each domain is assigned a weighting and the competencies are weighted in line with the overall weight of that domain. All weighting contributes to the total for the examination. The weights assigned to domains and associated competencies are listed in table 1.

Table 1: Domains, competencies and weighting for pre-registration examinations

DOMAINS	Weight (% of exam)	COMPETENCIES	No. of questions	Category of questions	Knowledge	Application	Problem solving
1. Public health	15%	1.1 Promotion of health and wellness	4	General (4)	20%	60%	20%
		1.2 Medicines information	4	General (4)			
		1.3 Professional and health advocacy	2	General (2)			
		1.4 Health economics	2	Calculations (1) General (1)			
		1.5 Epidemic and disaster management	1	General (1)			
		1.6 Primary healthcare	5	General (5)			
2. Safe and rational use of medicines and medical devices	26%	2.2 Patient counselling	6	General (6)	15%	55%	30%
		2.3 Patient medicine review and management	3	General (2) Calculation (1)			
		2.4 Medicines and medical devices safety	5	Calculations (3) General (2)			
		2.5 Therapeutic outcome monitoring	3	Calculations (1) General (2)			
		2.6 Pharmacist initiated therapy	10	Calculations (5) General (5)			
		2.7 Pharmacovigilance	2	General (2)			
		2.8 Clinical trials	2	General (2)			

DOMAINS	Weight (% of exam)	COMPETENCIES	No. of questions	Category of questions	Knowledge	Application	Problem solving
3. Supply of medicines and medical devices	33%	3.1 Medicine production according to GxP	8	Calculations (4) General (4)	5%	65%	30%
		3.2 Supply chain management	10	Calculations (5) General (5)			
		3.3 Formulary development	1	General (1) or Calculation (1)			
		3.4 Medicine dispensing	10	Calculations (7) General (3)			
		3.5 Medicine compounding	10	Calculations (10)			
		3.6 Medicine disposal/destruction	1	General (1)			
4. Organisation and management skills	5%	4.1 Human resources management	1	General (1)	10%	80%	10%
		4.2 Financial management	1	Calculations (1) or General (1)			
		4.3 Pharmaceutical infrastructure management	1	General (1)			
		4.4 Quality assurance	2	General (2)			
		4.6 Policy development	1	General (1)			

DOMAINS	Weight (% of exam)	COMPETENCIES	No. of questions	Category of questions	Knowledge	Application	Problem solving
5. Professional and personal practice	17%	5.1 Patient-centred care	3	General (3)	10%	45%	45%
		5.2 Professional practice	7	General (7)			
		5.3 Ethical and legal practice	8	General (8)			
		5.5 Leadership	1	General (1)			
		5.6 Decision-making	1	General (1)			
6. Education, critical analysis and research	4%	6.5 Critical analysis	3	General (3)	5%	40%	55%
		6.6 Research	2	General (2)			
TOTAL	**100%**		**120**				

(d) Type of questions

(i) General questions will be formatted to test general practice of pharmacy in community, institutional and manufacturing sectors.

(ii) The type of calculation questions will be as follows:

CS 1.4: Health Economics

- Cost-benefit analysis
- Cost-effectiveness analysis
- Cost-minimization analysis
- Cost differential between therapeutic agents
- Cost differential between branded drugs and generic equivalents
- Cost differential between dosage forms and routes of administration
- Cost differential of dosing regimen
- Cost differential of alternative treatment plans

CS 2.3: Patient medicine review and management

- Dose adjustment
- Pharmacokinetics
- Creatinine clearance

CS 2.4: Medicines and medical devices safety

- Calculate an appropriate dose
- Prepare, concentrate, or dilute compounded medications accurately
- Interpret osmolarity, isotonicity, and milliequivalents
- Prepare isotonic solutions
- Reconstitute dry powders to appropriate concentration

CS 2.5: Therapeutic outcome monitoring

- Dose adjustment
- Pharmacokinetics
- Creatinine clearance

CS 2.6: Pharmacist initiated therapy

- Amount of medication required for dispensing
- Suitability of doses
- Doses based on patient's weight
- Doses based on surface area
- Prepare, concentrate, or dilute compounded medications accurately.
- Reconstitute dry powders to appropriate concentration (including displacement volume)
- Calculation of BMI
- Calculation of peak flow reading

CS 3.1 Medicine production according to GxP

- NaCl equivalents
- Freezing point depression
- Solubility
- Master formulae
- Changing concentrations
- Trituration
- Molecular weight

- Reconciliation calculations in manufacturing operations (e.g. granulation yields; compression yields)
- Reconciliation calculations in packaging operations (i.e. packaging materials reconciliation)
- Density calculations in packaging operations (e.g. liquids packaging)
- Dilutions
- Formulations
- Isotonicity calculations

CS 3.2: Supply chain management

- Min/max order/reorder levels
- Acquisition costs
- % mark-up
- ABC analysis
- Lead-time
- Buffer/safety levels
- Distribution fees
- Patient bonus stock
- Batch supply cost analysis

CS 3.3: Formulary development

- Calculation of costs
- Cost-benefit analysis
- ABC analysis

CS 3.4: Medicine dispensing

- Amount of medication required for a prescription
- Suitability of doses
- Dosage
- Doses based on patient's weight
- Doses based on surface area
- Concentrations
- Intravenous injection doses
- Intravenous injection doses in paediatric groups
- Reconstitution for oral or parenteral use (including displacement volume)
- Rate of infusion

CS 3.5: Medicine compounding

- Master formulae
- Changing concentrations
- Solubility
- Reconstitution calculations
- Dilutions

CS 4.2: Financial management

- % mark-up
- Dispensing fee
- Budgeting

(e) Reference books

The **latest edition of any** reference may be used during the examination **except previous pre-registration examination papers.** Online references are currently not allowed, but

Council is investigating the possibility of using them in future and will inform interns accordingly when a resolution has been made.

The following references (the **latest editions**) are suggested:

- Pharmaceutical Calculations (H. C. Ansel)
- Pharmaceutical Practice (A. J. Winfield, et al)
- Calculations for Pharmaceutical Practice (A. J. Winfield & I. O. Edafiogho)
- South African Medicines Formulary (SAMF)
- Handbook - 128 -k on Injectable Drugs ("Trissel")
- Textbook of Adverse Drug Reactions
- MIMS
- A comprehensive handbook on pharmacology
- Daily Drug Use / Talmud
- Compendium of laws and regulations
- Good Pharmacy Practice (GPP) and the related Board Notices
- Essential Drug List and Standard Treatment Guidelines – PHC, Hospital and Paediatric
- Martindale: The Extra Pharmacopoeia
- BP and BPC
- Merck Manual or equivalent
- ePharmaciae (www.pharmaciae.org.za)
- South African Pharmacy Journal

(f) Tips for preparing for the pre-registration examination

Below are suggested approaches for preparing for and writing the pre-registration examination:

- **Become thoroughly familiar with the competency standards (CS) and the behaviours required of an entry-level pharmacist.** Decide how you will learn about each aspect of the competency standards and what learning resources you have or need to obtain. Discuss with your tutor anything you are not sure about, including aspects of the unit standards.

- **Decide on the reference texts that you will take into the examination.** Decide on a few references you are familiar with and take only those into the examination room instead of a suitcase of books you are unfamiliar with. A good rule of thumb is to take only as many books as you can carry comfortably.

- **Familiarise yourself with the content of your selected reference books.** Examine your selected references closely. Make sure you are aware of all the various types of information in the book(s). Very often there are useful tables, etc. that you are unaware of if you haven't inspected all the different sections of the book.

- **Be familiar with the contents of your pre-registration intern manual.** Work through the manual and ensure that you have gained experience in all the activities relating to the scope of practice of a pharmacist included in the manual.

- **Read the *Pharmaciae* published by Council.** Many current topics of relevance to the practice of pharmacy are discussed in the *Pharmaciae*.

- **Read the *South African Pharmaceutical Journal* (SAPJ) published by the Pharmaceutical Society of South Africa.** This will create an awareness of current trends, thoughts, controversies or practices in the profession.

- **Think about what you do in practice each day.** The entire period of your internship should serve as a preparation for your pre-registration evaluation.

- **Think about the tasks you perform every day in the particular sphere of pharmacy in which you practise.** Is the way in which you practise pharmacy ethical and legal? Are you aware of the legislation governing your actions? Are your recommendations/actions best practice – if so, why? If not, why not?

- **Practise solving problems and answering queries.** As problems and queries arise every day in the pharmacy where you work, practise finding solutions on your own. Always check with your tutor or another pharmacist if you are unsure.

- **Reflect on the contents of your CPD entries.** Your CPD entries should be well-developed by the time you write the pre-registration examination. Read through your CPD entries and reflect on the various items.

- **Attempt practice papers which are available on the secure site of the Council website (www.sapc.za.org)** for you to prepare for the examination. Attempt the paper under strict examination conditions. This will allow you to assess whether you are using the correct technique and to fine tune your strategy for the examination.

- **Calculations:** Do not memorise formulae or aids such as 'donkey triangles'. Rather understand the rationale behind the calculation and work from first principles. Practise doing calculations in the pharmacy to develop your skill in performing calculations which are required regularly. Please note that no formulae will be provided/included in the examination paper.

(g) Tips for writing the pre-registration examination:

- **Knowledge is in your head and references are for confirmation.** During an open book examination, you do not have sufficient time to look up every aspect. If you try to do so you will not have time to fully complete the examination. This is especially true if you search for the same small piece of information in more than one reference book. You must be able to understand and answer the question without using reference books for every single question. Only use the reference books if you are unsure of the answer to a question, or if you need confirmation and fine detail.

- **Allocate the available time proportionally to the various sections.** This might seem to be a very basic concept, but it is an area where candidates often fall short. Prior to the examination, calculate the time allowed per mark. Once you receive the paper quickly calculate how much time should be allocated to each section. Adhere to this guideline. If you have not completed a question within your allocated time allowance move on to the next question. You can come back to a question with which you are having difficulties. Rather complete those questions where you are confident of the answers and then spend time on questions where you will have to search for information.

- **Read the questions carefully.** Read the entire question slowly and ensure that you understand the question fully before you select your answer. Candidates often see a phrase in a question, decide that they know 'all about that' and select an answer

accordingly, whereas if they had spent time reading the entire question they would have realised their answers were irrelevant.

- **Calculations – is your answer realistic?** On completion of a calculation look critically at your answer: Is it realistic? **Ensure that you bring a working calculator to the exam.**

- Finally – have a good night's sleep before the examination and try to relax and enjoy the experience. Your performance will improve if your stress levels are low.

(h) Examination results

The following principles apply regarding examination results:

- The answer is auto-saved by the system as the intern clicks it.
- Once the examination has been submitted by the intern, the examination is marked electronically by the system and the results get moderated by Council's moderators to ensure the fairness of the examination.
- The results are expressed as **successful** where the intern has passed the examination or **unsuccessful** where the intern has failed the examination. The intern is deemed successful where a minimum of 50% mark is obtained for the examination **and** a subminimum of 60% is obtained for the calculations.
- Results are approved by Council's Pre-registration Committee, or a person to whom Council delegates the function e.g. the Registrar.
- The results are released to interns only after approval.

The examination **results are released within a month of the examination** or as determined by Council.

Interns, who have not been successful in the pre-registration evaluation (i.e. exam, CPD portfolio and progress reports) after completion of 12 months of internship, may **not be registered as community service pharmacists and therefore may not commence with community service** until they have completed the pre-registration evaluation successfully.

(i) Review of the examination results

Interns who have not been successful in the examination may apply for review of the examination by submitting a duly completed application form (www.sapc.za.org) to the SAPC within a month of the date on which the results are released. A fee for the review of the examination is published on the SAPC website.

The review is a face-to-face session at the SAPC offices and involves providing individual feedback to the intern on the areas where he/she lost marks and advising him/her on the calculation formulae and/or reference source(s) used for the best answer on the question. Feedback for the MCQ examination cannot be given on a question–by-question basis to protect the integrity of the examination questions bank.

3.2 CONTINUING PROFESSIONAL DEVELOPMENT (CPD) PORTFOLIO FOR INTERNS

Council resolved to introduce continuing professional development (CPD) for pharmacists and other persons registered with the Council. Registered persons are required to **submit a record of their CPD activities** on the online platform in accordance with the CPD cycle. A **web-based system** is used for the submission of details of CPD activities. Each registered person will be required to keep a portfolio of evidence which must be submitted to Council as required. Interns are, however, required to upload evidence under the implementation step of the CPD cycle online.

Continuing professional development has been defined in the *Regulations relating to pharmacy education and training* published in terms of the Pharmacy Act, 53 of 1974 as follows**–**

Continuing professional development means the process by which natural persons registered with Council continuously enhance their competency throughout their professional careers and encompasses a range of activities including continuing education and supplementary training.

(a) How to enter CPD activities online

To enter CPD activities, visit the SAPC website www.sapc.za.org and log on to the secure members only site with your P number, ID number and password. To access a password, follow the links provided to receive the password via SMS or email.

Once in the secure site, the annual declaration and the CPD links will be displayed on the left-hand side of the page. As its name implies, the annual declaration must be completed annually before CPD activities can be submitted. The CPD pages will not be available if the annual declaration is not completed for the current year.

Once the CPD link is selected, after completing the annual declaration, you will be redirected to the CPD main page where you can enter a new CPD entry following the cycle (i.e. reflection, planning, implementation and evaluation) as described below or view already entered CPD activities to make corrections as required.

	**REMEMBER: BEFORE THE FIRST CPD ENTRY CAN BE SUBMITTED, THE ANNUAL DECLARATION MUST FIRST BE COMPLETED.**

The CPD cycle is a process that involves four steps:

Step 1: **Reflection on practice** (Answers the questions - What do I need to know? What do I need to be able to do?)

Step 2: **Planning** (Answers the question – How can I learn?)

Step 3: **Implementation** (Describes the action taken)

Step 4: **Evaluation or reflection on learning** (Answers the questions – What have I learnt? and How is it benefiting my practice?)

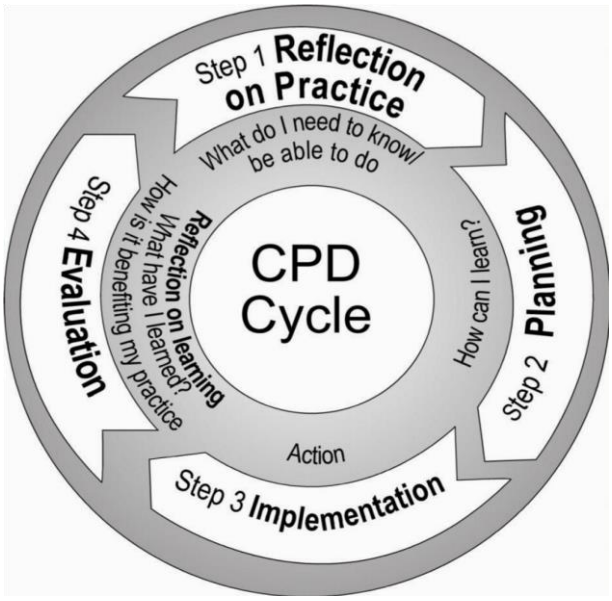


Figure 1: The CPD cycle outlining the four steps in the CPD process

The CPD cycle assists the registered person to maintain, update and develop their competencies by:

- Identifying individual learning needs
- Recognising the learning that may occur in the workplace
- Acknowledging that people learn in a variety of ways
- Planning and prioritising on how to address the learning activities
- Choosing a preferred learning style to gain knowledge
- Evaluating the outcome of the learning activity
- Applying knowledge to the person's personal practice situation.

Interns are required to complete ***all four steps*** of the CPD cycle for each online CPD activity. Information must be provided on each step in the CPD cycle undertaken.

(b) CPD requirements for interns

Below are CPD requirements for pharmacist interns

- Interns must submit **eight CPD entries** (eight different competence standards), all steps of the CPD cycle (figure 1) must be completed.
- Interns must be **competent in six of the eight entries submitted**. All eight entries must be assessed for the intern to be declared competent.
- Interns must select one outcome from each competence standard numbered 1 to 7 [thus seven entries] and one outcome from either competence standard 8, 9 or 10 [thus the eighth entry]. Each entry is based on a single outcome. **Competence standards 1 to 7 are compulsory.**
- Entries, together with suitable evidence, must be submitted online.
- Interns must adhere to the submission timelines.

All 10 competence standards (CS) required for an entry-level pharmacist are provided in Annexure A. Each CS has one or more outcomes e.g. 3.1, 3.2, 3.3, etc.

⚠	**The 2006 competence standards will still be used for the CPD portfolio in 2019. Council is in the process of converting to the new competency standards for the CPD portfolio and will advise interns on the implementation thereof.**

Interns are required to **submit one CPD entry per month**. Interns may record CPD entries but not submit until they have attended the intern/tutor workshop where clarity on the content required will be provided to interns and tutors.

The deadlines for submission of CPD entries are indicated in Table 6. **Results will be released every two months from the submission deadline,** after they are assessed and moderated. Interns must plan accordingly and must adhere to submission deadlines as CPDs submitted after the deadline will only be assessed and released in the subsequent period.

Table 6: CPD submission deadlines for 2019

LAST DATES FOR SUBMISSION OF CPD ENTRIES	NOTE THAT
14 January 2019	**(a) According to Council Policy, appeals must be submitted within one calendar month after the release of the results.** **(b) There will be no CPD assessments in December. Entries submitted after 15 October 2019 will only be assessed in January 2020.** **(c) Entries submitted after the deadline will be assessed in the next assessment cycle.**
30 April 2019	
18 June 2019	
13 August 2019	
15 October 2019	
13 January 2020	

⚠	**Please note that on submission of the 13th and subsequent CPDs, a fee determined by Council, will be charged. The fee is published on the Council website for Fees payable in 2019.**

(c) How will an assessment be conducted?

To be deemed competent for the CPD component of the pre-registration evaluation, the intern is required to submit 8 CPD entries, and be successful in six of the eight CPD entries. Competence standards 1-7 are compulsory.

To determine successful completion of an entry, interns should ask themselves the following questions (not limited) when compiling their CPD entries:

- What did I do?
- What was I trying to achieve?
- What went well and why?
- What did not go well and why?

- How did I do it?
- Why did I do what I did?
- Why did I do it this way?
- How did it affect me?
- How did it affect others?
- What were the consequences?
- What could I have done differently and how?
- Could I learn something from this?

The answers to the above would assist the intern to focus on the purpose of the CPD entry.

The entry must be personal and be written in the first person using the pronoun “I”. The entry must set the scene and tell a story.

Under implementation (step 3), the evidence must contain a link to the competence standard outcome with a reference to each subsection of the outcome. A link must also be shown between the evidence provided and the demonstration of competence. A reference to each piece of evidence must be provided.

An intern must also show how they will maintain this competence in the future. Learning needs and/or the need for further exposure to an aspect of practice should also be discussed.

(d) Matters to be considered during assessment

Competence Standard 1
Evidence relating to manufacturing, compounding or packing may be provided in terms of GMP in bulk packing.

Competence Standard 4
Evidence relating to pharmacist-initiated therapy should NOT include a prescription as the prescription does not constitute pharmacist-initiated therapy.

Competence Standard 6
Emphasis must be on the promotion of community health and the provision of information and advice to communities and NOT to individuals.

Competence Standards 8 to 10
One outcome from Competency Standards 8, 9 or 10 must be submitted.

Table 7: Criteria for assessment of a CPD entry.

Weight: 0 = not yet met the requirement; 1 =requirement partially met; 3 = requirement fully met.
NOTE that where the total weight is 1, then 0 = not yet met the requirement and 1 = requirement fully met.

STEP 1: REFLECTION (What do I need to know/be able to do?)	ASSESSMENT CRITERIA	ASSESSOR	MODERATOR	WEIGHT
Core Competency/Outcome	The learning title is linked to the competence standard and the selected outcome.			
Learning Title	There is a title which is descriptive and relevant to the outcome. The title is relevant to what the intern needs to learn and is not the same as that of the competence standard or outcome.			0 – 1
Describe the Learning Need	There is a description of the identified learning need and what the intern hopes to achieve in addressing the need. A description of how the intern hopes to address the deficiency or what the intern wants or needs to learn about is provided.			0 – 3
Total				4
Assessor Comments:		**Moderator Comments :**		

STEP 2: PLANNING (How can I learn?)	ASSESSMENT CRITERIA	ASSESSOR	MODERATOR	WEIGHT
Start Date	The date is current, i.e. during the internship period			0 – 1
Briefly Describe	The intern must describe the plan and provide a brief description of the reasoning behind the planning selection.			0 – 3
Total				4
Assessor Comments:		**Moderator Comments:**		

STEP 3: IMPLEMENTATION (Action)	ASSESSMENT CRITERIA	ASSESSOR	MODERATOR	WEIGHT
Supporting Documentation – Evidence	Supporting documents, also known as evidence, have been uploaded. The evidence is- (a) Valid – relevant to the outcome (b) Current – collected during the internship period (c) Authentic – must be verified by the tutor for correctness before submission. (d) Sufficient and appropriate, and covers at least 75% of the outcome. If there are factual errors or calculation errors in the evidence submitted, the evidence should be deemed **not** valid. All pieces of evidence submitted must be annotated. Interns should ask themselves the question "Why did I include this?" **NB: No marks will be allocated for authenticity, currency and sufficiency if the evidence submitted is not valid.**			0 – 3
Achievement Date	The achievement date is current, i.e. during the internship period.			0 – 1
Description	There is a brief description of what has been done by the intern "**ACTION** taken to achieve the specific outcome". Interns who score zero under 'supporting documents and evidence' automatically render the whole entry **NOT SUCCESSFUL.**			0 – 3
Total				**7**
Assessor Comments:		**Moderator Comments:**		

STEP 4: EVALUATION (What have I learnt? and How is it benefiting my practice?)	ASSESSMENT CRITERIA	ASSESSOR	MODERATOR	WEIGHT
Description	There is a brief description of what the pharmacist intern has **LEARNT,** and the learning is relevant to the evidence. The intern has contextualised what has been learnt. There is a description of how the learning has been applied and feedback is provided on the impact on practice. Examples have been provided showing where the knowledge and skills acquired have been applied.			0 – 3
Total				3
Assessor Comments:		**Moderator Comments:**		
Overall Comments: Assessors should be able to make a final decision that the intern has met or not yet met the requirement.				
GRAND TOTAL				**18**

(e) General - Matters to be noted

To earn three marks for description in each step of the cycle (reflection, planning, implementation and evaluation), all criteria indicated per step of the cycle must be met and the appropriate professional communication styles must be used, for example:

- no spelling or grammatical errors;
- entries must be properly punctuated; and
- trade names must be capitalized.

(f) Assessment criteria for the evidence

(i) Valid Evidence

Evidence must be valid, current, authentic and sufficient. It is the responsibility of the assessor to ensure that sufficient and appropriate evidence has been presented to make an accurate judgement about an intern's competence.

The following guidelines should be used in determining whether evidence is considered valid:

- Evidence must pertain to the outcome being addressed.
- If there are factual errors or calculation errors in the evidence submitted, the evidence should be deemed not valid.
- Further allocation of marks for evidence is summarised below:

0	3
• No evidence • Confidentiality breached • No annotation	• Valid • Current • Authentic • Sufficient

(ii) Current Evidence

Pharmacist interns are required to have exposure to all the standards required for entry-level pharmacists during the internship period. Only evidence collected **during** the internship period is regarded as current evidence. Activities undertaken during the intern's undergraduate studies are **not** deemed to be current.

(iii) Authentic Evidence

Council has implemented a system for a tutor of an intern to authenticate the intern CPD portfolio online. Once the intern has submitted the CPD entries online, these will be allocated to their tutor to verify and submit them to Council for assessment. The tutor will get an SMS notification that the intern has submitted CPD entries and that the tutor must logon to his/her secure profile on the SAPC website to verify and submit them. If the tutor is not happy with the quality of the intern CPD entry, he/she may, after discussing with the intern, return the affected CPD entry to the intern to make necessary corrections and submit again for verification. Once the tutor is happy with the quality of the intern CPD entries, he/she must submit them to Council for assessment. Tutors and interns must therefore pay close attention to CPD submission deadlines for assessment by Council. CPDs submitted by the intern and the tutor after the deadline will only be assessed in the next assessment period.

In the case of work which has been done jointly (e.g. research), interns must submit individual reports and include a declaration describing the role they played.

(iv) Sufficient Evidence

To be regarded as sufficient, the intern must provide clear evidence for all the subsections of an outcome where the outcome has three or less subsections. In the case of an outcome that contains four or more subsections the pharmacist intern must submit evidence that covers at least 75% of the subsections of an outcome. For example, in the case of Competence Standard 1, an intern would have to submit evidence for all subsections of outcome 1.1 which has three subsections (1.1(a) to (c)). But for outcome 1.7 which has six subsections (1.7(a) to (f)) they would only have to submit evidence for a minimum of five subsections of the outcome.

The same piece of evidence cannot be used for more than one outcome (i.e. for every outcome there should be a piece of evidence which is annotated appropriately).

Please note that images, the entire Act, the entire GPP, etc., are NOT regarded as sufficient evidence. Please do not upload the entire Act if your CPD entry only focuses on one aspect of the Act.

(g) Releasing results

The following principles are applied in releasing results for CPD entries:

- The results of candidates will be expressed as whether the candidate is **'competent' or 'not yet competent'**.
- Results are approved by Council or a person to whom Council delegates this function.
- **Results will be released in bulk** to candidates only after their CPD entries, submitted by the deadline, have been assessed and approved.

COUNCIL CANNOT RELEASE INDIVIDUAL RESULTS FOR INTERNS AND/OR TUTORS WHO MISS THE SUBMISSION DEADLINES. ENTRIES SUBMITTED AFTER THE DEADLINE WILL BE ASSESSED AND RELEASED IN THE PERIOD MARKED BY THE SUBSEQUENT SUBMISSION DEADLINE.

(h) Main reasons why interns fail their CPD entries

- It is not clear to the assessor WHAT it is that the intern did and/or WHAT unannotated evidence means.
- Competence Standard 4 is based on pharmacist-initiated therapy – if a prescription forms part of the evidence, it is **not** regarded as pharmacist initiated anymore and the intern will be penalised and fail.
- The intern did not provide sufficient evidence for all the subsections (a, b, c, etc.) of the outcome (as per annexure A).
- If an intern waits until the last submission deadline of the year and submits all eight entries at once, there may be a simple/common mistake in all eight entries that could result in the intern failing **all** eight entries. The intern will have to wait until February of the following

year to be re-evaluated. In this scenario, neither Council nor the assessor will be held responsible if the internship year is extended.

- An intern did not refer to *this* user manual and the CPD guidelines on the SAPC website www.sapc.za.org before completing the CPD entry.
- The intern's CPD entry did not relate to exposure to competence standards **DURING** the internship period.
- The evidence was not collected **DURING** the internship year.
- The intern included evidence obtained during their undergraduate years.

Interns may use the following checklist to assist them with preparing an adequate CPD portfolio-

Table 8: Checklist for CPD portfolio

ASSESSOR/MODERATOR CHECKLIST		
	YES	**NO**
BEFORE STARTING		
Am I clear what needs to be covered in each of the 4 phases of the CPD cycle?		
Have I made a note of the due dates for CPD submissions?		
CHOICE OF OUTCOME		
Have I carefully read all the outcomes for the Competence Standard (CS) before choosing one?		
Have I read all the subsections of the outcome before making the choice?		
Is my evidence sufficiently covering 75% of the sub-sections for the outcome I have selected?		
At the end of September, have I submitted 8 outcomes, one from each of the compulsory CS1 – CS7 plus one from CS8, CS9 or CS10?		
TITLE		
Is there a title?		
Is the title short, specific and related to the outcome?		
Is the title a concise statement in my own words (not just a copy of the CS or outcome)?		
REFLECTION		
Have I clearly stated what **I need to know or learn**?		
Have I stated my learning need in the first person, e.g. "I need to know/learn …"?		
Have I stated why I have identified this learning need for myself and not just stated that it is a required outcome?		
Have I made sure not to include details of planning and implementation here?		
PLANNING		
Have I clearly stated **how** I am going to learn?		
Have I identified which resources I will be using?		
Have I explained how I will be using the resources?		

Have I made sure NOT to just write what I intend to do (which is implementation)?		
Have I written this in the future tense?		
IMPLEMENTATION		
Have I described exactly **what** I did?		
Have I included **where, when, what and how**?		
Have I written this in the past tense?		
Have I referred to the labels of my evidence (i.e. the outcome subsections) in the text?		
Have I checked that what I did matches my learning need?		
Have I checked that what I did addresses all the subsections of the outcome?		
EVIDENCE		
Have I checked that I have **sufficient** evidence i.e. have I covered at least 75% of the subsections of the outcome?		
Have I **annotated** my evidence so that it is clear why I have included each piece?		
Have I **annotated** my evidence **with the subsections**, and does this match the subsections mentioned under Implementation?		
Is my evidence clear i.e. readable, not loaded upside down, etc.?		
Is my evidence properly verified i.e. is there a printed name, designation, P number, signature and date for both me and my tutor or, where applicable, supervising pharmacist?		
Have I made sure that all patient identifying details (such as name, surname, ID number) have been hidden?		
EVALUATION		
Have I clearly stated what I learnt from the action described under Implementation?		
Have I checked that my learning matches my learning need and is relevant to the outcome?		
Have I clearly described how this learning has impacted on the way I practice?		
Have I given a specific example of how I applied this learning i.e. something I did after the action described? Have I remembered that I don't have to provide evidence for this, but just have to describe it?		
Have I clearly noted my future learning needs?		
BEFORE PRESSING "SUBMIT FOR VERIFICATION BY TUTOR"		
Have I remembered that each section of the CPD is marked on a 0 or 3 basis i.e. everything that is required to be in a section needs to be there, otherwise I will get a zero (not like in 4th year when I got marks for partially correct/complete sections)?		

(i) Reanalysis (reassessment) of CPD entries/results and appeal for CPD entries submitted by pharmacist interns

Candidates may lodge appeals against evaluations conducted by Council within one calendar month of the date of the notification of the results in terms of Council's Appeal Policy.

Any candidate may request a reanalysis (reassessment) of their CPD entry in the manner described below:

- The candidate must lodge a request within one calendar month of the date of the notification of the results.
- The request must be in writing and must be submitted to the Registrar together with a non-refundable fee as determined by Council.
- The Registrar will forward the request for a re-mark to the moderator that was appointed for CPDs.
- Once the result of the re-mark has been received by Council and approved by the Registrar, it will be communicated to the candidate within 14 days of receipt of the result.
- Should the candidate not be satisfied with the reassessment/reanalysis, they may initiate the appeals process in terms of Council's Appeal Policy.

(j) Irregularities

The CPD entry submitted must reflect the work done personally by the intern. The submission will be subject to plagiarism software.

In the event of evidence of a candidate's dishonesty, or other irregularities in the conduct of a candidate, the results of the candidate will be withheld, and the matter referred to the Registrar of Council for appropriate action to be taken. The appropriate action initiated by the Registrar may include referral to the Committee of Preliminary Investigation.

(k) Courses and providers of continuing professional development

Information on **continuing education courses/lectures/seminars** can be obtained from professional pharmacy societies and accredited providers. The *Pharmaciae* and Council's website also publish information on various courses. It is strongly recommended that tutors select the courses for interns and allow them time off to attend. It would be ideal if the tutor and the intern could attend the courses together, especially those that are directly relevant to the internship programme.

The tutor could furnish the intern with additional information on the course subject prior to the commencement of the course. For example, a programme for the weeks preceding a continuing education course on **asthma** could contain some of the following:

- **Dispensing procedures and practice**
  - review the specific routines or precautions followed during the dispensing of asthma preparations, refills, etc.

- **Clinical aspects**
  - allergic asthmatic conditions
  - asthma in children
  - control of asthma

(The intern would be expected to review the drugs involved, indications for use, dosage, side-effects, contraindications and patient counselling on general lifestyles.)

- **Treatment of condition**
  asthma preparations available for use at the discretion of the pharmacist

- **Communication with patients, health professionals and the public**
  - counselling where needed
  - recommendations for the prevention and control of asthma attacks

- **Application of the legislation**
  - scheduling of asthma preparations
  - labelling requirements

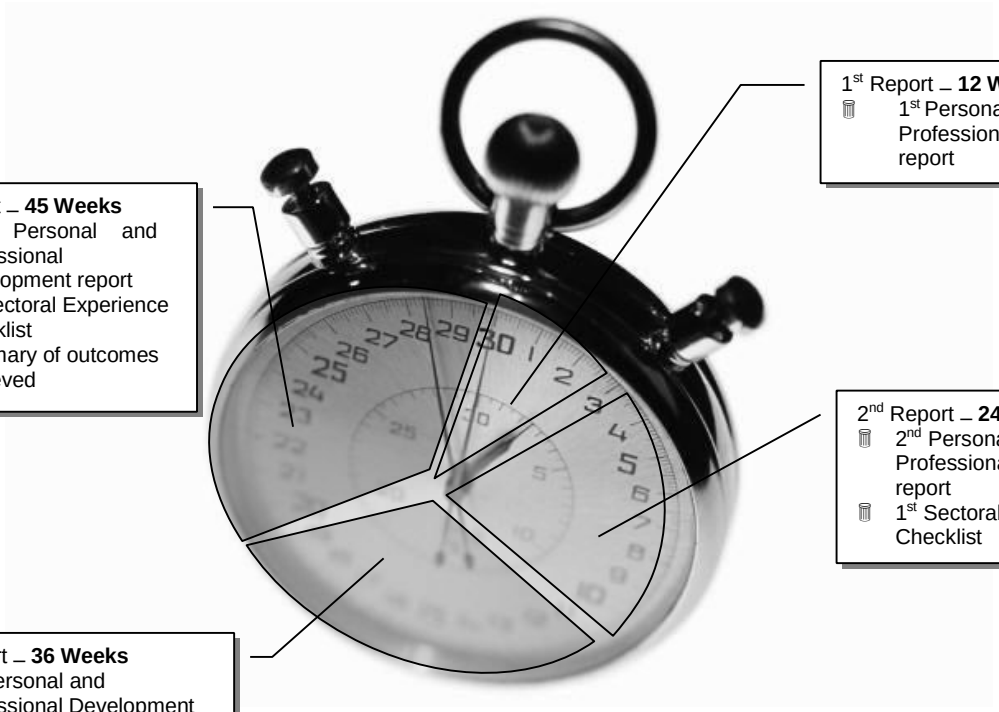
- **Good pharmacy practice and good manufacturing practice**
  discuss the importance of expiry dates of asthma preparations, aspects in the manufacturing of asthma preparations and pharmacoeconomic aspects of the various products

- **Drug information**
  assist the intern in accumulating information on the condition and correct usage of preparations and how to **communicate** information to a patient.

3.3 PROGRESS REPORTS

The following diagrams reflect the time periods for the submission of assessment reports on the progress of the intern during the internship.

COMMUNITY, HOSPITAL, AND MANUFACTURING PHARMACIST INTERNS



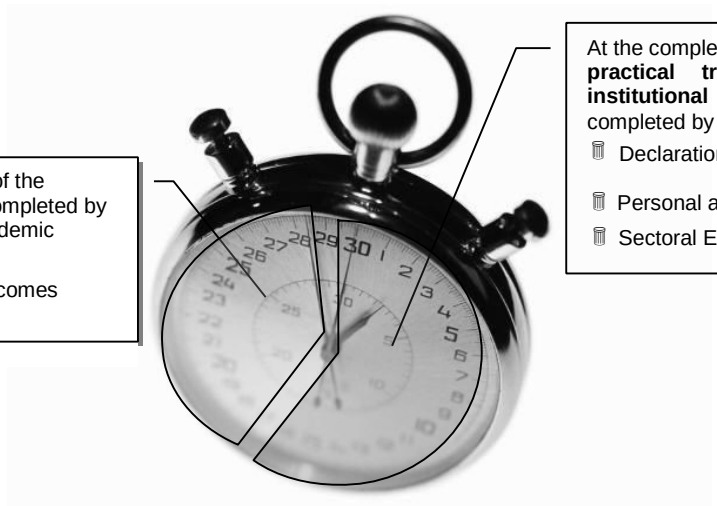
1st Report – **12 Weeks**
- 1st Personal and Professional Development report

4th Report – **45 Weeks**
- 4th Personal and Professional Development report
- 2nd Sectoral Experience Checklist
- Summary of outcomes achieved

2nd Report – **24 Weeks**
- 2nd Personal and Professional Development report
- 1st Sectoral Experience Checklist

3rd Report – **36 Weeks**
- 3rd Personal and Professional Development report

ACADEMIC AND MANUFACTURING PHARMACIST INTERNS



At the completion of the period of **400 hours of practical training in a community or institutional (hospital) pharmacy** (to be completed by a supervising pharmacist)
- Declaration of 400 hours
- Personal and Professional Development report
- Sectoral Experience Checklist

At the completion of the internship (to be completed by the tutor in the academic institution)
- Summary of outcomes achieved

⚠	**Tutors must complete and submit progress reports for interns online. Progress reports can be accessed by the tutor on the secure site of the SAPC website under the *Education* tab.**

(a) Assessment of the intern by the tutor

The assessment of the intern takes place on a systematic and regular basis and should involve positive reinforcement on appropriate performance and constructive criticism on performance that could improve. The intern should receive accurate feedback on their performance as reflected in daily and less regular assessments. Where appropriate, the intern must provide evidence that they have achieved the required standard.

The assessment of the performance of interns in **community and hospital pharmacies** takes place on the following occasions and in the following manner:

- on a day-to-day basis by the tutor in the execution of daily duties and activities and which is not necessarily recorded;
- the professional development of the pharmacist intern is assessed at 12, 24, 36 and 45 weeks of the programme;
- a sectoral experience checklist completed at 24 and 45 weeks of the programme to assess the level of competence of the intern within the sector;
- an assessment of the outcomes achieved by the intern at 45 weeks of the programme; and
- the intern can view and comment on the tutor's assessment regarding their performance once the assessment has been submitted by the tutor.

The assessment of the performance of **interns in academic institutions and in manufacturing pharmacies** takes place on the following occasions and in the following manner:

- on a day-to-day basis by the tutor at the academic institution in the execution of daily duties and activities and which is not necessarily recorded;
- at the completion of the period not less than 400 hours of practical training at a community or institutional (hospital) pharmacy, the supervising pharmacist submits a declaration of 400 hours completed by the pharmacist intern;
- the supervising pharmacist assesses the professional development of the pharmacist intern at the completion of the period of not less than 400 hours of practical training at a community or institutional (hospital) pharmacy;
- the supervising pharmacist completes a sectoral experience checklist at the completion of the period of not less than 400 hours of practical training at a community or institutional (hospital) pharmacy to assess the level of competency of the intern within the sector;
- the tutor at an academic institution and manufacturing pharmacy provides an assessment of the outcomes of the internship completed at the end of the internship period; and
- the intern can view and comment on the tutor's assessment regarding their performance once the assessment has been submitted by the tutor.

(b) Guidelines for tutor assessments (applicable to progress reports)

Background

The purpose of this section is to provide the tutor and the intern with guidelines that may be used in the assessment of the competence of a pharmacist intern. The assessment of competence is concerned with establishing whether the intern can meet the specified standards of performance required of an entry-level pharmacist in a consistent manner, and demonstrates evidence of knowledge, skills and attitudes at the required levels of competence.

In simple terms, an assessment is the process of gathering and judging evidence to determine the current level of performance against a given set of competence standards. It assesses what a person can do, not only what they know, and is measured against the requirements of the practice situation, not against a curriculum. Judgements are made on ability-based outcomes, including thinking and communication, ethical values and principles, and self-learning abilities and habits.

Assessment decisions are simply a matter of judgement as to whether or not evidence presented is sufficient to show that standards of performance have been met, and can continue to be met in the practice situation.

The process of assessment

An assessment of performance during the course of a pharmacist intern's normal work provides the most natural form of evidence. Because of this, it is generally the best method of assessing competence. Where such an assessment is not possible, simulated activities can be used as an alternative or supporting method of assessment. These activities could take the form of role plays or demonstrations carried out separately or in support of the assessment.

It is important to bear in mind that in the assessment process there are no pass or fail marks. The pharmacist intern needs only to demonstrate to the satisfaction of the tutor, that they are either competent or not yet competent. Assessments are carried out against criteria detailed in the manual for pharmacist interns and are not linked to a particular learning curriculum.

In the assessment of the intern, the tutor can make use of the following guidelines to determine how an intern is proceeding with a particular task:

- test **knowledge** (do they know what they are doing);
- test **competence** (are they able to perform the tasks and how well);
- test **efficiency** (can they be relied upon to perform a task accurately and safely within a reasonable time);
- determine if skills, knowledge and values can be used and **transferred** to different circumstances; and
- assess the performance within the **context of the competencies** required of a pharmacist at entry level.

An integrated approach to assessment aimed at assessing knowledge, understanding, problem solving, technical skills, attitudes and ethics should be used. Assessment processes should be aimed at enabling the tutor to evaluate the performance of the pharmacist intern in a number of areas:

- **Technical** – knowledge of pharmacy, problem solving, the application of theoretical concepts to practical problems.

- **Organisational** – ability to plan, attention to detail, ability to meet deadlines.
- **Communication** – clarity of written communications, ability to work within a team, effectiveness of oral communications.
- **Attitudes** – initiative, willingness to accept responsibility, ability to follow instructions.

Assessment activities should be:

- **flexible** in providing for the special needs of both the pharmacist intern and the environment;
- **valid** in that they assess only the outcomes required;
- **reliable** insofar that the assessment reflects the pharmacist intern's outcomes, regardless of how and where the assessment is carried out; and
- **transparent** in that all of the processes used, and their outcomes, are clear to both those assessing and those being assessed.

The methods used to assess evidence should allow for judgements to be made on the performance of the pharmacist intern against the criteria specified in the assessment forms in this pre-registration manual. The assessments should also assist in the provision of feedback to the intern. Furthermore, assessments will identify areas that require further experience or training before the pharmacist intern can be deemed to be competent.

Objective assessment against clear assessment criteria, followed by accurate and honest feedback, is a vital tool in learning gained by means of the assessment process.

Methods of assessment

Competence is focused on the performance of a role or set of tasks. The tasks are integrated and the ability to demonstrate the tasks as an outcome of a required competence would indicate the effective performance levels of the person. Performance in a competence-based approach may be assessed by four major forms of assessment:

- direct observation
- tests of practical or technical skills
- simulations
- questioning

The evidence of the competence of a person is demonstrated by the possession of a relevant set of attributes such as knowledge, skills and attitudes making up a particular competence.

The amount of **knowledge** needed is that amount necessary for a person to perform a task competently. It includes the ability to make rational decisions and judgements about the task. The knowledge to be assessed should be the core or essential knowledge that has been derived from a task analysis and is necessary to perform the task competently.

Methods of assessing knowledge:

- case studies
- reports
- evidence of prior learning
- oral questioning

- simulations

Attitudes determine how a person applies the knowledge and performs the tasks required of a particular competence. Attitudes which are important in a particular situation will depend on the circumstances of that particular situation and the following list, although not complete, is an indication

of the types of attitudes that may be required of a person involved in the provision of pharmaceutical care and services**:**

- a desire for lifelong learning
- respect for the convenience, comfort and beliefs of patients
- a desire to share knowledge and skills
- an eagerness to overcome difficulties
- a willingness to share in the whole range of community activities
- a desire to be of service to the community and individuals within the community
- a desire to cooperate with other members of the healthcare team within the community

Methods of assessing attitudes:

- direct observation of work activities
- evidence from prior achievements
- oral questioning
- self-evaluations and reports
- simulations

The ability to apply knowledge in the work environment is an indication of the acquired skills that a person may possess. The purpose of assessing skills is thus to determine whether a person can use the knowledge to actually perform a particular task rather than describing what should be done.

Skills are only effectively assessed by observing the performance of a person and making a judgement based on standardised observation criteria. Skills are not limited to the ability to manually perform a task but include the ability to integrate both knowledge and attitudes of a variety of tasks that may form part of a whole competence.

Methods of assessing skills:

- direct observation of work activities
- skills or work sample tests
- projects or assignments
- log books
- records of achievements or portfolios

Knowledge and understanding can also be conceived as inherent in performance, and any observation of performance is likely to provide evidence of knowledge and understanding as well as skills. Performance assessments can thus be seen as an integrated activity.

Assessments can be carried out by using one or a mix of the methods described above. Tutors should try wherever possible not to limit themselves to any single method or methods when alternatives might be equally effective. Methods used to assess the competency of an intern may include:

- direct observation of work activities in the pharmacy
- evaluation of the case studies completed by the pharmacist intern
- evaluation of the record of daily events maintained by the intern during the pre-registration period.

Suggestions on the assessment and feedback process

The following suggestions are provided to assist in the feedback process following an assessment:

- Where possible, provide positive feedback and make positive suggestions.
- Identify areas for improvement, for instance pharmaceutical knowledge.
- Allow for regular time to discuss the training/progress or assessments of the intern.
- Ask for the opinion of the intern on their performance.
- Avoid being too generous and try to establish an honest, fair and realistic level.
- Avoid letting one dominant positive/negative aspect overshadow the other less dominant characteristics.

4. Forms required during internship

The following forms, which may be required during the pre-registration year, are available on the SAPC website (www.sapc.za.org):

- Application for cession of contract of internship in terms of the Pharmacy Act, 53 of 1974
- Declaration of completion of 400 hours of practical training by interns in academic institutions or interns in manufacturing pharmacies in terms of the Pharmacy Act, 53 of 1974 (to be completed by the supervising pharmacist online)
- Progress reports which must be completed by the tutor online
- Application for registration as a pharmacist with a qualification in pharmacy obtained within the Republic in terms of the Pharmacy Act, 53 of 1974, as amended (to be completed online)

Please note that the relevant information, including application forms and details of the allocation process relating to the performance of pharmaceutical community service, will be forwarded to you by the Department of Health (DoH).

For more information about community service, please access the contact details from the website www.doh.gov.za.

Note: If the employer has agreed to pay for any applicant's registration fee, it still remains the responsibility of the applicant to ensure that payment is made on time. If not, the registration date or the pre-registration period will be affected.

The applicant must ensure that their courier address is up to date as the certificate for registration as a pharmacist on completion of pharmaceutical community service is sent to the courier address available on Council's register.

5. South African Pharmacy Council

The South African Pharmacy Council is an independent statutory body created because of the recognition of the pharmacy profession by the legislature in South Africa as a particular occupational group. The Council has been vested with statutory powers of peer review and is responsible for funding itself.

Objects of Council	
The objects in terms of the Pharmacy Act, 53 of 1974 are:	
1.	To assist in the promotion of the health of the population of the Republic
2.	To advise the Minister or any other person on any matter relating to pharmacy
3.	To promote the provision of pharmaceutical care which complies with universal norms and values, in both the public and the private sectors, with the goal of achieving definite therapeutic outcomes for the health and quality of life of a patient
4.	To uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and private sectors
5.	To establish, develop, maintain and control universally acceptable standards: • in pharmaceutical education and training • for the registration of a person who provides one or more or all of the services which form part of the scope of practice of the category in which such person is registered • of practice of the various categories of persons required to be registered in terms of this Act • of professional conduct required of persons to be registered in terms of this Act • of control over persons registered in terms of this Act, by investigating in accordance with the Act, complaints or accusations relating to the conduct of registered persons
6.	Promote transparency to the profession and the general public (Corporate governance)
7.	Maintain and enhance the dignity of the pharmacy profession
8.	Coordinate the activities of Council and its Committees
9.	Improve internal efficiency and effectiveness
10.	Build a pipeline of highly skilled workers to meet Council's mandate

Vision of South African Pharmacy Council

"Sustainable quality pharmaceutical services for all"

Council's Mission Statement

The mission statement of SAPC is:

We exist to:

- protect the public by improving health outcomes
- assist in promoting access to sustainable quality pharmacy services by embracing the use of innovation and technology

- ensure quality pharmaceutical services by developing, enhancing and upholding universally acceptable education and practice standards through stakeholder engagement

- promote the dignity of the profession through professional ethics and conduct, and ongoing competency

Council's Core Values

The core values of SAPC, illustrated by the acronym P.A.P.I are:

People first	-	we care, we serve, we collaborate, we belong to the community
Accountability	-	we are responsible and answerable for our actions
Professionalism	-	we will develop our staff to perform their work with expertise, dedication, care and act in a competent and excellent manner at all times
Integrity	-	we will be ethical, transparent and honest in conducting our business

Functioning of Council

The functioning of the Council can be described by giving a brief analysis of the different committees and the structure of the administration of Council. The Council meets at least three times per annum.

COUNCIL COMMITTEES

Executive Committee

The Executive Committee deals with matters which, in the opinion of the President, require urgent attention and any act performed or decision taken by the Executive Committee is of force and effect unless it is set aside or amended by the Council at its next meeting.

The Executive Committee deals with matters relating to conditions of employment, finance and any other matter which falls outside the terms of reference of other committees. The Executive Committee also deals with any matter which requires urgent attention.

Pre-registration Committee

The Pre-registration Committee considers all matters relating to the establishment, development, maintenance and control of universally acceptable standards for pre-registration of persons, including the evaluation of foreign pharmacy qualifications, pre-registration evaluation and exemptions from examinations. It may also deal with other matters delegated to it by the Council from time to time.

Education Committee

The Education Committee considers all matters relating to the establishment, development, maintenance and control of universally acceptable standards in pharmaceutical education and training, including the approval of providers of education and training and the evaluation of educational qualifications. It may also deal with other matters delegated to it by the Council from time to time.

Practice Committee

The Practice Committee considers all matters relating to the establishment, development, maintenance and control of universally acceptable standards of the practice of the various categories of persons required to be registered in terms of the Act, as well as the promotion of pharmaceutical care which complies with universal

norms and values, both in the public and the private sector, the registration of pharmacies, as well as the issuing of permits in terms of the Act or medicine related legislation. It may also deal with other matters delegated to it by the Council from time to time.

Committee of Preliminary Investigation

The Committee of Preliminary Investigation conducts investigations in terms of Chapter II of the *Regulations relating to the conduct of inquiries held in terms of Chapter V of the Act*.

Committee of Informal Inquiry

The Committee of Informal Inquiry conducts informal inquiries in terms of Chapter III of the *Regulations relating to the conduct of inquiries held in terms of Chapter V of the Act*.

Committee of Formal Inquiry

The Committee of Formal Inquiry conducts formal inquiries in terms of Chapter IV of the *Regulations relating to the conduct of inquiries held in terms of Chapter V of the Act*.

Health Committee

The Health Committee, appointed by Council in terms of the *Regulations relating to the management of a person unfit to practise for reasons other than unprofessional conduct*, considers allegations or information received by the Registrar that a person registered in terms of the Act may be unfit to practise.

CPD Committee

The CPD Committee is appointed by Council in terms of section 4(0) of the Act. In the Code of Conduct: *A pharmacist must keep abreast of professional knowledge to maintain a high standard of competency relative to his/her sphere of activity*.

6. Pharmacy Professional Organisations and Others

A list of pharmaceutical and other organisations has been compiled to assist the intern in becoming acquainted with the various professional bodies and heads of pharmaceutical services in various provinces that interact with the pharmacy profession.

The information has been compiled by the various organisations. Please note that this is not a complete list of pharmaceutical organisations in South Africa.

The intern is encouraged to contact these organisations for further information regarding membership or services offered.

Organisations

CONTACT DETAILS OF PHARMACY PROFESSIONAL ORGANISATIONS	
Pharmaceutical Society of South Africa (PSSA)	PO Box 75769 LYNNWOOD RIDGE, 0040 Tel 012 470 9550 Fax 012 470 9556 Email:pssa@pharmail.co.za Web: pssa.org.za
South African Progressive Pharmacists Association (SAPPA)	Cell: 083 6311019
Independent Community Pharmacist Association (ICPA)	Tel: 031 461 3700 Cell: 082 450 4472 Web: www.icpa.co.za Mr S Moodley
Pharmaceutical Industry Association of South Africa (PIASA)	PO Box 12123 VORNA VALLEY, 1686. Tel 011-8055100 Fax 011-805 5105 Email: info@piasa.co.za Web: www.piasa.co.za
National Association of Pharmaceutical Manufacturers (NAPM)	PO Box 32361 KYALAMI, 1684 Tel: 011 312 6966 Fax:086 529 4245 Web:www.napm.co.za
National Association of Pharmaceutical Wholesalers (NAPW)	PO Box 3069 HOUGHTON, 2041 Tel: 011 4420331 Email: napw@mweb.co.za
National Department of Health	Private Bag X828 PRETORIA, 0001 Tel 012-395 9306 Web: www.health.gov.za

7. Department of Health and the National Drug Policy

Department:
Health
REPUBLIC OF SOUTH AFRICA

Mission of the Department of Health

The mission of the Department of Health is to provide leadership and guidance to the health sector in its efforts to promote and monitor the health of all South Africans, and to provide caring and effective services through a primary healthcare approach.

Aims

The development of the National Health System (NHS) is one of the priorities of the Department of Health and has the following aims:

- unify the fragmented health services into a comprehensive and integrated system
- reduce disparities and inequities in health service delivery and health outcomes
- extend access to an improved health service.

The NHS will contribute to the reduction of morbidity and mortality, and the improvement of the general wellbeing of all South Africans, particularly women and children.

Structures

To provide equitable, accessible and appropriate health services requires a proper organisational and institutional framework, and thus part of the restructuring of the health system involved the division of health functions between the national and provincial departments of health.

The Department of Health includes, inter alia, the Directorates of Medicines Administration and Pharmaceutical Services, which are responsible for the pharmaceutical services provided for by the state hospitals and clinics. This responsibility is delegated further to the provincial pharmaceutical services in each of the nine provinces and they are responsible for the provision of pharmaceutical services within their own provinces.

The guiding principles for the reconstruction and development of the health sector are to:

- unify fragmented health services at all levels into a comprehensive and integrated NHS
- promote equity, accessibility and utilisation of health services
- extend the availability and ensure the appropriateness of health services
- develop health promotion activities

- develop the human resources available to the health sector
- foster community participation across the health sector
- improve planning in the health sector and the monitoring of health status and health services

The National Drug Policy

As part of the national health policy, the Department of Health has committed itself to a National Drug Policy (NDP), which was released by the Minister of Health in February 1996.

Some important issues addressed by the NDP are summarised below.

The pharmaceutical sector, as an integral part of the health sector, will be able to ensure equitable access to medicines that are appropriately selected and meet real health needs through the implementation of the National Drug Policy.

The cornerstone of the process is the selection of essential drugs and rationalising the use and expenditure of drugs from a published Essential Drug List (EDL).

Drug costs are relatively high in South Africa due to the pricing structure that presently applies. A pricing committee was appointed to develop a new pricing policy that will ensure affordability to both the state and the private medicine user.

Several pricing measures and cost-saving mechanisms have been considered, which include removing the profit motive on medicines at the level of distributor and health providers and introducing in its place a system of distribution and professional fees.

Objectives

1. Health objectives

- to ensure the availability and accessibility of essential drugs to all citizens
- to ensure the safety, efficacy and quality of drugs
- to ensure good dispensing and prescribing practices
- to promote the rational use of drugs by prescribers, dispensers and patients through the provision of the necessary training, education and information
- to promote the concept of individual responsibility for health, preventative care and informed decision-making

2. Economic objectives

- to lower the cost of drugs to both the public and private sectors
- to promote the cost-effective and rational use of drugs
- to establish a complementary partnership between government bodies and private providers in the pharmaceutical sector
- to optimise the use of scarce resources through cooperation with international and regional agencies

3. National development objectives

- to improve the knowledge, efficiency and management skills of pharmaceutical personnel
- to re-orientate medical, paramedical and pharmaceutical education towards the principles underlying the National Drug Policy

- to support the development of the local pharmaceutical industry and the local production of essential drugs
- to promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomics and other areas of the pharmaceutical sector

4. The role of the pharmacist

The NDP clearly spells out the role of the pharmacist. The pharmacist has a special role in the National Health Policy and the National Drug Policy, especially in quality assurance and the safe and effective administration of drugs. Pharmacists will be in a strong position to promote the rational use of drugs through their extensive knowledge.

- Community pharmacists have a central community educational role in patient instruction and in the correct use of drugs.
- Pharmacists will be involved in a multi-disciplinary approach to the rational use of drugs, and greater cooperation within the health team will facilitate consensus regarding the choice of drugs and protocols.
- Pharmacists will also play a critical role in primary healthcare and preventative health services.
- Pharmacies will be required to have available scientific sources of reference, and require access to additional essential information from a central drug information system.
- The policy will also aim at expanding and standardising the training of pharmacist's assistants. Pharmacist's assistants will be prepared for certain tasks in hospital pharmacies under the supervision of pharmacists, and for managing drug supply in primary care clinics under the indirect supervision of a district pharmacist.

The NDP developed for South Africa covers a wide range of activities that contribute to the effective production, supply, storage, distribution and use of medicines, ensuring that the people of South Africa receive the drugs that they need at a cost that they, and the system as a whole, can afford.

8. Heads of Pharmaceutical Services

NAME & SURNAME	POSTAL ADDRESS	CONTACT DETAILS	PROVINCE	E-MAIL ADDRESS
Ms NB Molongoana	PO Box 227 Bloemfontein 9300	Tel.051 411 0502 Fax.051 430 2208	FREE STATE	molongoanb@fshealth.gov.za
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Annexure A

COMPETENCE STANDARDS FOR CPD

INTRODUCTION

Pharmacists in each field of practice need to accept responsibility for the self-assessment and maintenance of their competence throughout their professional lives. Pharmacists are thus encouraged to identify their own learning needs in the context of their practice setting. They should plan how these needs will be met and then assess the impact of what has been achieved on their day-to-day practice.

Continuing professional development of a pharmacist is thus a cyclical process. The first step is to review and reflect on one's practice as a pharmacist. This review should include an assessment of one's knowledge, skills and attitudes. The second step is to plan what learning activities you can undertake or other steps that you need to take to address the gaps in knowledge and skills identified. In this process, areas in your practice as a pharmacist, which could be improved, can also be identified and addressed. Learning activities which could be undertaken include both informal and formal activities such as distance education, work shadowing, study groups, coaching, attendance of formal lectures, conferences and workgroups, special projects and assignments, computer aided learning and the reading of articles/journals. The third step is to undertake in your practice environment, the actions that you have identified as being important in the learning process. Learning activities undertaken and changes made to your practice must be documented in your portfolio. The fourth step is to reflect on and assess the impact that has been made by these efforts both on your development as a person and as a pharmacist, as well as the impact which has been made on your practice of the profession.

Competence standards have been developed, as a tool to help you to assess your own learning needs. Gaps in your knowledge and skills can be identified by comparing your own knowledge and skills with those required by the standards. Competence standards have also been structured in such a way that it will help you to identify areas within your practice setting, which could be modified and/or improved. Competence standards are based on the seven unit standards for entry-level pharmacists which have been accepted by the South African Pharmacy Council as the minimum competencies required for entry into the profession.

Three additional sections have been added. These deal with facilitating the development of pharmaceutical personnel, practising pharmacy professionally and ethically and the management of a pharmacy/pharmaceutical service. Because of the fact that pharmacists practise in such a variety of practice settings, provision has been made for you to check in the introduction of each standard whether or not the standard applies to you. For example, if you are practising as a pharmacist in a community pharmacy, the section of the questionnaire relating to manufacturing, compounding and packaging need not be completed if you do not perform these functions in your day-to-day practice.

Please take the time to use this tool.

1. COMPETENCE STANDARD ONE: ORGANISE AND CONTROL THE MANUFACTURING, COMPOUNDING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Does this standard apply to me?

The standard applies to all pharmacists whose practice includes the manufacturing, compounding and packaging of pharmaceutical products.

INTRODUCTION

The pharmacist has a crucial role to play in the manufacturing, compounding and packaging of pharmaceutical products.

In terms of the manufacturing of medicines, the entry-level pharmacist must be competent in the relevant baseline functions within the manufacturing processes. He/she must also be competent in the compounding of medicine on a small scale, as well as the packaging of products.

The pharmacist should at least have a good theoretical knowledge of the manufacturing of all dosage forms, including:

- the properties of ingredients used in the manufacturing process;
- manufacturing processes and apparatus;
- the properties of various dosage forms;
- the legal aspects relating to registration, clinical testing, storage and distribution of medicines and finished products;
- logistical aspects including acquisition, storage and distribution of material, ingredients and finished products;
- packaging of finished products, including stability characteristics and storage requirements; and
- understanding the principles of good management with respect to the manufacturing, compounding, packing and distribution of medicines to ensure a continuing comprehensive, ethical and cost-effective pharmaceutical service to the public/community.

The pharmacist should be expected to have a solid theoretical base line knowledge in manufacturing processes, which may be expanded upon as an elective to further education and training for a specialisation in the manufacturing pharmacy sector.

The competence standard presented here reflects those competencies required for the manufacturing pharmacist as determined by consultation with the pharmaceutical manufacturing industry. There are aspects of the standard that also apply to the pharmacist working in community or hospital pharmacy.

The outcomes and assessment criteria are workplace-related and represent the minimum assessment criteria for evaluations of competency within the pharmaceutical manufacturing workplace.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of authorising and controlling personnel, materials and equipment in the manufacturing, compounding and packaging of pharmaceutical products according to good manufacturing practice, and controlling the quality of these as well as leading the work team and assisting in the training of pharmacist's assistants in-training.

The following outcomes of this capability should be demonstrated by the pharmacist:

1.1 Plan the production process (manufacturing).

A person who has achieved this outcome is capable of:
(a) Scheduling the process in the work plan according to production requirements, area allocation, manpower, equipment and time. (b) Assuring availability of resources (materials, componentry) in the correct quantities. (c) Assuring documentation is available and correct.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.2 Organise resources and prepare materials in accordance with process documentation (manufacturing).

A person who has achieved this outcome is capable of:
(a) Assembling the production team according to the work schedule. (b) Assembling the materials/componentry as per batch documentation. (c) Assuring all materials/componentry have been released according to specifications. (d) **Controlling** and check accurate weighing/measurement of raw materials according to documentation and **standard operating procedures**. (e) Assuring that equipment/machinery is available as per the work schedule. (f) **Ensuring** environmental control where applicable. (g) **Ensuring preparation of production/compounding processes according to product specifications, labelling and batching and legal requirements.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.3 Organise resources and prepare materials in accordance with process documentation (institutional, community, manufacturing).

A person who has achieved this outcome is capable of:
(a) Assembling the materials/components. (b) Controlling and checking accurate weighing/measurement of raw materials according to documentation and **standard operating procedures**. (c) Assuring that equipment/machinery is available. (d) **Ensuring environmental control where applicable.** (e) **Ensuring preparation of production/compounding processes according to product specifications, labelling and batching and legal requirements**.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.4 Prepare for line-opening/line clearance (manufacturing).

A person who has achieved this outcome is capable of:
(a) Ensuring that the work stations are clear of materials and products. (b) Performing line-opening according to standard operating procedures. (c) Ensuring that personnel adhere to **procedures** insofar as hygiene and dress code. (d) **Checking batch records and other applicable documentation with respect to the process being performed for the correct identity and batch details.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.5 Control the production of pharmaceutical products (manufacturing).

A person who has achieved this outcome is capable of:
(a) Ensuring the addition of raw materials according to batch documentation and **standard operating procedures**. (b) Assuring that the mixture is processed/compounded according to production procedures/method on manufacturing record sheet. (c) Controlling and **authorising** the preparation process up to final dosage form. (d) Monitoring and adjusting process to ensure compliance with product specifications where necessary (in-process quality control) according to batch documentation. (e) Ensuring that any other related actions to enable the manufacturing/compounding process to run according to schedule are carried out. (f) Controlling and authorising the packaging of bulk products in containers or into patient ready units. (g) **Controlling and authorising the labelling of containers according to product specifications**.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.6 Control the production of pharmaceutical products (institutional, community, manufacture).

A person who has achieved this outcome is capable of:
(a) Ensuring the addition of raw materials or component products according to standard operating procedures. (b) Assuring that the mixture is processed/compounded according to correct procedures/methods. (c) Packaging of products in containers or into patient ready units. (d) **Labelling of containers according to legal requirements**.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.7 Ensure that in-process control, quality testing and quality awareness is maintained throughout the process (manufacturing).

A person who has achieved this outcome is capable of:
(a) Ensuring that all raw materials and componentry are tested and released according to standard operating procedures prior to use. (b) Ensuring that batch integrity is maintained according to batch documentation and standard operating procedures. (c) Ensuring that cross-contamination cannot occur according to standard operating procedures. (d) Ensuring that in-process testing is carried out in accordance with documentation and procedures. (e) Ensuring that all personnel adhere to quality measures and systems according to Good Manufacturing Practices. (f) **Ensure that the final product is released according to specifications**.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.8 Manage deviations; take corrective action and record findings (manufacturing).

A person who has achieved this outcome is capable of:
(a) Evaluating discrepancies and taking corrective action according to standard operating procedures. (b) Recording findings and reporting to management where applicable. (c) Taking measures to prevent re-occurrence of deviations according to standard operating procedures.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.9 Ensure systems and procedures are adhered to (manufacturing).

A person who has achieved this outcome is capable of:
(a) Adhering to and applying standard operating procedures during pharmaceutical operations.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.10 Ensure documents are completed and records maintained (manufacturing).

A person who has achieved this outcome is capable of:
(a) Demonstrating an understanding of the application and importance of documentation. (b) Assisting in the compilation, control and maintenance of documentation. (c) Controlling record-keeping and the application of documentation in the pharmaceutical processes.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.11 Control and lead the line-closing/shutdown of the pharmaceutical process (manufacturing).

A person who has achieved this outcome is capable of:
(a) Ensuring that the area is cleared and cleaned according to standard operating procedures. (b) Checking for completion of documentation and records. (c) Controlling the reconciliation of product/component/printing material. (d) Controlling returns to the correct storage bins according to standard operating procedures. (e) Evaluating discrepancies and taking corrective actions. (f) Ensuring the correct disposal of waste products and hazardous substances according to standard operating procedures. (g) Assuring that products are placed in quarantine awaiting final release.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.12 Lead and participate in the work team.

A person who has achieved this outcome is capable of:
(a) Planning and **organising** the work team to optimise output, quality and cost. (b) Identifying, clarifying, responding to and resolving work related problems within the team to achieve optimum performance. (c) Identifying and responding to industrial relations issues timeously in a way that balances the interests of worker and management within the legal requirements. (d) Organising and conducting regular meetings with team members to determine courses of action to deal with problems affecting productivity. (e) Evaluating staff performance in key performance areas against agreed outcomes. (f) Establishing and maintaining effective lines of communication within the team.

Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

1.13 Training of pharmacist interns and pharmacist's assistants in-training to achieve the capability in manufacturing, compounding and packaging of pharmaceutical products.

A person who has achieved this outcome is capable of:
(a) Familiarising the pharmacist interns and pharmacist's assistants in-training with the standard operating procedures in manufacturing, compounding and packaging / pre-packing of pharmaceutical products. (b) Familiarising the pharmacist interns and the pharmacist's assistants in -training with the terminology in manufacturing, compounding, packaging / pre-packing of pharmaceutical products. (c) Familiarising the pharmacist interns and the pharmacist's assistants in-training with the equipment and machinery in manufacturing, compounding, packaging / pre-packing of pharmaceutical products. (d) Familiarising the pharmacist interns and the pharmacist's assistants in-training with the operating processes in manufacturing, compounding, packaging / prepacking of pharmaceutical products. (e) Familiarising the pharmacists' assistants and pharmacist interns with the quality control procedures in the manufacturing, compounding and packaging of pharmaceutical products. (f) Assisting the pharmacist interns and pharmacist's assistants in-training in the self-assessment of their capabilities against determined unit standards. (g) Assisting tutor and providing in-service guidance to the pharmacist interns and the pharmacist's assistant in-training in manufacturing, compounding, packaging / pre-packing of pharmaceutical products. (h) Assessing progress of the pharmacist interns and the pharmacist's assistants in-training and providing feedback. (i) Assisting the pharmacist interns and pharmacist's assistants in-training in solving relevant learning problems experienced in manufacturing, compounding, packaging / pre-packing of pharmaceutical products.
Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Assure	• To confirm and certify that the specified outcomes have been achieved.
Authorise	• To confirm, approve and allow manufacturing, compounding and packaging processes according to batch specifications.
Compounding	• Includes calculations, preparation from manufacture record sheets, weighing and temperature controls in the small scale manufacturing of pharmaceutical products. • Includes sterile and non-sterile manufacturing according to a protocol or formulary.
Control	• To confirm outcomes against specified standards.
Documentation:	• Documentation includes Master Manufacturing Schedules, Master Packaging Schedules and other records. • Initiation and/or provision of documentation for the initiation, control of packaging run, specifying materials, controlling over-printing of batch numbers and facilitating reconciliation after packaging. • Work schedule documentation is prescribed by the standard operating procedures.
Ensure	• To assume the responsibility that the critical outcomes are achieved to the required standards.
Good Manufacturing Practices	• Internationally accepted standards of manufacturing practice (e.g. currently embodied in the Good Manufacturing Practices document).
Information	• Information on the packaging processes, materials and packaging criteria is obtained from either standard operating procedures or from Good Manufacturing Practices documentation. • Sources of authority and information will be the standard operating procedures.
Legal requirements	• Drug control legislation. • Health and safety legislation. • Legislation regulating the pharmacy profession. • Labour legislation.
Materials	• Materials include raw materials and bulk materials ready for processing. • Bulk products processed and ready for processing or packaging into smaller units.
Organise	• To co-ordinate, arrange and take responsibility for the achievement of the specified outcomes.
Packaging machinery and Pre-packing equipment	• Packaging machinery or pre-packing equipment applicable to the designated work area.

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Packaging process	• Identified as the process which divides the bulk product into smaller packs in accordance with the manufacturing specification, documentation and consumer needs. • Assessment criteria should be measured within the specific packaging process viz. tablets, liquids, ointments, and according to standard operating procedures and good manufacturing practices described for each of these packaging processes.
Production machinery (equipment)	• Knowledge and competency on production machinery is applicable to the equipment/ machinery used in the designated area.
Resources	• Human, raw and packaging materials, equipment, time.
Standard Operating Procedures	• Procedures as determined for the manufacturing process that defines the purposes, performance outcomes, performance standards for the manufacturing process. • Procedures that define the person responsible for the performance, and the source and date of authority for these definitions for each function performed in the pharmaceutical environment.

Assessment (Tick appropriate box) - In general, does **Standard 1** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

2. COMPETENCY STANDARD TWO: ORGANISE THE PROCUREMENT, STORAGE AND DISTRIBUTION OF PHARMACEUTICAL MATERIALS AND PRODUCTS

Does this standard apply to me?

The standard applies to all pharmacists who play a role in organising the procurement, storage and distribution of pharmaceutical materials and products.

INTRODUCTION

The procurement, storage and distribution of pharmaceutical products is a major determinant in the availability of drugs and health care costs. Given the impact of procurement activities on the operation and effectiveness of health services, it is essential that these activities be managed by pharmacists trained in using sound procedures, with access to reliable stock control, consumption and distribution information. Effective procurement, storage and distribution of medicines requires managerial, pharmaceutical and economic expertise.

The pharmacist plays an important role in the procurement of medicines, quantification of drug requirements, approval and selection of suppliers, quality control programmes and the relevant financial mechanisms required in this process. The management of effective medicine stock levels and the maintenance of the safety and efficacy of stock are also an important responsibility of the pharmacist.

Obtaining good quality drugs involves careful selection of suppliers and products who adhere to Good Manufacturing Practices, knowledge of packaging, storage and transport requirements of drugs and a sound knowledge of the relevant legislation.

The pharmacist is an important role player in the distribution of medicines. Effective drug distribution ensures a constant supply of drugs, effective storage of drugs and cost effective accessibility of medicines to the community at large. Operational planning and logistic skills are essential in maintaining a cost-effective distribution system.

The pharmacist should at least have a good knowledge of the components of the procurement, storage and distribution of pharmaceutical products including but not limited to:

(a) the principles of stock control with respect to storage conditions, security, legal aspects and stock rotation;
(b) the financial implications of procurement, storage and distribution of medicines;
(c) an understanding of the management principles involved in the procurement, storage and distribution of medicines and other pharmaceutical products;
(d) the relevant legislation applicable in the effective control of medicines and other related substances;
(e) communication skills, including the ability to apply technological advances in communication in the procurement and distribution process, and to maintain effective communication lines between suppliers and users of medicines; and
(f) record keeping, statistical methodologies and research methods to ensure optimum medicine supplies to the patient and/or community.

The competencies required for the procurement, storage and distribution of medicines include the ability to lead and participate in a work team, and to assist in the training of staff members to ensure that effective medicine distribution occurs.

The standard presented here reflects those competencies required for the pharmacist to demonstrate capability in controlling the acquisition, storage and distribution of pharmaceutical materials as determined by consultation with the pharmaceutical manufacturing industry, the pharmaceutical distribution industry, hospital pharmacy and community pharmacy.

The outcomes and assessment criteria are workplace related and represent the minimum assessment criteria for the evaluation of competency within the pharmacy workplace.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of controlling the procurement, ordering, receiving, sampling, releasing, storing, preparing for dispatch, controlling transport and keeping records of pharmaceutical materials and products in compliance with legal and technical requirements.

The following outcomes of this capability should be demonstrated by the candidate:

2.1 Organise and control the procurement and receipt of pharmaceutical materials and products.

A person who has achieved this outcome is capable of:
(a) Establishing the items and quantities to be procured according to requirements and procurement policies. (b) Identifying and authorising suppliers according to legal requirements and standard procurement policy. (c) Authorising and controlling placement of orders according to legal requirements and procurement policy. (d) Controlling the receipt of new stock according to legal and documentation requirements, i.e. scheduled products. (e) Controlling and maintaining batch traceability. (f) Confirming the integrity and quality of the materials and products received. (g) Managing identified stock shortages and breakages according to standard operating procedures. (h) Demonstrating a knowledge of processing the needs and requirements of the supplier.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

2.2 Organise and control the storage of stock.

A person who has achieved this outcome is capable of:
(a) Organising and controlling storage conditions to maintain product integrity. (b) Controlling and maintaining batch traceability. (c) Controlling working stock levels according to issuing requirements. (d) Identifying causes for reported deviations and taking appropriate corrective action. (e) Handling returned, damaged and expired stock according to legal requirements and standard operating procedures. (f) Authorising and maintaining documentation according to legal requirements and standard operating procedures. (g) Assuring product security according to legal requirements and standard operating procedures. (h) Organising and controlling stock-taking according to standard operating procedures. (i) Ensuring the maintenance of record keeping to enable the detection of discrepancies and to monitor stock levels.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

2.3 Organise and control the distribution of pharmaceutical materials and products.

A person who has achieved this outcome is capable of:
(a) Controlling and organising the processing of received orders according to legal requirements, product characteristics and good distribution practices. (b) Controlling and authorising the packaging of orders for pharmaceutical materials and products to ensure product integrity and security. (c) Controlling and organising the handling of hazardous substances according to safety and legal requirements. (d) Controlling packaging and handling procedures to assure product integrity, security and breakage avoidance. (e) Controlling and maintaining batch traceability to account for defective stock control. (f) Controlling and organising delivery schedules and endpoints timeously and according to legal requirements. (g) Authorising the procedures taken on the receipt of returned products. (h) Demonstrating a knowledge of the processing of the needs and requirements of the customer.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

2.4 Lead and participate in the work team.

A person who has achieved this outcome is capable of:
(a) Planning and organising the work team to optimise output, quality and cost. (b) Identifying, clarifying, responding to and resolving work related problems within the team to achieve optimum performance. (c) Training team members in the implementation of standard operating procedures. (d) Identifying and responding to industrial relations issues timeously in a way that balances the interests of worker and management within the legal requirements. (e) Organising and conducting regular meetings with team members to determine courses of action to deal with problems affecting productivity. (f) Evaluating staff performance in key performance areas against agreed outcomes. (g) Establishing and maintaining effective lines of communication within the team.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

2.5 Training of pharmacist interns and pharmacist's assistants in-training to achieve capability in the procurement, storage and distribution of pharmaceutical materials and products.

A person who has achieved this outcome is capable of:
(a) Familiarising pharmacist interns and pharmacist's assistants in-training with the standard operating procedures in the procurement, storage and distribution of pharmaceutical materials and products. (b) Familiarising the pharmacist interns and pharmacist's assistants in-training with the terminology in the procurement, storage and distribution of pharmaceutical materials and products. (c) Familiarising the pharmacist interns and pharmacist's assistants with the equipment and machinery in the procurement, storage and distribution of pharmaceutical materials and products. (d) Familiarising the pharmacist interns and pharmacist's assistants and with operating processes in the procurement, storage and distribution of pharmaceutical materials and products. (e) Familiarising the pharmacist interns and pharmacist's assistants with the quality control procedures in the procurement, storage and distribution of pharmaceutical materials and products. (f) Assisting the pharmacist interns and pharmacist's assistants in the self-assessment of their capabilities against determined unit standards. (g) Providing in-process guidance to the pharmacist interns and pharmacist's assistants in the procurement, storage and distribution of pharmaceutical materials and products. (h) Assessing progress of the pharmacist interns and pharmacist's assistants and providing feedback. (i) Assisting the pharmacist interns and pharmacist's assistants to solve relevant learning problems.

Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Appropriate storage conditions	• Stocks are stored according to correct temperatures, light, and humidity. • Stocks are stored in environmentally controlled conditions. • Stocks are stored in correct areas allowing effective stock control. • Stocks are stored maintaining cold chain where appropriate. • Correct storage of hazardous substances and surgicals.
Assure	• To confirm and certify that the specified outcomes have been achieved.
Authorise	• To confirm, approve and allow the procurement, storage and distribution of pharmaceutical products.
Batch traceability	• Integrity of batch traceability. • Mock recall and systems checks. • Stock warehouse movement and maps. • Order processing. • Goods returned for credit. • Goods dispatched. • Batch trace reports.
Control	• To confirm outcomes against specified standards.
Ensure	• To assume the responsibility that the critical outcomes are achieved to the required standards.
Organise	• To co-ordinate, perform, arrange and take responsibility for the achievement of the specified outcomes.
Product integrity	• Maintenance of physical and chemical properties (e.g. by means of cold chain).
Standard procurement policies include	• Availability. • Price where appropriate. • Delivery time. • Quality. • Service/guarantees. • Credit facilities where appropriate. • Legal requirements. • Maintain the integrity of the product.

Assessment (Tick appropriate box) - In general, does **Standard 2** form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, ☐ I have assessed my competency in this standard and can provide evidence in all of the elements. ☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

3. COMPETENCY STANDARD THREE: DISPENSE AND ENSURE THE OPTIMAL USE OF MEDICINES PRESCRIBED TO THE PATIENT.

Does this standard apply to me?

The standard applies to all pharmacists who are required to dispense medicines in their current pharmacy practice.

INTRODUCTION

The role of the pharmacist in drug supply has altered significantly by moving from a product centred approach to pharmaceutical care which is patient centred. A decrease in the need to compound medicines and an increase in the complexity and potency of available medicines have resulted in the need for the pharmacist's involvement in the use of the drugs by the patient. The pharmacist plays a crucial role in the therapeutic process, by ensuring the quality use of medicine in the country.

The quality use of medicines includes patient care encounters, prescription review, and medicine utilisation review. It includes the dispensing process and the provision of pharmaceutical care by the pharmacist. Pharmaceutical care may be defined as "to find and solve the drug therapy problems of each individual patient" and has three essential elements, namely:

- a philosophy of practice;
- the patient care process; and
- a practice management system.

This includes addressing and caring for the needs of the patient by practising according to a patient care model in the pharmacy, developing an appropriate care plan to resolve problems and determine the goals of therapy and to do follow-up evaluations. An effective practice management system must also be developed by the pharmacist.

The dispensing process, as a component of pharmaceutical care, may be seen as that process in which the pharmacist prepares and distributes to a patient a course of therapy on the basis of a prescription. It involves the correct interpretation of the wishes of the prescriber and the accurate preparation and labelling of medicine for use by the patient as advised. The term *dispensing process* may be seen as covering all the activities involved, from receiving the prescription to issuing the prescribed medicine to the patient including:

- receiving and validating the prescription;
- understanding and interpreting the prescription;
- preparing the items for issue;
- recording the actions taken; and
- issuing the medicine to the patient with clear instructions and advice.

The aim of any drug management system is to deliver the correct medicine to the patient requiring such medicine. The pharmacist is also required to demonstrate competency in the management of rational drug use with underpinning knowledge that will ensure that the quality use of medicines provides for:

- the provision of the correct drug for a particular indication;

- the appropriate drug in terms of safety, efficacy, and suitability;
- the appropriate dosage;
- correct dispensing, including the provision of the correct information about the prescribed medicines; and
- ensuring patient adherence to the treatment.

Pharmacist intervention plays a major role in the provision of medicines to the patient, and the pharmacist should demonstrate an understanding of the reasons for pharmacist interventions, how to identify problems, how to correct the problems, and how and when to provide possible alternatives to ensure the quality use of medicines.

- Good dispensing practices ensure that an effective form of the correct drug is delivered to the right patient, in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the efficacy of the drug. The pharmacist should have a knowledge of the components of the dispensing process and ensure the optimal use of medicines as prescribed to the patient, including but not limited to the following:
    - an understanding of how medicines are formulated and manufactured;
    - the capability to prepare medicine extemporaneously;
    - the interpretation of prescriptions and other orders for medicines in accordance with legislation and codes of professional conduct and practice;
    - the selection of drugs and the use of essential drug lists and formularies;
    - the provision of advice to patients and other health care professionals about medicines and their usage, including knowledge of health care systems and the relationships of the community/patient to health care in general.
    - the pharmacotherapy of various conditions for which treatment may be initiated at a primary level;
    - communication skills, including the ability to illicit an appropriate patient profile and the ability to provide information to ensure the quality use of medicines and/or non-treatment advice;
    - the pharmacodynamics, pharmacokinetics and pharmacoeconomics of medicine therapy;
    - the legal aspects relating to the practice of pharmacy; and
    - an understanding of the principles of good management, good pharmacy practice, and multidisciplinary co-operation.

The standard presented here reflects those competencies required for the pharmacist to demonstrate capability in dispensing medicines and ensuring the optimum use of prescribed medicines by the patient, including the implementation and monitoring of a pharmaceutical care plan. The standard was determined by consultation with hospital and community pharmacists and other relevant health professionals. The outcomes and assessment criteria are workplace related and represent the minimum assessment criteria for the evaluation of competency within the pharmacy workplace.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of supplying medicines to humans and animals on the prescription of an authorised prescriber. This implies the gathering of all information required to assess and prepare a prescription, applying pharmaceutical techniques and principles; providing information and counselling to the patient/care giver on the optimal use

of the prescribed medicine; implementing a care plan and monitoring the therapeutic outcomes thereof.

3.1 Read and evaluate the prescription.

A person who has achieved this outcome is capable of:
(a) Verifying the authenticity and validity of the prescription. (b) Verifying patient and **prescriber** information according to legal requirements. (c) Ensuring **completeness** of prescription information and identifying the entity responsible for payment. (d) Identifying prescription **anomalies** that may prevent dispensing. (e) Assisting the patient in resolving identified anomalies where possible or communicating with the prescriber where appropriate.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.2 Communicate with the prescriber where necessary.

A person who has achieved this outcome is capable of:
(a) Contacting the **prescriber** and communicating identified anomalies clearly, accurately and professionally. (b) Working out an **alternative plan** of action with the prescriber and/ or patient that resolves the identified anomalies.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.3 Obtain patient profile.

A person who has achieved this outcome is capable of:
(a) Accessing the **patient profile** or obtain necessary information required to produce a patient profile. (b) Obtaining personal, medication and clinical information from the patient, their care giver or prescriber. (c) Reviewing the patient's medication history. (d) Identifying patient, prescriber and entity responsible for payment.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.4 Interpret the prescription.

A person who has achieved this outcome is capable of:
(a) Reading and interpreting the prescriber's instructions correctly. (b) Interpreting suitability of the prescribed items according to **item descriptors.** (c) Interpreting specific instructions from the prescriber. (d) Verifying the prescribed medication with the patient medication history. (e) Determining the feasibility of generic substitution according to legal requirements and communicating to the patient.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.5 Verify prescription with patient profile to ensure the optimal use of medicines.

A person who has achieved this outcome is capable of:
(a) Assessing the prescription to ensure optimal use of medicines in terms of: • **therapeutic aspects** • appropriateness for the individual • social, legal and economic aspects (b) Acquiring and documenting relevant information from accepted sources according to Good Pharmacy Practice guidelines and legal requirements. (c) Deciding on the need for referral back to the prescriber. (d) Demonstrating sensitivity for **alternative customs** and approaches to health care.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.6 Implement a care plan.

A person who has achieved this outcome is capable of:
(a) **Giving appropriate advice clearly and accurately where necessary.** (b) **Issuing appropriate medicine and providing advice on medicine where appropriate.** (c) **Recommending non-drug management, including no treatment and appropriate information and/or advice.** (d) **Ascertaining whether the patient understood the information and/or advice given.** (e) **Administering drug or** treatment**.** (f) Intervening **in the medicine needs of the patients where appropriate.** (g) **Completing all** records **and keeping records in the appropriate prescribed manner in accordance with legal requirements.**

Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.7 Prepare the prescription.

A person who has achieved this outcome is capable of:
(a) Identifying generic substitutes for the issuing of prescription items according to legal requirements. (b) **Preparing** prescription items according to good pharmacy practice and legal requirements. (c) Applying **pharmaceutical principals and techniques** to the preparation of the prescription.
Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.8 Provide drugs, instructions and advice on the use of the prescribed medication.

A person who has achieved this outcome is capable of:
(a) Handling the medicine to the patient in a **professional and ethical manner.** (b) Communicating in a manner which demonstrates sensitivity for **alternative customs** and approaches to health care. (c) Providing the patient with instructions on the **safe and efficacious use of medicines.** (d) Providing additional instruction using **instructional aids** where appropriate. (e) Demonstrating the correct method of administration of the medicine where appropriate.
Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.9 Counsel patients to encourage compliance with the recommended therapy regimens.

A person who has achieved this outcome is capable of:
(a) Establishing what the patient already knows about the medicine and the needs for counselling. (b) Formulating counselling plan according to the needs of the patient to ensure the **safe and efficacious use of medicines.** (c) Requesting feedback from the patient to confirm understanding of the information provided in the counselling process.

Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.10 Maintain records.

A person who has achieved this outcome is capable of:
(a) Maintaining the necessary legal and **professional records** according to Good Pharmacy Practice guidelines and regulatory requirements.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.11 Monitor the drug therapy.

A person who has achieved this outcome is capable of:
(a) Assessing the patient for signs of **compliance** with, effectiveness and safety of the medicine. (b) Identifying areas for **modification** and taking the appropriate action.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

3.12 Training of pharmacist interns and pharmacist's assistants in-training to achieve capability in dispensing and to ensure the optimal use of medicines prescribed to the patient.

A person who has achieved this outcome is capable of:
(a) Familiarising pharmacist interns and assistants in-training with the correct procedures in dispensing and to ensure the optimal use of medicines prescribed to the patient. (b) Familiarising the pharmacist interns and assistants in-training with the terminology used in dispensing and to ensure the optimal use of medicines prescribed to the patient. (c) Familiarising the pharmacist's assistants and pharmacist interns with the equipment and pharmaceutical processes in dispensing and to ensure the optimal use of medicines prescribed to the patient. (d) Familiarising the pharmacist's assistants and pharmacist interns with the quality control procedures in dispensing and to ensure the optimal use of medicines prescribed to the patient. (e) Assisting pharmacist's assistants and pharmacist interns in the self-assessment of their capabilities against determined unit standards. (f) Providing in-process guidance to the pharmacist's assistants and pharmacist interns in dispensing and to ensure the optimal use of medicines prescribed to the patient. (g) Assessing progress of the pharmacist's assistants and pharmacist interns and provide feedback. (h) Assisting pharmacist's assistants and pharmacist interns with solving relevant learning problems in dispensing and ensuring the optimal use of medicines prescribed to the patient.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Alternative customs	• Homeopathy • Traditional medicine • Herbalism • Ayurvedic medicine • Other complementary medicine
Alternative plan	• Substitution of generic • Alternate therapy • Omit medicine • Refer back to prescriber • Change dose
Anomalies	• Completeness of the prescription • Entity responsible for payment

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Completeness	• The name, gender, age, address of the patient • Prescribers name, qualifications and address • Prescription date • Drug name, quantity and directions • Repeatability and repeat intervals of the prescription
Compliance	• Dose and Dose schedule • Method of administration • Storage • Duration of therapy
Instructional aids	• Pictograms • Written instructions and/or explanations • Braille • Product information leaflets • Appropriate languages
Item descriptors	• Product name, ingredients, quantities, dosage, instructions • Side effects, drug misuse or abuse, contra-indications, incompatibilities, adverse drug reactions, • Non-compliance, prolonged use, drug interactions, • Therapeutic use and pharmacological indications • Dosage form, strength, method of administration, duration of treatment
Modification	• Education on compliance • Dose • Choice of therapy • Dosage form • Dose schedule • Duration of therapy • Referral • Adverse Drug reactions
Patient profile	• Personal, medication and clinical information of a patient
Pharmaceutical principles and techniques	• Physical and chemical medicine properties • Physical and chemical medicine incompatibilities • Physical and chemical container incompatibilities • Pharmaceutical preparation techniques • Sterile dispensing principles and techniques
Prepare	• Calculations • Counting quantities required • Selection, admixing and/or extemporaneous preparation • Packing and labelling
Prescriber	• Medical practitioners • Veterinarian • Other persons authorised by current legislation
Professional and ethical manner	• As embodied in “Supply to the Patient” and the Code of Conduct in the current Good Pharmacy Practice in South Africa document

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Professional Records	• Prescription record • Schedule and substance registers required by law • Patient clinical profile • Patient medication record
Safe and efficacious use of medicines	• Dose levels and frequency, appropriate administration times, methods of administration, duration of therapy • Concomitant intake of food, alcohol and other medicines • Storage conditions • Changes in drug formulations and/or drug dosage forms • Side effects of medicines • Special precautions • Indications for use and the benefits of the medicine
Therapeutic aspects	• Laboratory results • Standard treatment protocols • Multi-drug treatments • Drug characteristics • Disease/symptoms/syndrome

Assessment (Tick appropriate box) - In general, does **Standard 3** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

4. COMPETENCY STANDARD FOUR: PROVIDE PHARMACIST INITIATED CARE TO THE PATIENT AND ENSURE THE OPTIMAL USE OF MEDICINE

Does this standard apply to me?

The standard applies to all pharmacists who are required to give advice and recommendations, and whose actions have a direct impact on patient outcomes.

INTRODUCTION

The pharmacist plays an important role in the provision of accessible and affordable healthcare to the community. The availability of specialised pharmaceutical knowledge at a primary level is an important component in the delivery of effective primary health care.

The pharmacist is often required to make important clinical decisions in the pharmacy based entirely on the patient's history, observation of symptoms, and the application of the pathogenesis and symptomology of a variety of disease conditions. Specific competencies and skills are required by the pharmacist to develop a pharmaceutical care plan that will result in the appropriate treatment of the identified condition, the provision of advice and/or the referral of the patient for further medical attention. Of particular importance is that the pharmacist knows when to refer a patient to a medical practitioner or other health care professional.

The provision of pharmacist initiated care incorporates the practice of pharmaceutical care in ensuring the quality use of medicines by the patient. It includes the dispensing process and the provision of pharmaceutical care by the pharmacist.

Pharmaceutical care may be defined as "to find and solve the drug therapy problems of each individual patient" and has three essential elements, namely:

- a philosophy of practice;
- the patient care process; and
- a practice management system.

This includes addressing and caring for the needs of the patient by practising according to a responsible patient care model in the pharmacy, developing an appropriate care plan to resolve problems and determine the goals of therapy and to do follow-up evaluations. An effective practice management system must also be developed by the pharmacist.

In the provision of rational pharmacist initiated care to the patient and ensuring the quality use of medicines, emphasis is placed on the ability of the pharmacist to develop a pharmaceutical care plan that will result in the appropriate treatment of the identified condition, the provision of advice and/or the referral of the patient for further medical attention.

The pharmacist should at least have a good knowledge of the components of providing care at a primary level including but not limited to the following:

- the pathogenesis and symptomology of a variety of disease conditions encountered at a primary care level;
- the pharmacotherapy of various conditions for which treatment may be initiated at a primary level;

- communication skills, including the ability to illicit an appropriate patient profile and the ability to provide information to ensure the quality use of medicines and/or non-treatment advice;
- the pharmacodynamics, pharmacokinetics and pharmacoeconomics of medicine therapy at a primary care level;
- the properties of various dosage forms and their application in pharmacy practice;
- the legal aspects relating to the practice of pharmacy;
- an understanding of the principles of good management, good pharmacy practice, and multidisciplinary co-operation;
- treatment modalities, including the use of essential drug list medicines, applied drug information and the monitoring of therapeutic outcomes to ensure positive outcomes of pharmacist initiated treatment at primary care levels;
- pharmaceutical knowledge, including dosage forms, quality assurance, pharmaceutical stability, and good dispensing practice; and
- an understanding of the promotion of animal health and the effects thereof on the health care of the community.

The pharmacist is expected to have a solid base-line knowledge of disease pathogenesis, symptomology, epidemiology, treatment modalities and pathophysiology to ensure competency in the provision of primary care therapy to the community.

The pharmacist must have an understanding of the components of providing rational pharmacist initiated care to the patient and ensuring the quality use of medicines including the principles of patient profiles, pharmacist initiated treatment and pharmaceutical care in primary care treatment.

The standard presented here reflects those competencies required for the entry level pharmacist to demonstrate capability in assessing the medicine and health needs of the patient, identifying signs and symptoms of various disease conditions, and implementing and monitoring a pharmaceutical care plan. The standard was determined by consultation with hospital and community pharmacists and other relevant health professionals. The outcomes and assessment criteria are workplace related and represent the minimum assessment criteria for the evaluation of competency within the pharmacy workplace.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of assessing the medicine and health needs of the patient, identifying the patient's signs and symptoms, devising, documenting and implementing a pharmaceutical care plan and monitoring the outcome.

The following outcomes of this capability should be demonstrated by the candidate:

4.1 Determine the reason for request for service.

A person who has achieved this outcome is capable of:
(a) Communicating effectively to determine the person's needs. (b) Approaching the person in a manner, which shows sensitivity to needs and culture. (c) Deciding on the basis of information obtained to provide product, advice or information or to **take patient history.** (d) Refer the person for further investigation by another health care professional where warranted.

Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.2 Provide requested information.

A person who has achieved this outcome is capable of:
(a) Interpreting request for level, content and final use. (b) Deciding whether to refer or accept the request. (c) Sourcing information and evaluating for relevance and scientific correctness. (d) Communicating information promptly, clearly and accurately. (e) Checking the recipient's understanding. (f) Ascertaining that the information supplied meets the needs of the recipient.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.3 Provide and advise on the appropriate and safe use of products where requested.

A person who has achieved this outcome is capable of:
(a) Determining whether the product can be provided according to legal and good pharmacy practice requirements, e.g. age of person. (b) Ensuring the **safe use** of products.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.4 Elicit patient history.

A person who has achieved this outcome is capable of:
(a) Deciding on an appropriate environment to use for consultation according to good pharmacy practice guidelines. (b) Accessing previous patient medication records where available. (c) Taking accurate, complete and systematic patient history. (d) Interpreting history to decide whether to refer, apply first aid or proceed with symptom identification.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐

IF YES, on the basis of the evidence I have identified I can do this.

4.5 Refer patient to other health care professionals where appropriate.

A person who has achieved this outcome is capable of:
(a) Referring the patient to an appropriate health care professional if: • the patient condition warrants further investigation; • therapy taken by patient fails in purpose; • therapy taken by patient causes an untoward effect; or • consequences of drug abuse or toxic doses of drugs or chemicals cannot be treated. (b) Referring the patient in a professional and ethical manner.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.6 Identify patient signs and symptoms.

A person who has achieved this outcome is capable of:
(a) **Observing the patient for behaviour and obvious physical signs.** (b) Identifying signs and symptoms. (c) Performing appropriate **diagnostic tests.** (d) **Using correct test methodology and sampling procedures.** (e) **Interpreting signs, symptoms and data correctly.** (f) **Demonstrating sensitivity for alternative customs and approaches to health care.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.7 Devise an appropriate care plan in consultation with patient.

A person who has achieved this outcome is capable of:
(a) Identifying the cause of observed signs and symptoms by reconciling the latter with the history, observations, examination, and the diagnostic tests performed. (b) **Referring** the patient if the interpreted information requires further investigation by another health care professional in accordance with good pharmacy practice guidelines. (c) Selecting the appropriate **care plan** according to the interpretation of patient information. (d) Devising an appropriate plan to provide for patient advice, treatment or intervention If not referred. (e) Demonstrating sensitivity for **alternative approaches** and customs in health care. (f) Applying **first aid measures** where necessary. (g) Planning follow-up monitoring and evaluation process in consultation with the patient.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.8 Monitor, evaluate and adjust care plan.

A person who has achieved this outcome is capable of:
(a) Following up care plan and assessing the patient for compliance, effectiveness and safe use of the medicine. (b) Evaluating feedback and adjusting care plan appropriately.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.9 Implement the care plan.

A person who has achieved this outcome is capable of:
(a) Referring the patient professionally and ethically where necessary. (b) Providing an emergency supply of medicines where the situation warrants it. (c) Giving appropriate advice clearly and accurately where necessary. (d) Issuing appropriate medicine and providing advice on medicine where appropriate. (e) Recommending non-drug management including no treatment and appropriate information and/or advice. (f) Ascertaining whether the patient understood the information and/or advice given. (g) Administering drug or treatment. (h) Intervening in the medicine needs of the patients. (i) Keeping all records in the appropriate prescribed manner in accordance with legal requirements.

Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

4.10 Training pharmacist interns to provide pharmacist initiated care to the patient and ensure the optimal use of medicines.

A person who has achieved this outcome is capable of:
(a) Familiarising the pharmacist interns with the correct procedures in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine. (b) Familiarising the pharmacist interns with the terminology used in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine. (c) Familiarising the pharmacist interns with the correct methods of eliciting patient history, referring the patient to another health care professional where appropriate and advising the patient on the safe use of requested medicines. (d) Familiarising the pharmacist interns with the principles of identifying patient signs and symptoms, and devising, implementing and monitoring an appropriate care plan in consultation with the patient. (e) Assisting the pharmacist interns in the self-assessment of their capabilities against determined unit standards. (f) Providing guidance to the pharmacist interns in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine. (g) Assessing progress of the pharmacist interns and providing feedback. (h) Assisting the pharmacist interns in solving relevant learning problems in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine.
Assessment (Tick appropriate box)
Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Alternative approach	• Homeopathy • Traditional medicine • Herbalism • Ayurvedic medicine • Other complementary medicine
Care plan	• Referral • Provision of advice • Pharmacist initiated prescription • Treatment or intervention (singly or in combination) • Chronic patient care • First aid
Diagnostic tests	• In accordance with current Specific Guidelines for Pharmacy Practice document • Tests performed: ◻ Diabetes (blood, glucose) ◻ Blood cholesterol levels hypertension ◻ Malaria infection ◻ HIV (if qualified as counsellor) ◻ Fertility and pregnancy (urinary) ◻ Peak respiratory flow rate (peak flow meter) • Urine diagnostic testing for: ◻ Infection ◻ Renal disorders ◻ Metabolic diseases (diabetes mellitus)
First aid measures	• Current and recognised first aid principles • The symptoms of poisoning, drug abuse, drug overdose and other toxic substances • Appropriate treatment of: ◻ Exposure to toxic doses of drugs or chemicals ◻ Ingestion of toxic doses of drugs or chemicals ◻ Substance abuse
General Care giver	• The person other than the patient receives the medicine on behalf of the patient
Identify signs and symptoms	• Verbal information • Visual examination • Vital signs observation • Basic examination of identified areas related to disease conditions • Physical • Behavioural
Intervened	• Change of dose • Change of therapy

Patient history	• Past conditions • Present symptoms • Past treatments • Drug history • Clinical history • Demographics • Socio-economic milieu • Family history
Records	• Patient history • Examination and test results • Care plan implementation • Therapy or drugs administered • Outcomes
Referral	• In accordance with the current Specific Guidelines for Pharmacy Practice
Safe use of chemicals	• Identification of chemical • Label clearly and completely • Attach cautionary and advisory instructions • Correct and safe storage • Appropriate packaging • Safe disposal
Treatment	• immunise • Dress wound • Administer initial dose • Administer injections, • Cardiopulmonary resuscitation • Administer first aid

Assessment (Tick appropriate box) - In general, does **Standard 4** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

5. COMPETENCY STANDARD FIVE: PROVIDE INFORMATION AND EDUCATION ON HEALTH CARE AND MEDICINE

Does this standard apply to me?

The standard applies to all pharmacists who are required to give advice, recommendations and actions which have a direct impact on patient outcomes.

INTRODUCTION

The provision of drug and health care information and education forms an integral part of the scope of practice of the pharmacist. This requires the provision of information to the patient and to other members of the healthcare team.

The entry level pharmacist should at least have a good knowledge of the components of communicating information on the use of drugs, disease states and health care to the patient and other health care workers, including but not limited to:

- identifying the information needs;
- appropriate communication of the information;
- common human and veterinary disease states;
- sourcing and interpreting information from relevant reference sources; and
- the relevant legislation.

Education of the patient on the prevention and treatment of commonly encountered disorders and healthy life styles also forms an important component of this capability.

The standard presented here reflects those competencies required for the entry level pharmacist to demonstrate capability in assessing and supplying the information needs of the patient and other health care workers. The standard was determined by consultation with the pharmaceutical manufacturing industry, the pharmaceutical distribution industry, hospital and community pharmacy. The outcomes and assessment criteria are workplace related and represent the minimum assessment criteria for the evaluation of competency within the pharmacy workplace.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of accessing, interpreting, evaluating and supplying information on the nature and use of drugs, disease states and health care to the public, health care providers and patients

The following outcomes of this capability should be demonstrated by the candidate:

5.1 Provide information on request.

A person who has achieved this outcome is capable of:
(a) Identifying **information** needs. (b) Interpreting request for level, content and final use of information. (c) Deciding to either refer or accept the request. (d) **Using appropriate** source. (e) **Evaluating information for relevance and scientific integrity.** (f) **Communicating information promptly, clearly and accurately.** (g) **Verifying that information was understood.** (h) **Ascertaining that the information supplied meets the need of the recipient.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

5.2 Initiate and/or participate in the provision of health care education and information to the public and other health care professionals on request.

A person who has achieved this outcome is capable of:
(a) **Identifying targeted educational and information need.** (b) **Selecting appropriate method of delivery of information.** (c) **Accessing relevant information and process.** (d) **Communicating information clearly and accurately.** (e) **Ensuring that the information was understood by the audience.** (f) **Ascertaining that the information supplied met the perceived needs of the target audience.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

5.3 Interpret scientific information to provide basis for rational drug use.

A person who has achieved this outcome is capable of:
(a) Retrieving data from appropriate **sources.** (b) Evaluating information for relevance against need. (c) Interpreting data to draw conclusions on rational drug use and evidence-based treatment.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐

IF YES, on the basis of the evidence I have identified I can do this.

5.4 Training of the pharmacist intern in providing information and education in health care and medicine.

A person who has achieved this outcome is capable of:
(a) Familiarising the pharmacist intern with the correct procedures in conducting and providing effective education and information programmes. (b) Familiarising the pharmacist intern with the terminology used in conducting and providing effective education and information programmes. (c) Familiarising the pharmacist intern with the correct methods of organising the retrieval and presentation of relevant information to meet the educational and other information needs of the public and other health care providers. (d) Familiarising the pharmacist intern with the principles of communicating information in a clear and systemic manner and to present conclusions on rational drug uses clearly and convincingly. (e) Assisting the pharmacist intern in the self-assessment of their capabilities against determined unit standards. (f) Providing guidance to the pharmacist intern in conducting and providing effective **education and information** programmes to the public and other health care professionals. (g) Assessing progress of the pharmacist intern and providing feedback. (h) Assisting the pharmacist intern in solving relevant learning problems in conducting and providing effective education and information programmes.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Education and information	• Immunisation • Family planning • Family health promotion • Infectious diseases • Coronary heart disease and stroke prevention • Cancer prevention, screening and care • Mental health promotion • HIV/AIDS and STD prevention • Prevention of accidents and trauma management • Pregnancy, breast feeding and infant nutrition • Travel and holiday health care • Smoking cessation

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
	• Substance abuse prevention • Healthy life style promotion • Environmental awareness (water supply, pollution, living conditions) • Rational drug usage and drug induced diseases • Nutrition • Product information (prescription and over the counter/self-medication) • Self-medication • Drug resistance patterns and treatments • Veterinary medicines • Pet care • Animal health • Product training for sales representatives • Technical product information to health care providers and institutions • Product information within the company • Undergraduate training of pharmacists • Pharmaceutical information to health care providers and other institutions and educators • Continuing education of pharmacists • Availability of medicines • Product and service information
Information	• Health care • Use of medicines • Animal health, veterinary medicines and products • Safe use of chemical substances for industrial, hobby and home use
Patient type/condition on which information may be provided	• Paediatrics • Gerontology • Mother and child • Chronic diseases • Acute diseases • Disabled patient (physically and mentally) • Terminally ill patient • Geriatrics
Sources	• Drug Information centres • Electronic data • Clinical literature

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Users of information	• Patients • Health care providers • Managed health care providers • Academic and educational institutions • Pharmaceutical industry • Public / State • Hospitals • Medical aid organisations • Traditional healers

Assessment (Tick appropriate box) - In general, does **Standard 5** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

6. COMPETENCY STANDARD SIX: PROMOTE COMMUNITY HEALTH AND PROVIDE RELATED INFORMATION AND ADVICE

Does this standard apply to me?

This standard applies to all pharmacists who are involved with promoting community health and providing related information and advice.

INTRODUCTION

As an accessible member of the health care team, the pharmacist plays an important role in the maintenance of the health of the community. The promotion of health by the implementation of disease prevention programmes in the community at large, screening programmes to identify community health deficiencies and responding to epidemiological trends in the community are important roles of the pharmacist in his or her role as a health care provider.

The pharmacist should at least have a good knowledge of the components of community health including but not limited to:

- identifying the health education needs of the community;
- communicating the relevant information to the community;

- conducting screening programmes within the community that will promote good health and healthy life-styles;
- applying national health policies, for example, immunisation programmes, and primary and preventative programmes;
- involvement in community health projects; and
- the relevant legislation.

The pharmacist must also have a good base-line knowledge of community health educational requirements and the capability to assist in the development of appropriate programmes that will ensure that community centred concerns including infectious diseases, substance abuse, and occupational health, are communicated effectively and addressed with the community at large.

The standard presented here reflects those competencies required for the pharmacist to demonstrate capability in assessing and providing for the community health needs of the community. The standard was determined after consultation with the hospital and community sectors of pharmacy. The outcomes and assessment criteria are workplace related and represent the minimum assessment criteria for the evaluation of competency within the pharmacy workplace.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of identifying community health needs, planning and implementing promotive and preventative programmes, including screening, directly observed therapy and immunisation. The following outcomes of this capability should be demonstrated by the candidate:

6.1 Identify the health education needs of the community.

A person who has achieved this outcome is capable of:
(a) Identifying trends in requests for information and medicine relating to community and occupational health needs. (b) Relating identified trends to community health needs.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

6.2 Promote promotive and preventative health education.

A person who has achieved this outcome is capable of:
(a) Deciding on an appropriate response to the identified. (b) Identifying health education needs. (c) Selecting a method of delivery that is appropriate to the nature of the identified education needs and the target community. (d) Retrieving and processing information relevant to the identified needs. (e) Communicating information clearly and accurately. (f) Verifying for the effectiveness of the education programme. (g) Ascertaining that the information supplied meets the perceived needs of the target audience. (h) Preparing and providing community health education programmes for presentation by members of the community.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

6.3 Initiate and participate in community health projects.

A person who has achieved this outcome is capable of:
(a) **Identifying and evaluating existing and potential local** community health projects**.** (b) **Initiating and/or participating in** community health projects. (c) **Participating in directly observed therapy (DOT) programmes.** (d) **Participating in screening tests for public health authorities.** (e) **Initiating an appropriate response to the requirements of the** community health projects**.** (f) **Participating according to identified role for the pharmacist.** (g) **Following up and evaluating outcomes of the projects.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

6.4 Conduct screening programmes to identify health deficiencies in the community.

A person who has achieved this outcome is capable of:
(a) Identifying areas where screening can be done to identify health deficiencies and deviations in the community. (b) Planning, organising and publicising screening activity. (c) Checking operation of equipment, materials and reagents. (d) Conducting an effective screening programme. (e) Identifying patients needing follow-up care and advice and/or referring appropriately. (f) Following up for patient compliance for referral advice. (g) Maintaining documentation according to legal requirements and Good Pharmacy Practices.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

6.5 Note and respond to epidemiological trends in the community, including reporting notifiable diseases.

A person who has achieved this outcome is capable of:
(a) Noting and monitoring epidemiological trends in the local community. (b) Deciding whether to initiate formal research. (c) Providing community education. (d) Referring to appropriate authority. (e) Advising community leaders (e.g. school principals). (f) Detecting and reporting notifiable diseases according to legal requirements.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

6.6 Participate in developing, establishing and managing drug and health policies.

A person who has achieved this outcome is capable of:
(a) **Providing appropriate** input **in the formulation of** drug and health policies **in conjunction with a multi-disciplinary team.** (b) **Participating in** monitoring **the implementation of the policies.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

6.7 Training the pharmacist intern in the promotion of community health and the provision of information and advice.

A person who has achieved this outcome is capable of:
(a) Familiarising the pharmacist intern with the correct procedures in identifying the health education needs and the epidemiological trends in a local community and devising appropriate programmes. (b) Familiarising the pharmacist intern with the application of pharmaceutical skills and knowledge to conduct effective screening programmes in the community to identify health deficiencies in the community. (c) Familiarising the pharmacist intern with the correct methods of organising effective community health projects, screening programmes and educational programmes. (d) Familiarising the pharmacist intern with the principles of communicating information in a clear and systemic manner and to report epidemiological trends and notifiable diseases clearly and convincingly to relevant officials. (e) Assisting the pharmacist intern in the self-assessment of their capabilities against determined unit standards. (f) Providing guidance to the pharmacist intern in conducting and providing effective community education, information and screening programmes to the community. (g) Providing guidance to the pharmacist intern to relate pharmaceutical, economic, social and governmental systems when providing input to health and drug policies. (h) Assessing progress of the pharmacist intern and providing feedback. (i) Assisting the pharmacist intern in solving relevant learning problems in conducting and providing effective community education, information and screening programmes.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Community health project	• Immunisation • Family planning • Family health promotion • Coronary heart disease and strokes • Cancer and mental health • HIV/AIDS and sexual health • Accident prevention • Occupational health • Infectious diseases • Pregnancy, breast feeding and infant nutrition • Travel and holiday health care

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
	• Smoking cessation • Substance abuse • Healthy life style • Environmental awareness • Self-care promotion • Nutrition • Correct drug use • Self-medication • Infectious disease prevention
Drug and health policies	• Essential drug lists • Standard treatment protocols • Immunisation programmes • National health policy • Hospital drug policies • Primary and preventative programmes • Formularies • Infection control
Education programmes	• Coronary heart disease and strokes • Cancer • Mental health • HIV/AIDS and sexual health • Accident prevention • Occupational health • Infectious diseases • Pregnancy, breast feeding and infant nutrition • Travel and holiday health care • Smoking cessation • Substance abuse • Healthy life style
Input	• Availability of medicines • Dosages • Treatment protocols • Drug-drug and drug-disease interactions • Medicine safety • Rational drug use • Compliance issues • Administration • Post marketing surveillance data • Cost-effective use of medicines

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Method of delivery	• Personal contact • Printed material • Presentations: □ Personal □ Television □ Video □ Radio □ Electronic media □ Community networking
Monitoring	• Correct choice of drugs • Correct treatment protocols
Notifiable diseases	• As defined by the relevant health authority regulations
Screening programmes	• Diabetes (blood glucose) • Tuberculosis immunity (skin test) • Blood cholesterol level • Hypertension • Cancer (breast examination information) • Malaria • HIV (if qualified as councillor) Fertility and pregnancy • Peak respiratory flow rate (peak flow meter) • Urine diagnostic testing

Assessment (Tick appropriate box) - In general, does **Standard 6** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

7. COMPETENCY STANDARD SEVEN: PARTICIPATE IN RESEARCH TO ENSURE THE OPTIMAL USE OF MEDICINES

Does this standard apply to me?

The standard applies to all pharmacists.

INTRODUCTION

As a member of the health care team, the pharmacist plays an important role in the performance of research. Although traditionally in pharmacy, research has been centred on the pharmaceutical sciences, there is an increasing need for research into aspects of pharmacy practice in order for a basis to be formed for the future development of policy. Practising pharmacists are increasingly taking part in health systems research, which must be encouraged as a means of providing data bases for future development. Such research is often conducted in collaboration with other health care providers.

Pharmacists should be able to participate in research including research into pharmacy practice, as well as the use of drugs in therapeutics. This research may include investigations into prescribing practices, patterns of drug usage, the monitoring of adverse reactions, the pharmacist's advisory role, computerised data handling, health economics, legislation, and the various aspects of abuse and non-rational use of drugs. Another important role filled by pharmacists in South Africa is in the registration process of medicines.

The pharmacist should at least have a basic knowledge of the following components including but not limited to:

- research methodology;
- the registration process of medicines;
- research and development of medicines; and
- research into health-systems.

The standard presented here reflects those competencies required for the pharmacist to demonstrate the capability to participate in research. The standard was determined after consultation with the pharmaceutical industry, the pharmaceutical distribution industry, hospital and community pharmacy. The outcomes and assessment criteria are workplace related and represent the minimum assessment criteria for the evaluation of competency of outcome criteria for a competent pharmacist.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of participating in research and applying research findings to health care.

The following outcomes of this capability should be demonstrated by the candidate:

7.1 Participate in the research and development of medicines and health care strategies.

A person who has achieved this outcome is capable of:
(a) Interpreting stated research problem. (b) Surveying and evaluating secondary data for relevance and scientific integrity, whilst demonstrating sensitivity for alternative customs and approaches to health care. (c) Developing appropriate research design, implementing research design. (d) Collating and analysing data. (e) Drawing valid conclusions. (f) Writing a credible report and disseminating timeously. (g) Responding professionally to peer comments.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.2 Participate in the registration of medicines.

A person who has achieved this outcome is capable of:
(a) **Collating** data **relevant to the registration of a medicine.** (b) **Compiling medicine registration application according to the relevant act for submission to the health authority.** (c) **Maintaining, updating and reviewing** documentation **for product licences according to legal requirements.** (d) **Communicating effectively with health authorities.** (e) **Supplying principals with required information.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.3 Compliance with the legal requirements relating to the registration and control of medicines.

A person who has achieved this outcome is capable of:
(a) Applying for and maintaining of the relevant licences, e.g. a manufacture or wholesale licence (MCC), premises licence (DoH), site recording with SAPC. (b) Registration of the Responsible Pharmacist. (c) Demonstrating an understanding of the legal issues regarding signing of documents. (d) Understanding the Acts pertaining to the registration and control of registered and unregistered/investigational medicines, e.g. the Medicines and Related Substances Act, 101 of 1965, Pharmacy Act, 53 of 1974 and/or Foodstuffs, Cosmetics and Disinfectants Act, 54 of 1972 and/or Fertilizer, Farm feeds, Agricultural Remedies and Stock Remedies Act, 36 of 1947. (e) Understanding the special provisions for the use of unregistered medicines for either compassionate use or clinical research. (f) Assuring that third party contracts and technical/GMP agreements are in place. (g) Assuring Quality Management systems are in place. (h) Assuring product labelling, advertising and promotional activity compliance. (i) Assuring timeous payments of applicable SAPC and MCC annual fees. (j) Obtaining required import and export permits.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.4 Ensure proper record keeping or maintenance of documents.

A person who has achieved this outcome is capable of:
(a) Applying the basic principles of the record keeping and document control. (b) Compilation and control of Standard Operating Procedures. (c) Maintaining adequate medicine application documentation systems. (d) Maintaining proper records of amendments/variations to medicine applications or dossiers. (e) Maintaining proper records of regulatory commitments. (f) Ensuring regulatory compliance and change control. (g) Providing principals with required information, e.g. guidelines, applications, amendments, agreements, contracts. (h) Applying Quality Risk Management. (i) Understanding Master Batch Documentation and Executed Batch Records. (j) Understanding the principles of recognised Pharmacopoeias as the basis of medicines control through adequate specification and control procedures. (k) Understanding the principles of the control of active pharmaceutical ingredients (API's), inactive pharmaceutical ingredients (IPI's) and other items used in the manufacture of medicines. (l) Understanding the principles of change control regarding all aspects of the control of medicines. (m) Understanding the principles and requirements for the writing of package inserts and patient information leaflets based on approved reference books.

(n) Understanding the requirements for characterisation of API's and batch to batch conformity. (o) Understanding the principles of stability testing of API's and final products. (p) Understanding the principles of product development. (q) Understanding, interpreting and applying statistical analysis. (r) Principles of demonstrating bioequivalence. (s) Demonstrating an ability to compile and maintain Site Master Files
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.5 Compile and maintain a medicine registration dossier.

A person who has achieved this outcome is capable of:
(a) Evaluating and conducting due diligence on a registration dossier. (b) Using the appropriate type of medicine registration application format. (c) Compiling a medicine registration application in accordance with MCC and other guidelines, where relevant relating to medicine registration e.g. ICH, WHO, FDA, EMA, etc. (d) Compiling and updating of the Package Insert (PI) and Patient Information Leaflet (PIL). (e) Compiling, maintaining and understanding the significance of pharmaceutical development, specifications and control procedures for APIs, IPIs, container closure systems, finished pharmaceutical product; formulation/composition, manufacturing, stability of APIs and finished pharmaceutical products, pharmaceutical and biological availability, nonclinical and clinical evidence. (f) Be able to compile a Common Technical Document (CTD). (g) Demonstrating an understanding of regulatory compliance and change control. (h) Demonstrating an understanding of amendment and maintenance of the registration dossier.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.6 Pharmacovigilance.

A person who has achieved this outcome is capable of:
(a) Understanding pharmacovigilance and the requirements locally and internationally in this regard. (b) Reporting adverse reactions/events. (c) Managing safety related complaints and recalls. (d) Demonstrating an understanding of Risk Management. (e) Demonstrating an ability to audit and to be audited. (f) Demonstrating an understanding of Medical Information services. (g) Understanding import and export requirements. (h) Demonstrating an ability to communicate with Health Authorities. (i) Demonstrating an ability to identify and supply principals with required information. (j) Handling complaints.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.7 Promotional material and activities.

A person who has achieved this outcome is capable of:
(a) Ensuring that all claims are supported by scientific data and do not go beyond the data as approved in the package insert. (b) Complying with the SA Code of Practice for the Marketing of Health Products, and other relevant legislation. (c) Checking if the packaging material meets the requirements of the regulations relating to labelling and the registration dossier. (d) Checking the accuracy of the packaging material (i.e. no spelling errors and correct information and grammar). (e) Understanding advertising and marketing of medicines and has the ability to approve artwork and certify promotional activities. (f) Understanding advertising and marketing of medicines and has an ability to approve and certify, as applicable, promotional material and activities.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.8 Ensure quality assurance in the registration of medicine

A person who has achieved this outcome is capable of:
(a) Providing grammatically correct text and the correct scheduling status for printed packaging materials. (b) Checking compliance of a medicine with the approved registration dossier. (c) Interpreting Master Batch Documentation and Executed Batch Records. (d) Releasing a medicine for sale.

(e) Compiling and maintaining Site Master Files. (f) Assuring self-inspections. (g) Assuring annual product review. (h) Demonstrating an ability to handle deviations and change control.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

7.9 Training the pharmacist intern in the participation in research to ensure the optimal use of medicines.

A person who has achieved this outcome is capable of:
(a) Familiarising the pharmacist intern with the correct procedures in developing and managing an effective research design, collating and analysing data and drawing valid conclusions. (b) Familiarising the pharmacist intern with the application of pharmaceutical skills and knowledge to apply research principles and current technology to collate and interpret data and present research findings according to scientific standards. (c) Familiarising the pharmacist intern with the correct methods of relating pharmaceutical research findings to social, legal, and economic systems when drawing conclusions on health strategies from such findings. (d) Familiarising the pharmacist intern with the principles of communicating research findings in a clear and scientific manner and to present these in scientific journals of international standing. (e) Assisting the pharmacist intern in the self-assessment of their capabilities against determined unit standards. (f) Providing guidance to the pharmacist intern in conducting and participating in research to ensure the optimal use of medicines. (g) Providing guidance to the pharmacist intern to relate pharmaceutical, economic, social and governmental systems to research findings when providing input to health and drug policies. (h) Assessing progress of the pharmacist intern and providing feedback. (i) Assisting the pharmacist intern in solving relevant learning problems in conducting and participating in research to ensure the optimal use of medicines.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Data and documentation	• Chemistry • Pharmacology • Pre-clinical • Clinical • Pharmaceutical
Research area	• Drug delivery systems • Manufacturing processes • New chemical entity • Epidemiology of disease • Disease prevention and management • Drug-efficacy and safety trials • Patient compliance with drug therapy • Design, utilisation and effectiveness of formularies • Pharmacoeconomics, drug utilisation underlying evidence based medicine • Market/consumer • Patient-acceptability research • Quality of life research • Emergent diseases • Post marketing drug surveillance • Drug resistance patterns

Assessment (Tick appropriate box) - In general, does **Standard 7** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

8. COMPETENCY STANDARD EIGHT: FACILITATE THE DEVELOPMENT OF PHARMACEUTICAL PERSONNEL

Does this standard apply to me?
The standard applies to all pharmacists who play a role in the development of pharmacy personnel.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of self–development and development and management of personnel.

The following outcomes of this capability should be demonstrated by the candidate:

8.1 Self-development.

A person who has achieved this outcome is capable of:
(a) Assessing his or her knowledge, skills and values, and identify areas which require improvement to meet current practice needs and standards. (b) Identifying appropriate resources and activities, which are available for learning. (c) Applying new knowledge obtained from continuing professional development to my daily practice. (d) Modifying his or her behaviour in response to feedback from peers, co-workers or allied health professionals. (e) Understanding the need for planning as it relates to life-long learning. (f) Maintaining a portfolio of professional and personal development.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

8.2 Development/management of personnel.

A person who has achieved this outcome is capable of:
(a) Defining the accepted standards, policies and procedures that personnel follow. (b) Giving and receiving constructive feedback. (c) Acknowledging the roles of other team members. (d) Demonstrating patience, understanding, approachability, fairness and other relevant interpersonal skills. (e) Working as a member of a team. (f) Cooperating with others in cases of conflicting views and applying effective negotiation skills. (g) Determining the training requirements of learners against criteria (standard operating procedures and unit standards). (h) Ensuring development of on-the-job coaching and assessment against criteria.

(i) Ensuring that evidence of competency is gathered by learners and collated in portfolios of evidence for tracking current learning acquired as well as the recognition of prior learning (RPL).
(j) Facilitating the competency of learners in the use of relevant terminology, equipment, and standard operating procedures required in pharmacy activities.
(k) Continuously updating portfolios of evidence with evidence of new competencies acquired.
(l) Facilitating problem solving during the learning process to ensure effectiveness and efficiency of development.
(m) Regularly providing feedback regarding learner development in the workplace.
(n) Evaluating team performance in key performance areas against agreed outcomes.
(o) Facilitating team training and development to ensure best practice.
(p) Establishing and maintaining effective lines of communication within the team.

Assessment (Tick appropriate box)

Does this outcome form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES, on the basis of the evidence I have identified I can do this.

Assessment (Tick appropriate box) - In general, does **Standard 8** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

9. COMPETENCY STANDARD NINE: PRACTISE PHARMACY PROFESSIONALLY AND ETHICALLY

Does this standard apply to me? **The standard is compulsory for all pharmacists.**

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of working professionally in pharmacy practice, complying with legal requirement and code of conduct, practising pharmacy within a South African cultural framework and communicating effectively.

The following outcomes of this capability should be demonstrated by the candidate:

9.1 Work professionally in pharmacy practice.

A person who has achieved this outcome is capable of:
(a) **Evaluating information given for relevance, scientific correctness, accuracy and clarity.** (b) **Interpreting written and verbal information and presenting it to the patient/caregiver in an appropriate verbal and/or written manner.** (c) **Developing a trusting, professional relationship with individual patients.** (d) **Being accessible to patients and communicating effectively with patients.** (e) **Documenting his or her interventions and follow up on the outcome of interventions.** (f) **Documenting communication with other health care providers.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

9.2 Practise pharmacy within a South African cultural framework.

A person who has achieved this outcome is capable of:
(a) Demonstrating sensitivity to alternative approaches and customs in health care. (b) Demonstrating sensitivity to alternative customs and approaches to health care during the research process. (c) Explaining the pharmacist's role in the health care system. (d) Respecting confidentiality related to patients' issues and information. (g) Respecting the right of patients to make their own choice.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

9.3 Comply with legal requirements and code of conduct.

A person who has achieved this outcome is capable of:
(a) Practising pharmacy in a manner consistent with the professional code of conduct. (b) Fulfilling the legislative requirements pertaining to pharmacy practice including the control of medicine. (c) Complying with legislative requirements for health and safety in the workplace. (d) Developing a professional relationship with other health care providers. (e) Understanding and applying legislative principles and current good pharmacy practice guidelines affecting the operation of pharmacies and the supply of medicine. (f) Maintaining appropriate boundaries with patients, staff and other health professionals according to established ethical and professional practice guidelines. (g) **Maintaining knowledge of changing standards of professional practice and practise accordingly.**
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

9.4 Communicate effectively.

A person who has achieved this outcome is capable of:
(a) Communicating effectively with patients face to face. (b) Communicating effectively with patients by telephone. (c) Communicating effectively with other health care professionals in person. (d) Communicating effectively with other health care professionals by telephone. (e) Listening actively. (f) Asking the questions that fit the situation. (g) Communicating with patients to identify the level, content and final use of information in a culturally sensitive manner.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

Assessment (Tick appropriate box) - In general, does **Standard 9** form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, ☐ I have assessed my competency in this standard and can provide evidence in all of the elements. ☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.

10. COMPETENCY STANDARD TEN: MANAGE THE PHARMACY/ PHARMACEUTICAL SERVICE.

Does this standard apply to me?

The standard is compulsory for all pharmacist who are in managerial or supervisory positions.

CAPABILITY AND OUTCOMES

A person who has achieved this standard is capable of managing the pharmacy / pharmaceutical service.

The following outcomes of this capability should be demonstrated by the candidate:

A person who has achieved this outcome is capable of:
(a) Identifying relevant pharmacy practice issues or problems that she/he could and should eliminate. (b) Readily approaching peers, co-workers or other health professionals for assistance as necessary. (c) Supervising personnel. (d) Developing, maintaining and applying standard operating procedures. (e) Dealing effectively with multiple demands. (f) Know staff security measures. (g) Preparing and interpreting various financial statements relating to my practice setting. (h) Practising in a financially responsible manner in order to maintain a viable pharmacy practice. (i) Explaining the principles of inventory management and putting these into practice. (j) Communicating changes in legislation to staff (e.g. Rx to OTC etc.). (k) Demonstrating a working knowledge of labour legislation. (l) Ensuring that standard operating procedures are available, ensure best practice and are in an instructional format. (m) Following and understand quality control procedures in pharmacy activities. (n) Ensuring that the pharmacy work team is organised to optimise output, quality and cost. (o) Identifying, clarifying and responding to work-related problems and ensuring that they are resolved within the team to achieve optimum performance. (p) Identifying and responding to labour relations issues timeously in a way that balances the interests of personnel and management within the legislative requirements. (q) Organising and conducting regular meetings with team members to determine courses of action to deal with problems affecting the pharmacy/ pharmaceutical service.
Assessment (Tick appropriate box) Does this outcome form part of my current practice of pharmacy? **Yes** ☐ **No** ☐
IF YES, on the basis of the evidence I have identified I can do this.

Assessment (Tick appropriate box) - In general, does **Standard 10** form part of my current practice of pharmacy?

Yes ☐ **No** ☐

IF YES,

☐ I have assessed my competency in this standard and can provide evidence in all of the elements.

☐ I have assessed my competency in this standard and will undertake CPD in the outcomes that I currently cannot provide evidence for, in order to meet all the requirements of this standard.