GUIDANCE DOCUMENT FOR CPD FOR PERSONS REGISTERED WITH THE SAPC

DRAFT GUIDANCE DOCUMENT FOR CONTINUING PROFESSIONAL DEVELOPMENT (CPD) FOR PERSONS REGISTERED WITH THE SOUTH AFRICAN PHARMACY COUNCIL

INTRODUCTION

1. The South African Pharmacy Council (SAPC) has resolved to introduce continuing professional development for pharmacists and other persons registered with the Council who have completed the relevant qualification required for purposes of registration. Pharmacy interns and pharmacist's assistants who are still undergoing training are excluded from the requirements relating to CPD.

2. Persons registered with the SAPC will be required to submit a record of their CPD activities in accordance with the CPD cycle. A web based system will be used for the submission of details of CPD activities.

3. In the case of persons who do not have access to the Internet special arrangements will be made (e.g. submission on a CD). A paper based submission may be allowed in exceptional circumstances.

4. Each registered person will be required to keep a portfolio of evidence. The evidence may be kept in electronic format. The SAPC may require the portfolio of evidence to be submitted at any time. Evidence may be submitted electronically. Hyperlinks must be inserted were appropriate.

5. The SAPC will assess submissions to ensure that persons registered with the SAPC have complied with the requirements relating to participation in and recording of CPD. At this stage competence to practise will not be assessed. An element of trust will, however, be involved in that registered persons have an ethical obligation to ensure that they are competent to practise.

6. 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 competence throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training'.

7. Continuing professional development will be regulated in terms of the Pharmacy Act, 1974. A set of regulations entitled *Regulations relating to continuing professional development for persons registered in terms of the Pharmacy Act* will be published. Consequential amendments may need to be made to other sets of regulations or rules e.g. the Rules relating to acts or omissions in respect of which the Council may take disciplinary steps and the *Regulations relating to the registration of persons and the maintenance of registers* to accommodate the CPD process.

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WHY IS CONTINUING PROFESSIONAL DEVELOPMENT NECESSARY

1. Pharmacists and pharmacist's assistants are health care professionals whose professional responsibilities include seeking to ensure that people derive maximum therapeutic benefit from their treatment with medicines. This obligation requires them to keep abreast of developments in pharmacy practice and the pharmaceutical sciences, professional standards requirements, the laws governing pharmacy and medicines and advances in knowledge and technology relating to the use of medicines. This can only be achieved by an individual's personal commitment to continuing professional development.

2. It is a professional obligation for pharmacists and pharmacy support personnel to remain informed about the profession in scientific, social, political and legal terms and to maintain a level of competence sufficient to provide pharmaceutical services, including pharmaceutical care, effectively and efficiently. CPD must address emerging health needs and be relevant to the health priorities of the country.

3. Patients have a right to be confident that all professionals providing health care remain competent throughout their professional working lives. The mandate for the SAPC as the regulatory authority is to protect the public. Council should ensure that persons registered with the SAPC undertake CPD to maintain their competence to practise. CPD will assist Council to identify pharmacy personnel who have been unable to maintain their competence to practise. Implementation of CPD will improve the knowledge and skills of registered persons, and improve the quality of services provided to patients.

4. It is imperative that CPD should be relevant to the practice of the registered person. Furthermore CPD should be concerned with, and encourage and enhance, career development.

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WHO MUST PARTICIPATE IN CONTINUING PROFESSIONAL DEVELOPMENT

1. Participation in CPD is mandatory for all persons registered with the South African Pharmacy Council (SAPC) who have completed the relevant qualification and who perform any one or more of the functions which fall within the scope of practice of the category in which they are registered. This requirement is also applicable to pharmacists performing community service.

2. All persons registered with the South African Pharmacy Council who perform any one or more of the functions relating to the scope of practice of a pharmacist or pharmacist's assistant as laid down in the *Regulations relating to the practice of pharmacy* published in terms of the Pharmacy Act 53 of 1974 must comply with the requirements relating to CPD determined by the SAPC.

3. Pharmacy schools will be required to prepare pharmacy students to participate in and record CPD activities.

4. Provision will be made for persons registered with the SAPC to be designated on the applicable register as either practising or non-practising. The designation ‘practising’ will apply to those persons who are performing functions which fall within the scope of practice of the category in which he/she is registered. The designation ‘non-practising’ will apply to those persons who are not performing functions which fall within the scope of practice of the category in which he/she is registered.

5. Persons registered with the SAPC will be required to make a declaration as to whether they are practising or not practising i.e. performing functions relating to the scope of practice of the category in which they are registered or whether they intend to perform such functions in the following year.

6. This declaration will be made when a person registers with Council for the first time in a particular category as well as on an annual basis at the time of payment of the annual fee for persons registered with the SAPC. Registered persons will also be reminded of the onus placed on them in terms of ‘Ethical Rule’ 22 to only perform functions that they are competent to perform.

7. The SAPC will issue a certificate to each registered person indicating whether he/she is designated as practising or not practising (practice certificate).

8. Any person registered with the SAPC who is designated as practising will be required to make a declaration on an annual basis that he/she will comply with the requirements of the SAPC with regard to CPD.

9. If a person who has declared that he/she is not practising and he/she wishes to commence practising he/she must inform Council that he/she wishes to change his or her designation at least 30 days prior to commencing the performance of functions that fall within the scope of practice of the category in which he/she is registered. A fee may be levied by Council for the change of designation of a person from practising to non-practising and *vice versa.*

10. A person who is restored to the register after removal from the register for any reason will be required to make a declaration as to whether he/she intends practising or not practising.

11. Persons who return to active practice after not practising for a period of time may be required to comply with certain conditions that the Council may determine.

12. In the case of a person who changes from the designation ‘non-practising’ to ‘practising’ or who is restored to the registers of Council and designated on the register as ‘practising’, he or she must retain the designation of ‘practising’ until the end of January of the year following the year during which his or her designation was changed to ‘practising’ or his or her name was restored to the register and designated as ‘practising’.

13. Information relating to whether a person is designated as practising or not practising will be recorded on the applicable registers of persons as maintained by the SAPC.

14. A person registered with Council may submit an application for deferment of compliance with the requirements relating to CPD for reasons acceptable to Council such as illness, personal circumstances etc. Such applications may be prospective or retrospective. Deferment may be granted by Council for a specified

period of time and subject to conditions determined by Council. Applications for deferment will be dealt with on a case by case basis.

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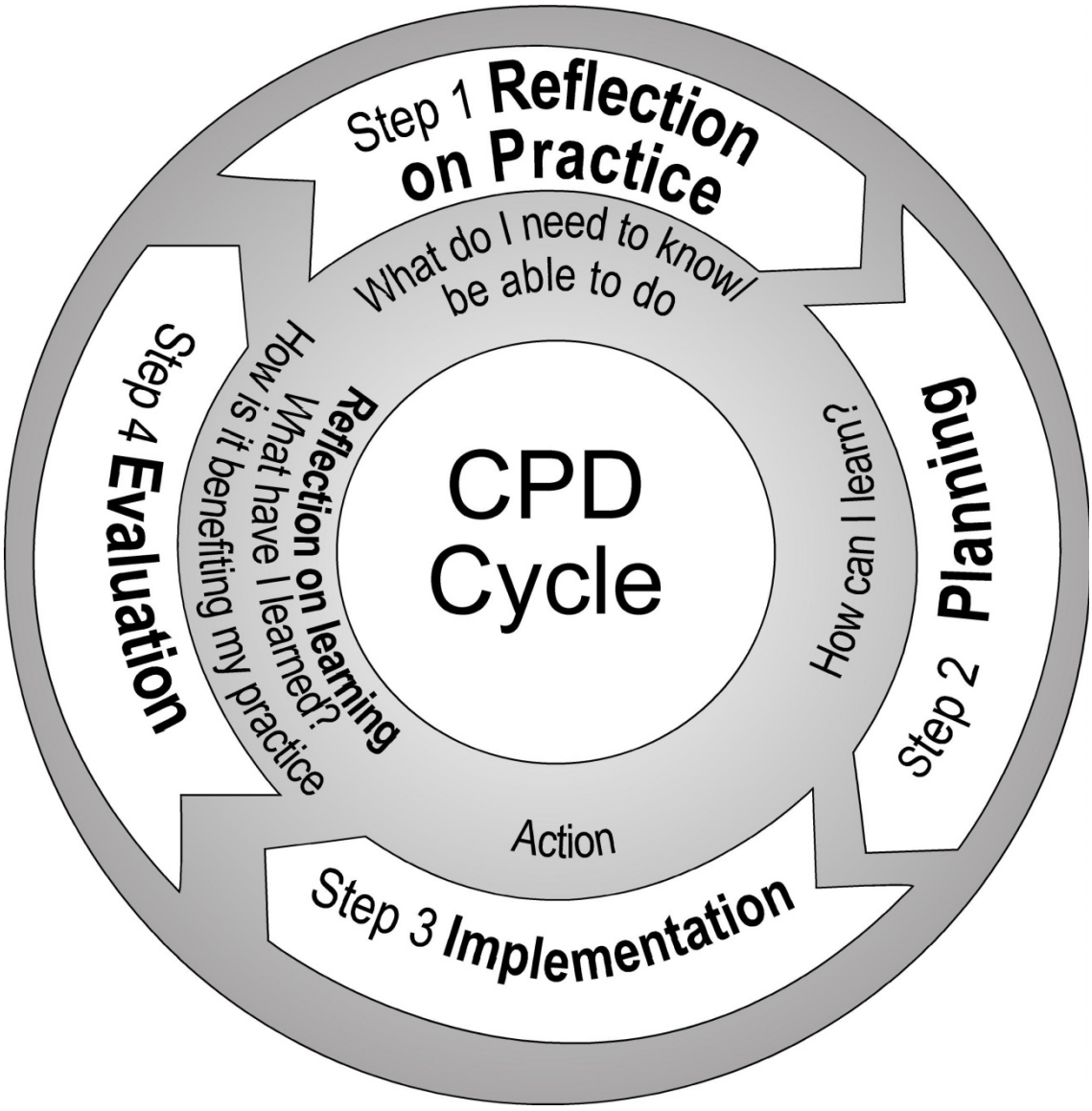
REQUIREMENTS RELATING TO CPD FOR PERSONS REGISTERED WITH THE SAPC

1. A person who is registered with the SAPC in one of the categories prescribed in terms of Section 14 of the Pharmacy Act, 1974 and who is designated on the register as 'practising' may have his or her designation on the register changed by Council from 'practising' to 'non-practising' if he/she does not comply with the requirements of Council relating to participation in CPD and the recording thereof in the format approved by the SAPC.

2. All persons registered with the Council who are designated as 'practising' will be required to participate in CPD by following the CPD cycle shown in Figure 1 below. The CPD cycle is a process that involves four steps viz:

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

FIGURE 1. THE CPD CYCLE



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

Identifying his or her 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 his or her preferred learning style to gain knowledge;

Evaluating the outcome of the learning activity;

Applying knowledge to his or her own practice situation.

3. Each person who is required to participate in CPD must record his or her CPD activities in the web based format required by Council. In the case of persons who

do not have access to the web based system special arrangements will be made for the submission of the required information by the registered person.

4. Information must be provided on each step in the CPD cycle undertaken.

5. A web based database will be used whereby persons will enter the required details of their CPD related activities on a website administered by the SAPC or an agent of the SAPC.

6. It will be possible to download a blank template for the recording of CPD activities and upload entries when Internet access is available.

7. Initially only pharmacists will be required to record and submit the required information. At a later stage the system of compulsory recording and submission will be extended to other persons registered with the SAPC.

8. Persons registered with the Council will also be required to keep a portfolio of evidence. The format of the portfolio may be determined by the individual. Council could request submission of the portfolio in cases where the registered person fails to record his or her activities as required by Council or for any other reason that Council may determine. When requested portfolios of evidence may be submitted electronically.

9. Each person will be required to complete a **Personal Profile Sheet (PPS)** - Appendix A. The PPS provides a summary of the person's qualifications and area of practice. The PPS will also assist a person registered with the SAPC to reflect on the activities that form part of his or her daily practice and future development. Competencies required by the registered person during his or her daily practice must be identified.

10. It will be compulsory to include the information specified in the PPS in the CPD record of activities captured on the web. This information must be updated on an annual basis as necessary.

STEP 1: Reflection on practice

1. A key part of CPD is the identification of learning needs through reflection on practice. Each individual is best placed to identify these needs. It is important when identifying needs to be honest and open in reflecting on practice.
2. A number of tools are available but not compulsory, to assist in determination of learning needs. These include but are not limited to the Competence Standards Review (Appendix B) and the Personal Development Plan (Appendix C). Completion of the Competence Standards Review and the Personal Development Plan is *NOT* compulsory.
3. The Competence Standards Review may be used by pharmacists to determine learning needs. The document includes the competence standards developed by the SAPC, which will assist pharmacists to assess their own learning needs. The competence standards are based on the seven unit standards for entry-level pharmacists, which have been accepted as the minimum competencies required for entry into the profession. Three more standards have been added *viz:*

    - Facilitate the development of pharmaceutical personnel;

- Practise pharmacy professionally and ethically; and
- Manage the pharmacy/pharmaceutical service.

4. The competence standards have been structured in such a way that pharmacist's mayidentify area within their practice setting which could be modified and/or improved. This will assist the pharmacist to identify gaps in knowledge and skills.

5. The Personal Development Plan (Appendix C) may be used to analyse learning gaps and to link development, career and business plans to service needs and their delivery. Completion of a personal development plan will assist in the development of a CPD learning plan. This tool may be useful for any of the categories of persons registered with the SAPC.

STEP 2: Planning

1. Planning is the second step after reflection on practice or self-audit. Having identified learning needs, pharmacists and pharmacy support personnel should prioritise, taking into consideration the relevance, urgency and importance of the learning objectives. The importance of a learning objective with an identifiable outcome is a measure of the likely impact of meeting his or her learning needs. The importance of the learning need will be determined by how frequently a pharmacist will use the acquired knowledge or skill in his or her work. Urgency is simply a measure of how soon pharmacists need to meet a learning need.

2. The **Learning plan (Appendix D)** is designed to assist pharmacists and pharmacy support personnel to record their planned learning activities. It will be compulsory to include an annual learning plan in the CPD portfolio retained by the individual.

STEP 3: Implementation

1. Implementation is the step where pharmacists and pharmacy support personnel put into action what they have planned following identification of the learning needs and drafting of a learning plan.

2. Registered persons will be required to record any learning events/activities undertaken. These could include a wide range of activities including, self study, attendance of journal clubs, lectures, symposia, attendance of courses, workshops as well as formal education programmes. Instances where the person delivers a presentation or provides input at a course/symposium/workshop etc may also be included if it contributes to the personal and professional growth/learning of the person.

3. In cases where a formal course/workshop/symposium has been attended evidence of learning must be retained by the practitioner. Such evidence must be retained in the individual's portfolio of evidence. Although this evidence will not be submitted on a regular basis, the SAPC could ask for the submission of the evidence at any point as part of the assessment process.

4. Persons registered with the SAPC will be required to record at least 12 learning events/activities for each 12 month period. In cases where a person has been designated as 'practising' on the applicable register for a portion of the previous 12 month period, he/she will be required to complete the specified number of events/activities on a *pro rata* basis.

5. A CPD learning activity guide – not an exhaustive list, (Appendix F) has been developed whereby different learning events/activities are sited to guide pharmacists as to the type of activities that will be considered for CPD purposes. The guide will facilitate the varying needs of registered persons with regard to CPD as well as differences in availability and access to formal learning activities.

6. It must be noted that although assessments will be performed on the different learning activities submitted, the CPD system for persons registered with the SAPC is not a point based system but rather a hybrid system involving the four steps in the CPD cycle.

STEP 4: Evaluation – Reflection on learning

1. Evaluation is the step where pharmacists and pharmacy support personnel assess progress made on achieving their learning objectives. It is a reflection of what he/she has learnt. Pharmacists and pharmacy support personnel should be able to apply the knowledge and skills they have gained. It is also necessary to reflect on whether the need identified during reflection on practice has been met.

Evaluation can be used to identify further learning activities in an ongoing CPD cycle.

2. Registered persons will have access to the web-site at all times in order to enable them to enter the details of their CPD activities subject to one hour downtime due to system maintenance.

3. All the required entries relating to CPD activities of an individual for the preceding year (1 January to 31 December) must be up to date on the data base by 1 February of the following year and submitted to Council. As is the case with the payment of annual fees, a three month grace period for submission will be allowed. The time frames will thus be exactly the same as for the payment of annual fees by pharmacists to Council.

4. Assessment of entries relating to CPD activities of individual persons registered with the SAPC for the preceding year will commence on 1 May of the next year.

5. If an individual has not provided any details with regard to his or her CPD activities the name of the individual will be automatically flagged by the system.

6. Council will monitor the level of activity of persons required to record their CPD activity on an ongoing basis. Mechanisms will be put in place whereby persons registered with Council could be reminded of their obligation to comply with the CPD requirements e.g. by SMS.

7. An audit trail will be available to view the history of the capturing of data on the data base by individuals.

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ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS RELATING TO CPD

1. Assessment means a process of measuring compliance with the requirements of the criteria relating to CPD.

2. Monitoring and assessment of CPD activities will assist Council to ensure that registered persons are participating in activities that will improve their knowledge and skills as well as the quality of service that they provide to patients, either directly or indirectly.

3. The emphasis of the SAPC in the assessment will be on compliance with the requirements relating to CPD rather than on the competence of registered persons to practise. All persons registered with the SAPC will, however, be expected to self assess their competence to practise.

4. The primary mode of assessment of CPD activity will be the review of the record of CPD activities. The focus of the assessment is on compliance with the CPD requirements. This differs from the internship portfolio where assessment relies on measurement of competences acquired.

5. Where necessary, the SAPC may require the registered person to submit his or her portfolio of evidence. The portfolio may be submitted electronically or in hard copy.

6. Council shall on an annual basis assess the compliance of a sample of registered persons with CPD requirements. A percentage of persons registered with Council in each category who are designated on the applicable register as practising will be assessed on an annual basis. The percentage of persons who will be assessed will be determined by Council on an annual basis and may be increased as capacity to do the assessments increases.

7. The primary mode of assessment of CPD activity will be a review of the record of CPD activities. This number will include those persons who are flagged on the system as a result of no recording of activities having taken place.

8. Those persons who have changed their designation from non-practising to practising in the last year will be included in the group of persons who will be assessed.

9. A set of assessment criteria will be developed as a tool to assess the level of compliance of individuals (refer Appendix E – Assessment criteria). The assessment criteria will be made available on the website.

10. Assessors will be persons registered with Council as such, appointed by the SAPC in terms of the *Regulations relating to pharmacy education* to assess the compliance of registered persons with the requirements relating to CPD. Training on the assessment process will be provided to the assessors by the SAPC. A fee for the conducting of assessments will be payable by the SAPC to assessors.

11. The assessor's performance will be continually monitored to ensure that they remain fair and consistent in the assessment of records of CPD activities. Assessors will be required to maintain strict confidentiality at all times in relation to records of CPD activities assessed.

12. The assessment process will be subject to the normal process of moderation and verification. Sample sizes for moderation will be determined by Council.

13. If following assessment a registered person is found to be non-compliant with the requirements relating to participation in and recording of CPD activities the Council may after communication with the person concerned decide on one or more of the following options –

    - request a further assessment;
    - grant the registered person a deferment for a specified period of time subject to compliance with certain conditions which may be determined by Council;
    - require the registered person to follow a support/remedial programme determined by Council;
    - require the registered person to be subject to another method of assessment;
    - as a final step, take disciplinary action against the person in terms of Chapter V of the Pharmacy Act, 1974.

14. After discussion of an individual case by the CPD or other relevant committee of the SAPC e.g. Practise Committee with regard to the option to be followed, in the case of a person who is non-compliant with the requirements relating to CPD the Registrar will inform the person concerned of the decision taken.

15. If a registered person fails to comply with the decision of Council relating to his or her CPD activities and the recording thereof after the specified time period has elapsed his or her registration designation may be changed from 'practising' to 'non-practising'.

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APPEALS

1. In a case where a person registered with the SAPC feels that his or her rights have been adversely affected by a decision of Council he/she may lodge an appeal with the appeal committee appointed in terms of Chapter XII of the *Regulations relating to the registration of persons and the maintenance of registers.*

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TIME FRAME FOR IMPLEMENTATION OF MANDATORY RECORDING OF CPD FOR PERSONS REGISTERED WITH THE SAPC

1. The implementation of CPD for **pharmacists** registered with the SAPC will be as follows -

Phase	Description	Dates
Phase 1	Voluntary participation in CPD – self determination and self assessment	2009
Phase 2	Preliminary study using volunteers and tutors for the development of the CPD system	1 November 2009 – 31 September 2010
Phase 3	Mandatory recording of CPD. During this phase CPD records will not be assessed	Subject to publication of the regulation relating to CPD
Phase 4	Pilot phase for testing the assessment tool	2010 – 2014
Phase 5	Mandatory recording of CPD with assessment of CPD records	1 January 2015

2. A phased approach will be used in the roll out of CPD to other persons registered with the SAPC drawing on the lessons learned in the introduction of CPD for pharmacists.

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Appendix B - Competence Standards Review

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Appendix A - Personal Profile Sheet (PPS) - Compulsory

PERSONAL PROFILE SHEET (PPS)

Registration Number:									
P Number									

Title:																		
Surname:																		
First Names:																		

Area of practice

Insert [x] in drop down box

Academia	
Community	
Consultant pharmacy	
Clinical trial	
Hospital (Institutional)	
Managed care	
Regulatory affairs	
Pharmaceutical industry	
Professional Administration and Management	
Research	
Wholesale/distribution	
Other (please specify)	

Current employment position held

Insert [x] in drop down box

Pharmacy owner/ Major shareholder			Manager	
Locum			Pharmacist	
Other (please specify)				

Status of employment

Insert [x] in drop down box

Full-time			Part-time	
Other (please specify)				

Pharmacy qualification and year obtained

Insert [x] in drop down box

BPharm/BSc Pharm (SA qualification)		Year completed	
Dip Pharm (SA qualification)		Year completed	
Qualification obtained outside SA		Year completed	
SAPC Professional Examinations completed		Year completed	
Other primary qualifications (Please specify)		Year completed	

Insert [x] in drop down box

Post-Graduate Qualifications:

M Pham		Year completed	
M ScPharm		Year completed	
D Pharm		Year completed	
PharmD		Year completed	
PhD		Year completed	
Other post-graduate qualifications (Please specify)		Year completed	

Please assign a number to each task in the box below using the following scoring system -

1.	I spend most of my time each day doing this
2.	I spend some of my time each day doing this
3.	I spend some time doing this occasionally during a week
4.	I spend some time doing this occasionally in a month
5.	I never do this

The compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof		The manufacturing of any medicine or scheduled substance or the supervision thereof	
The application for the registration of a medicine in accordance with the Medicines actregistration of medicine		The purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, re-packaging, supplying or selling of any medicine or scheduled substance or the supervision thereof	
The re-packaging of medicines		The promotion of public health.	
Procurement, storage and distribution of medicine		Management and administration (excluding human resources development)	
Dispensing medicines and ensuring the optimal use thereof including the provision of pharmacist-initiated therapy		The formulation of any medicine for the purposes of registration as a medicine	
Providing information and education relating to medicine		Training and human resource development	
The initiation and conducting of pharmaceutical research and development		The distribution of any medicine or scheduled substance	

Comment

Insert any additional comment which may be need to describe your current practice.

Signature:											
		Date:	D	D	/	M	M	/	Y	Y	Y	Y

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Appendix B - Competence Standards Review – Not Compulsory

COMPETENCE STANDARD MAIN REVIEW

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 in order 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 each standard, whether or not the standard applies to you. This provision should be used in instances where the aspect of practice identified does not relate to your particular practice setting.

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 standards apply 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 manufacture 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;
- 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; 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, community, hospital):

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 need help to 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 with process documentation (hospital, community):

A person who has achieved this outcome is capable of
(a) Assembling the materials/componentry (b) Controlling and check 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 (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 **authorise** preparation process up to final dosage form (d) Monitoring and adjust 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 authorise 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 (manufacturing)

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 take corrective action according to standard operating procedures (b) Recording findings and report 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, community, hospital)**

A person who has achieved this outcome is capable of
(a) Adhering to and apply 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/componentry/printing material (d) Controlling returns to the correct storage bins according to standard operating procedures (e) Evaluate discrepancies and take 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 (manufacturing)**

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, clarify, respond to and resolve work related problems within the team to achieve optimum performance (c) Identifying and respond 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 maintain 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 (manufacturing, community, hospital)**

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 / pre-packing of pharmaceutical products (e) Familiarising the pharmacists' assistants and pharmacist intern 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 provide 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 provide 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.	
Ensure	• To assume the responsibility that the critical outcomes are achieved to the required standards
Control	• To confirm outcomes against specified standards
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
Organise	• To co-ordinate, arrange and take responsibility for the achievement of the specified outcomes
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
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
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.
Packaging machinery and Pre-packing equipment	• Packaging machinery or pre-packing equipment applicable to the designated work area
Production machinery (equipment)	• Knowledge and competence on production machinery is applicable to the equipment/ machinery used in the designated area

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Materials	• Materials include raw materials and bulk materials ready for processing • Bulk products processed and ready for processing or packaging into smaller units
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 patient responsible for the performance, and the source and date of authority for these definitions for each function performed in the pharmaceutical environment**
Good Manufacturing Practices:	• **Internationally accepted standards of manufacturing practice (e.g. currently embodied in the Good Manufacturing Practices document)**
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.
Resources	• Human, raw and packaging materials, equipment, time
Legal requirements	• Drug control legislation • Health and safety legislation • Legislation regulating the pharmacy profession • Labour legislation

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 competence in this standard and can provide evidence in all of the elements

☐ I have assessed my competence 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. **COMPETENCE 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:

- the principles of stock control with respect to storage conditions, security, legal aspects and stock rotation;
- the financial implications of procurement, storage and distribution of medicines;
- an understanding of the management principles involved in the procurement, storage and distribution of medicines and other pharmaceutical products;
- the relevant legislation applicable in the effective control of medicines and other related substances;
- 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;
- 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 authorise suppliers according to legal requirements and standard procurement policy (c) Authorising and control 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 maintain 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 take appropriate corrective action (e) Handling returned, damaged and expired stock according to legal requirements and standard operating procedures (f) Authorising and maintain documentation according to legal requirements and standard operating procedures (g) Assuring product security according to legal requirements and standard operating procedures (h) Organising and control 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 authorise the packaging of orders for pharmaceutical materials and products to ensure product integrity and security (c) Controlling and organise 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 maintain batch traceability to account for defective stock control (f) Controlling and organise 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, clarify, respond to and resolve work related problems within the team to achieve optimum performance (c) Training team members in the implementation of standard operating procedures (d) Identifying and respond to industrial relations issues timeously in a way that balances the interests of worker and management within the legal requirements (e) Organising and conduct 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 maintain 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.	
Ensure	• To assume the responsibility that the critical outcomes are achieved to the required standards
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.
Product integrity	• Maintenance of physical and chemical properties (e.g. by means of cold chain).
Control	• To confirm outcomes against specified standards.
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.
Organise	• To co-ordinate, perform, arrange and take responsibility for the achievement of the specified outcomes.
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
Appropriate storage conditions	• Stocks are stored according to correct temperatures, light, and humidity • Stocks are stored in environmentally controlled conditions • Stocks stored in correct areas allowing effective stock control • Stocks stored maintaining cold chain where appropriate • Correct storage of hazardous substances and surgicals

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 competence in this standard and can provide evidence in all of the elements

☐ I have assessed my competence 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. COMPETENCE 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 competence 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 ensuring 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 pharmaco-economics of medicine therapy;
- the legal aspects relating to the practice of pharmacy ;
- 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 identify entity responsible for payment (d) Identifying prescription **anomalies** that may prevent dispensing (j) Assisting the patient in resolving identified anomalies where possible or communicate 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 communicate identified anomalies clearly, accurately and professionally (b) Working out an **alternative plan** of action 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 **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 communicate 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 document 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 (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

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 provide 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 keep 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

3.6 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

3.7 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

3.8 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

3.9 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

3.10 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 take 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

3.11 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 intern 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's intern 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 pharmacists' assistants and pharmacist's intern with the equipment and pharmaceutical processes in dispensing and to ensure the optimal use of medicines prescribed to the patient (d) Familiarising the pharmacists' assistants and pharmacist's intern with the quality control procedures in dispensing and to ensure the optimal use of medicines prescribed to the patient (e) Assisting pharmacists' assistants and pharmacist intern in the self assessment of their capabilities against determined unit standards (f) Providing in-process guidance to the pharmacists' assistants and pharmacist's intern in dispensing and to ensure the optimal use of medicines prescribed to the patient (g) Assessing progress of the pharmacists' assistants and pharmacist's intern and provide feedback (h) Assisting pharmacists' assistants and pharmacist intern solving relevant learning problems in dispensing and to ensure 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.	
Patient profile	• Personal, medication and clinical information of a patient
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
Anomalies	• Completeness of the prescription • Entity responsible for payment
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
Prepare	• calculations, • counting quantities required, • selection, admixing and/or extemporaneous preparation • packing and labelling
Professional and ethical manner	• As embodied in Supply to the Patient and the Code of Ethics in the current Good Pharmacy Practice in South Africa document
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
Instructional aids	• Pictograms • Written instructions and/or explanations • Braille • Product information leaflets • Appropriate languages
Therapeutic aspects	• Laboratory results • Standard treatment protocols • Multi-drug treatments • Drug characteristics • Disease/symptoms/syndrome
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
Professional	• Prescription record

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Records	• Schedule and substance registers required by law • patient clinical profile • patient medication record
Compliance	• Dose and Dose schedule • Method of administration • Storage • Duration of therapy
Modification	• Education on compliance • Dose • Choice of therapy • Dosage form • Dose schedule • Duration of therapy • Referral • Adverse Drug reactions
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
Prescriber	• medical practitioners • veterinarian • and other persons authorised by current legislation

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 competence in this standard and can provide evidence in all of the elements

☐ I have assessed my competence 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. COMPETENCE 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 outcome

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 pharmaco-economics 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;

- 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 competence 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 diseases 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 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 evaluate 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 product can by 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 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 patient to appropriate health care professional if: • patient condition warrants further investigation; • therapy taken by patient fails in purpose • therapy taken by patient causes an untoward effect • consequences of drug abuse or toxic doses of drugs or chemicals can not be treated (b) Refering 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 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 cause of observed signs and symptoms by reconciling the latter with the history, observations, examination, and the diagnostic tests performed (b) **Referring** patient if interpreted information requires further investigation by another health care professional in accordance with good pharmacy practice guidelines (c) Selecting 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 assess the patient for compliance, effectiveness and safe use of the medicine (b) Evaluating feedback and adjust 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 situation warrants it** (c) **Giving appropriate advice clearly and accurately where necessary,** (d) **Issuing appropriate medicine and provide 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's intern with the correct procedures in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine (b) Familiarising the pharmacist intern with the terminology used in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine (c) Familiarising the pharmacist's intern 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 intern 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 intern in the self assessment of their capabilities against determined unit standards (f) Providing guidance to the pharmacist intern in providing pharmacist initiated care to the patient and to ensure the optimal use of medicine (g) Assessing progress of the pharmacist intern and provide feedback (h) Assisting the pharmacist intern 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.	
Safe use of chemicals	• Identification of chemical • Label clearly and completely • Attach cautionary and advisory instructions • Correct and safe storage • Appropriate packaging • Safe disposal
Patient history	• past conditions • present symptoms • past treatments • drug history • clinical history • demographics • socio-economic milieu • family history

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
Identify signs and symptoms	• Verbal information • Visual examination • Vital signs observation • Basic examination of identified areas related to disease conditions • Physical • Behavioural
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
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) • pharmacist
Referral	• In accordance with the current Specific Guidelines for Pharmacy Practice
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
Treatment	• immunise • dress wound • administer initial dose • administer injections, • cardiopulmonary resuscitation • administer first aid
Intervened	• change of dose • change of therapy
Records	• patient history • examination and test results • care plan implementation

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
	• therapy or drugs administered • outcomes
General Care giver	• The person other than the patient receives the medicine on behalf of the patient

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 competence in this standard and can provide evidence in all of the elements

☐ I have assessed my competence 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. COMPETENCE STANDARD FIVE: PROVIDE INFORMATION AND EDUCATION ON HEALTH CARE AND MEDICINE

Does this standard apply to me?

The standards applies to a pharmacist whose required to give advise, recommendations and actions have a direct impact on patient outcome

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;
- 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 information 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 drawn 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 e 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 provide 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.	
Information	• Health care • Use of medicines • Animal health, veterinary medicines and products • Safe use of chemical substances for industrial, hobby and home use
Sources	• Drug Information centres • Electronic data • Clinical literature
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 • 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

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
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
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
Information	• Health care • Use of medicines • Animal health, veterinary medicines and products • Safe use of chemical substances for industrial, hobby and home use
Sources	• Drug Information centres • Electronic data • Clinical literature
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 • 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

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
	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
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
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
Information	• Health care • Use of medicines • Animal health, veterinary medicines and products • Safe use of chemical substances for industrial, hobby and home use
Sources	• Drug Information centres • Electronic data • Clinical literature

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 competence in this standard and can provide evidence in all of the elements ☐ I have assessed my competence 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. COMPETENCE STANDARD SIX: PROMOTE COMMUNITY HEALTH AND PROVIDE RELATED INFORMATION AND ADVICE

Does this standard apply to me?

Promote community health and provide 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;
- 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 preventive 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 process 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 provide 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 evaluate existing and potential local** community health projects (b) **Initiating and/or participate 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 refer 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 monitor 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 provide 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** ☐

RANGES

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
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
Notifiable diseases	• As defined by the relevant health authority regulations

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
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
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
Monitoring	• Correct choice of drugs • Correct treatment protocols
Method of delivery	• Personal contact • Printed material • Presentations: • Personal • Television • Video • Radio • Electronic media • Community networking

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
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
Community health project	• Immunisation • Family planning • Family health promotion • 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 • Environmental awareness • Self care promotion • Nutrition • Correct drug use • Self medication • Infectious disease prevention

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 competence in this standard and can provide evidence in all of the elements

☐ I have assessed my competence 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. COMPETENCE 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;
- 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 evaluate secondary data for relevance and scientific integrity, whilst demonstrating sensitivity for alternative customs and approaches to health care (c) Developing appropriate research design, implement research design (d) Collating and analysing data (e) Drawing valid conclusions (f) Writing a credible report and disseminated 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 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 provide 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

NOTE: BOLD PRINT IN THE TEXT OF ACTIVITIES IS EXPANDED IN THE RANGES.	
	• Design, utilisation and effectiveness of formularies • Pharmaco-economics, drug utilisation underlying evidence-based medicine • Market/consumer • Patient-acceptability research • Quality of life research • Emergent diseases • Post marketing drug surveillance • Drug resistance patterns
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 • Pharmaco-economics, drug utilisation underlying evidence-based medicine • Market/consumer • Patient-acceptability research • Quality of life research • Emergent diseases • Post marketing drug surveillance • Drug resistance patterns
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 • Pharmaco-economics, drug utilisation underlying evidence-based medicine • Market/consumer • Patient-acceptability research • Quality of life research • Emergent diseases • Post marketing drug surveillance • Drug resistance patterns

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 • Pharmaco-economics, 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 competence in this standard and can provide evidence in all of the elements

☐ I have assessed my competence 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. COMPETENCE STANDARD EIGHT: FACILITATE THE DEVELOPMENT OF PHARMACEUTICAL PERSONNEL

Does this standard apply to me?
The standard applies to all pharmacists who a play 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 apply 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

8.3 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 apply 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 competence in this standard and can provide evidence in all of the elements ☐ I have assessed my competence 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. COMPETENCE 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 present 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 (h) **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** ☐

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 competence in this standard and can provide evidence in all of the elements ☐ I have assessed my competence 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. COMPETENCE 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, maintain and apply 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, clarify and respond to work-related problems and ensure that they are resolved within the team to achieve optimum performance. (p) identifying and respond to labour relations issues timeously in a way that balances the interests of personnel and management within the legislative requirements. (q) organising and conduct 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 competence in this standard and can provide evidence in all of the elements ☐ I have assessed my competence 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

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Appendix C - Personal Development Plan – Not Compulsory

APPENDIX C:
Personal Development Plan

Registration Number: _____

Surname: _____

First names: _____

Your Current Job:_____

Permanent residential address: _____
_____
_____
_____

Postal address _____
_____
_____

Telephone numbers _____(W)
_____(H)
_____(C)

Telefax _____

E-mail address _____

The following questions will help to establish some CPD priorities relating to your current roles

1. Describe up to three incidents in your workplace during the recent years that caused you to feel had made a difference or were a personal and /or professional success.

   - _____
   - _____
   - _____

2. Evaluating your response to the previous question, try to identify a learning need that relates to each incident that might help you build on that success.

   - _____
   - _____
   - _____

3. Describe up to three incidents in your workplace during the past years that caused you to feel uncomfortable, unhappy, ill-at-ease, threatened or simply fed-up.

   - _____
   - _____
   - _____

4. Evaluating your response to the previous question, try to identify a learning need that relates to each incident that might help you handle similar situations more effectively.

- _____
- _____
- _____

The following four questions will help you establish how your current role(s) may change over the coming years, and how you may prepare for these changes.

5. If your work place has developed a plan for the next five years, briefly summarise the three points of that plan that will most affect you.

- _____
- _____
- _____

6. What learning needs do you have that relate to these three points?

- _____
- _____
- _____

7. If you work within the Department of health, can you identify three local, provincial and national policies and priorities that will affect you, patients and other users of your services and organisations for whom you work?
   - _____
   - _____
   - _____

8. What learning needs do you have arising from each of these policies and priorities?
   - _____
   - _____
   - _____

Your career:The following questions should help you focus on your key career goals over the coming years

9. Looking at your career plans for the next five years, identify three new things that you want to be doing within that time frame.
   - _____
   - _____
   - _____

10. What learning needs do you have that relate to each of these career aspirations
    - _____
    - _____
    - _____

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Appendix D - Learning plan - Compulsory

LEARNING PLAN:

Registration Number

Surname _____

First names _____

1) I have identified learning gaps that I need to improve my knowledge and skills and are as follows:

a.
b.
c.

2) I have identified gaps in the following outcomes and are as follows:

a.
b.
c.

3) I have identified the following options or methods of improving my knowledge and skills:

a.
b.
c.

4) I have identified the following recourses/institution to assist me in improving my knowledge and skills:

NB: give details on 4 if it is relevant to learning needs

a.
b.
c.

5) I have identified the following target dates on which I need to start improving my learning needs:

a.
b.
c.

6) I have identified the following target dates on which I need to complete my learning needs:

a.
b.
c.

7) I have identified the following expected outcomes in respect of my learning needs:

Learning needs	Expected outcomes

8) I have identified how the expected outcomes will assist me in my present work or personal development

Expected Outcomes	How it will assist me

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Appendix E –Assessment criteria - Compulsory

Appendix E: Criteria for the assessment of CPD activities of persons registered with the South African Pharmacy Council) (Adapted from the Quality criteria of the Royal Pharmaceutical Society of Great Britain)

FOR LEARNING THAT STARTS AT REFLECTION ON PRACTICE	**FOR LEARNING THAT STARTS AT PLANNING**	**FOR LEARNING THAT STARTS AT IMPLEMENTATION (ACTION)**	**FOR LEARNING THAT STARTS AT EVALUATION**
REFLECTION	**PLANNING**	**IMPLEMENTATION**	**EVALUATION**
There is a description of the learning objective being set.	There is a description of the learning activity.	A date is given for when an activity(ies) was undertaken and the time taken.	There is a description of how learning has been applied.
There is a description of how the learning objective relates to the competences required of the registered person.	There is a description of the pharmacist's consideration of the appropriateness of this activity.	There is a description of what the pharmacist has learnt.	There is a description of feedback.
PLANNING	**ACTION**	**EVALUATION**	
There is a description of the different options available to meet the pharmacist's learning objective.	A date is given for when an activity (ies) was undertaken and the time taken.	There is a description of an example of how the learning has been applied.	
There is a description of the pharmacist's consideration of the appropriateness of different options.	There is a description of what the pharmacist has learnt.	There is a description of feedback	
ACTION	**EVALUATION**		
The pharmacist has indicated which activities have been selected to be undertaken from the identified options.	There is a description of an example of how the learning has been applied.		
There is a description of what the pharmacist has learnt.	There is a description of feedback		
EVALUATION			
There is a description of an example of how the learning has been applied.			
There is a description of feedback.			
Where the learning objective has been partly met, there is a description of what aspect of the learning objective has not been met.			

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APPENDIX F – CPD LEARNING ACTIVITY''

DRAFT: CPD LEARNING ACTIVITIES

DEFINITIONS

''Learning activity'' are the three levels of activities, the non measurable outcomes, the measurable and the formal structured programmes.

1. All persons registered in terms of section 14 of the Act are required by Council to record their CPD activities on line. The recorded CPD should be relevant to the practice of the registered person or be concerned with or, encourage and enhance career development.

2. Participants are expected to perform a minimum of twelve entries per annum/one year cycle.. .

3. The entries must be current (recorded within a month of completion) to the period of exposure to the learning activity and should ideally be spread evenly throughout the year. The following are examples of different types of learning activities:

    3.1 Non measurable learning activities: These are learning activities undertaken or presented on a once-off, non-continuous basis and do not necessarily have a clearly measurable outcome.

    3.2 Measurable / structured learning programmes: These are learning activities presented by an Accredited Service Provider or training institution, carried out in a period covering not more than six months.

    3.3 Structured learning / formal programme: This includes learning activities that are planned, recorded and/or presented by an accredited training institution, or evaluated by an accredited assessor, with a measurable outcome. These are learning activities performed in a period exceeding seven months..

3.4

LEARNING ACTIVITIES
NON MEASURABLE

- self study;
- written assignments submitted to a non-accredited organisation;
- events presented by a non-accredited organisation or individual,
- breakfast meetings, presentations or journal clubs;
- case study discussions;
- formally or informally organised special purpose teaching/learning ward rounds ;
- Conferences, symposia, refresher courses, short courses without a measurable outcome

MEASURABLE / STRUCTURED LEARNING PROGRAMS

- certificate acquired in participation on a short course, multiple choice questions in a journal including electronic journal with a pass rate of 60% from an accredited institution or provider;
- Principal author or co-author of a peer reviewed publication or chapter in a book;
- Review of an article/chapter in a book;
- Keynote speaker at an accredited conference;
- Invited guest/occasional lecturer to present an accredited activity;
- External examiner of an undergraduate examination paper or Master and Doctoral theses on completion.

FORMAL STRUCTURED PROGRAMMES

- Diploma, post graduate studies studied in a period not less than seven months e.g. MBA, MPA, MBL, MSc (Med), LLB, carried out in a period of more than seven months

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Appendix G – Scope of practice of all pharmacy personnel

Pharmacist

(a) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:

(b) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy ;

(c) dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine;

(d) furnishing of information and advice to any person with regard to the use of medicine;

(e) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met; and

(f) the provision of pharmacist initiated therapy ;

(g) the compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof;

(h) the manufacturing of any medicine or scheduled substance or the supervision thereof;

(i) the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, repackaging, supplying or selling of any medicine or scheduled substance or the supervision thereof; and

(j) the application for the registration of a medicine in accordance with the Medicines Act.

(k) the formulation of any medicine for the purposes of registration as a medicine;

(l) the distribution of any medicine or scheduled substance;

(m) the repackaging of medicines;

(n) the initiation and conducting of pharmaceutical research and development; and

(o) the promotion of public health.

Pharmacist's assistant (Basic)

(a) the sale of Schedule 1 medicines or scheduled substances;

(b) assist with the compounding, manipulation or preparation of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(c) assist with the manufacturing of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(d) the re-packaging of medicine;

(e) the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances; and

(f) the provision of information to individuals in order to promote health.

Pharmacist's assistant (Post basic)

(a) the sale of Schedule 1 and Schedule 2 medicines or scheduled substances;

(b) assist with the compounding, manipulation or preparation of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(c) assist with the manufacturing of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;

(d) the re-packaging of medicine;

(e) the distribution and control of stock of Schedule 1 to Schedule 7 medicines or scheduled substances;

(f) the ordering of medicine and scheduled substances up to and including Schedule 7 according to an instruction of a person authorised in terms of the Medicines Act to purchase or obtain such medicine or scheduled substance;

(g) the reading and preparation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container following the interpretation and evaluation of the prescription by a pharmacist;

(h) the provision of instructions regarding the correct use of medicine supplied; and

(i) the provision of information to individuals in order to promote health.

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Appendix H – Explanation of practising and non-practising

INTERPRETATION OF PRACTISING AND NON-PRACTISING IN RELATION TO CONTINUING PROFESSIONAL DEVELOPMENT

According to the regulations relating to continuing professional development,

> **"Practising"** means any person designated on the applicable register as a person who is currently performing any one or more of the services or acts relating to the scope of practice of the category in which he or she is registered or intends to perform such functions;
>
> **"Non-Practising"** means any person designated on the applicable register as a person who is not currently performing any one of the services or acts relating to the scope of practice of the category in which he or she is registered and does not intend to do so;

Abbreviations

HOPS	Heads of Pharmaceutical services
CEO	Chief Executive Officer
COO	Chief operational Officer
WFP	World Food Program
FET	Further Education and Training
HET	Higher Education and Training
MCC	Medicine Control Council
SAPC	South African Pharmacy Council
DOH	Department of Health
DUR	Drug Utilisation Review
MSH SPS	Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS)

The following are scenarios that further explain the concepts of practising and non-practising, however, this is not an exhaustive list.

Members of the profession employed by virtue of being registered with SAPC as pharmacist or pharmacist support personnel to perform the following duties;	**Practising**	**Examples**
administration in public and private sector whose daily job is e.g. drafting policies, monitoring and evaluation of policy as well as policy implementation;	Practising	HOPS, Directors, Deputy Directors , CEO, SPS, MSH,
Administration, consulting and research organizations ;	Practising	Pharmacist in USAID, WHO, WFP
medical evaluations and review e.g. DUR pharmacist;	Practising	Pharmacist in PBM
regulatory;	Practising	SAPC, MCC, Law enforcement at DOH
teaching, tutoring of pharmacy students, personnel and other health care professionals;	Practising	Lecturing at universities, technikons, and other institutions FET, HET etc
involvement in the cool face of pharmacy in dispensing as locums or full time (community, and institutional hospitals etc), manufacturing and wholesalers etc;	Practising	Community/retail/institutional
Members of the profession currently registered with SAPC as pharmacist or pharmacist support personnel who are not currently performing any one of the services or acts relating to the scope of practice of the category in which they are registered and do not intend to do so;	Non-practising	Employed as florist manage or assist in a mortuary or bottle store

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