

# EXTERNAL INTEGRATED SUMMATIVE ASSESSMENT (EISA) MANUAL FOR PHARMACIST'S ASSISTANTS (BASIC), NQF LEVEL 4

# 2024

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services for all*



**South African  
Pharmacy Council**  
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# Foreword by the Registrar

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Dear Learner,

On behalf of the South African Pharmacy Council (SAPC), I wish to congratulate you on meeting the requirements to sit for the External Integrated Summative Assessment. We look forward to welcoming you within the ranks of qualified pharmacy support personnel.

We implore you to take this opportunity to learn and develop as a future pharmacy support personnel. We trust that you will receive support and guidance from your education and training provider, the pharmacy where you are working and the profession at large.

As part of your assessment, you need to meet specific requirements to be deemed competent and progressed to a qualified Pharmacist's Assistant role. This manual will assist you in preparing for these assessments. Take time to carefully read through its contents and engage with the SAPC during the various workshops we will conduct during the course of this year. You may also contact the Office of the Registrar with any questions you may have.

As you are the coalface of delivering pharmaceutical services, whether within a manufacturing, wholesale, hospital or community pharmacy, it is important that you have the passion and love for both your calling and health care in general. It is this passion that will drive you to acquiring new knowledge and skills necessary to ensure your continued growth and competence in the pharmacy profession.

I wish you well and encourage you to prepare timeously for the assessments.



VM Tlala  
**Registrar/CEO**

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# 1. Introduction

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In terms of the Occupational Qualifications Sub-Framework (OQSF), learners who successfully complete the requirements of the learning programmes offered by a Skills Development Provider (SDP) for the Occupational Certificate: Pharmacist's Assistant (Basic) (part qualification), Pharmacist's Assistant (Post-Basic) and Pharmacy Technician, must successfully complete an External Integrated Summative Assessment (EISA) before they can be awarded the qualification for registration with Council as a pharmacy support personnel (PSP).

The EISA will also serve as a pre-registration assessment for current Pharmacist's Assistants (Basic) intending to enrol as Pharmacist's Assistant (Learner Post-Basic) on the NEW Occupational Certificate qualification and pharmacy students who have successfully completed their first year of study and intending to register as Pharmacist's Assistants (Basic).

The EISA is a national assessment leading to the awarding of an Occupational Certificate and ensures that the assessments of the Occupational Qualifications are standardised, consistent and reliable<sup>1</sup>. The EISA is based on a set of Exit-Level Outcomes (ELO) which describe the knowledge, skills and attitudes required for a generalist PSP.

## Competence and Exit-Level Outcomes for the Occupational Certificate

The evaluation of competence is based on the Exit-Level Outcomes (ELOs) developed for pharmacy support personnel. **These ELOs form the basis of the Occupational Certificate qualification registered with the South African Qualifications Authority (SAQA) and the curriculum registered with the Quality Council for Trades and Occupations (QCTO) and contain all the knowledge, skills and attitudes required from a pharmacy support personnel.** Although it is not always directly evident how the combination of knowledge, skills and attitudes contribute to the demonstration of competence, extensive knowledge of the principles of pharmacy is essential to enable pharmacy support personnel to apply their skills in effectively dealing with the demands of pharmacy practice in the various sectors of the profession.

### The following ELOs describe the essential knowledge and skills required of PSPs:

- ELO 1: Apply basic scientific knowledge to provide technical support in delivering pharmaceutical services.
- ELO 2: Provide technical support for receiving, storing, picking, packing and distributing orders. To perform stock counts and participate in stock-taking in compliance with cGMP, GWDP and GPP requirements.
- ELO 3: Provide technical support for the manufacture, packaging and re-packaging of non-sterile medicines and scheduled substances in compliance with GMP guidelines under the supervision of a Pharmacist.
- ELO 4: Provide technical support for the compounding, manipulation and preparation of non-sterile medicines and scheduled substances (extemporaneous compounding) in compliance with standards as described in the GPP rules and GMP guidelines under the supervision of a Pharmacist.

The associated assessment criteria for the exit-level outcomes are provided for in Appendix A.

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<sup>1</sup> Quality Council for Trades and Occupations (QCTO), EISA brochure

## 2. Guidelines for the External Integrated Summative Assessment (EISA)

This manual is a guide for Pharmacy Support Personnel to ensure a successful External Integrated Summative Assessment (EISA) experience. It aims to explain the process and contents of the assessment as well as the assessment of the candidate's performance.

### 2.1 EXTERNAL INTEGRATED SUMMATIVE ASSESSMENT (EISA) ELIGIBILITY CRITERIA (ENTRANCE REQUIREMENTS)

Candidates need to meet specific requirements before they can sit for the assessment, referred to in Table 1.

**Table 1: Requirements for candidates to sit for the EISA**

|   |   |
|---|---|
| Pharmacist's Assistant (Learner Basic) registered for the new Occupational Certificate qualification  | <p>Learners must have completed a minimum of six (6) months of training with an accredited provider and must have;</p> <ul style="list-style-type: none"> <li>• Successfully completed the three components of the qualification i.e. Knowledge, Practical and Work Experience;</li> <li>• Received a statement of results from the accredited provider stating that the learner is ready for the EISA;</li> <li>• Completed the practice EISA; and</li> <li>• Booked online for the EISA.</li> </ul> |
| Currently qualified Pharmacist's Assistants (Basic) intending to enrol as Pharmacist's Assistant (Learner Post-Basic) on the new Occupational Certificate qualification | <ul style="list-style-type: none"> <li>• Registered qualified Pharmacist's Assistant (Basic)</li> <li>• Completed the practice EISA; and</li> <li>• Booked online for the EISA.</li> </ul>  |
| Pharmacy student who has successfully completed their first year of study and intending to register as Pharmacist's Assistant (Basic)                                   | <ul style="list-style-type: none"> <li>• Registration as a Learner Basic - Former BPharm student</li> <li>• Completed 400hrs in an approved pharmacy and under the direct personal supervision of a pharmacist;</li> <li>• Submitted at least one progress report;</li> <li>• Completed the practice EISA; and</li> <li>• Booked online for the EISA.</li> </ul>  |

#### 2.1.1 EISA workshops

Council will conduct virtual workshops to guide candidates with preparing for the assessment. The workshop presentations will be available on the SAPC website following the workshops.

## 2.1.2 Practice assessment

It is **COMPULSORY** for all candidates to participate in the practice assessment before they attempt the EISA. The purpose of the practice assessment is to provide candidates with an opportunity to experience the online/remote assessment conditions prior to writing the assessment. The practice assessment is conducted before the EISA. The date for the practice assessment is provided in Table 2 below. The EISA practice assessment will not contribute towards the candidate's EISA.

**The practice assessment will be written over three and a half (3<sup>1/2</sup>) hours.** Practice assessment papers are available on the secure site of the SAPC website.

## 2.1.3 Booking for the EISA

Candidates are required to **book online** to write the EISA. The booking must be made on the secure site for registered persons on the SAPC website ([www.sapc.za.org](http://www.sapc.za.org)). On booking, candidates are required to select the venue from which they will be writing the assessment. The assessment booking must be submitted at least **four (4) weeks prior to the assessment date**. A booking fee of R692.00 is payable at the time of booking for the EISA. A late booking fee of R346.00 will be charged for bookings submitted less than four (4) weeks and up to fourteen (14) days before the assessment date. Bookings submitted less than fourteen (14) days before the assessment date will not be accepted.

The applicable fees are published by Council each year and are available on the Council website. The scheduled date for the EISA is indicated in Table 2. Council will publish other dates once determined.


**Table 2: EISA dates for 2024**

| PRACTICE EISA   | EISA                 |
|---|----------------------|
| 07 March (Thursday)   | 27 March (Wednesday) |
| * THESE DATES ARE SUBJECT TO CHANGE. Please refer to <a href="http://www.sapc.za.org/Learner_Assessment">www.sapc.za.org/Learner_Assessment</a> |                      |

## 2.2 ASSESSMENTS


### 2.2.1 Format of the assessment

- (i) The EISA will be conducted online. The assessment will be written either remotely and/or at a designated venue.
- (ii) The assessment will be conducted as an **open-book** assessment using the SAPC online/remote platform.

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

- (iii) The assessment will be **one (1) paper** comprising of general practice and calculation-type questions and a minimum of **one hundred (100) multiple-choice questions (MCQs)**.

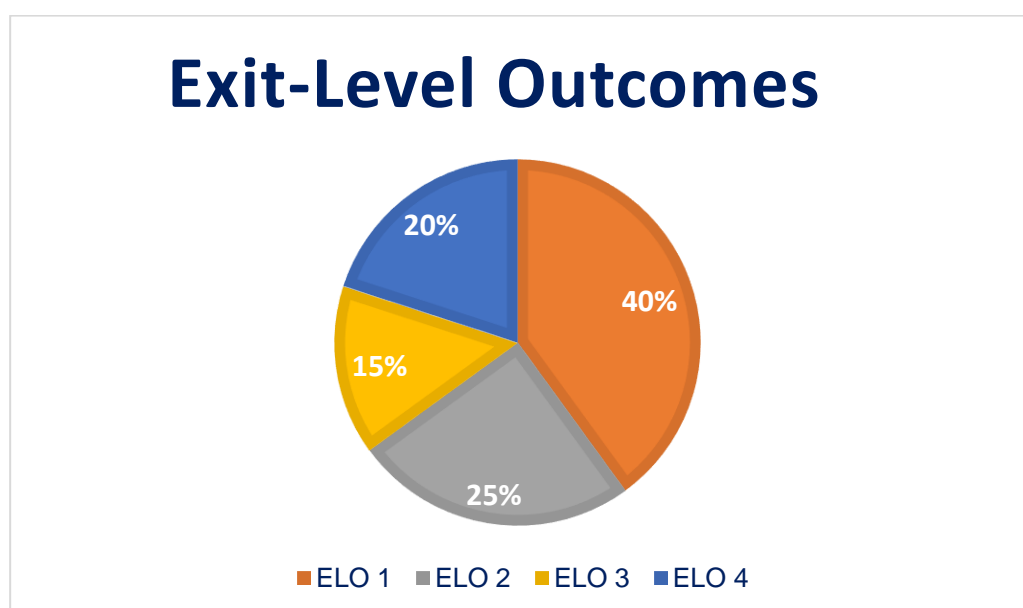
- (iv) The **general practice questions** will amount to not more than eighty four percent ( $\leq 84\%$ ) of the paper and **calculations** will amount to not less than sixteen percent ( $\geq 16\%$ ) of the paper.
- (v) The paper will be written over three and a half (**3 $\frac{1}{2}$  hours**).
- (vi) Each MCQ consists of a stem describing a problem or practice scenario and will have four answer options, one of which will be the most correct/appropriate answer.

|   |   |
|---|---|
|  | Although the MCQs are quicker to answer than the response-type questions, paging through books in open book assessments may waste time. Candidates must, therefore, understand the concepts to apply to given scenarios and know which reference sources contain specific information to remain time efficient in the assessment. |
|---|---|

- (vii) Each question will be worth **one (1) mark** and no negative marking will be applied.
- (viii) The **pass mark** for the assessment will be fifty percent (50%) and a subminimum of fifty percent (50%) will be applied to the calculation and general sections of the paper, respectively.

### 2.2.2 Assessment content

- (i) The assessment questions will test knowledge and comprehension, application and analysis, as well as synthesis and evaluation.
- (ii) Each assessment question will be set in accordance with the Exit-Level Outcomes and occupational tasks required for candidates to perform in the workplace.
- (iii) Each Exit-Level Outcome is assigned a weighting and the occupational tasks are weighted in line with the overall weight of that Exit-Level Outcome. All weighting contributes to the total for the assessment. The weights assigned to Exit-Level Outcomes and associated occupational tasks are listed in Table 3.



**Figure 1:** Distribution of questions in the EISA according to Exit-Level Outcomes

**Table 3: Exit-Level Outcomes, Occupational Tasks and weighting for the External Integrated Summative Assessment (EISA) for the Pharmacist's Assistant (Basic), NQF Level 4**

Given a question or scenario concerning scope of practice or legislation, the learner must correctly identify the MOST appropriate answer.

| Occupational Tasks  | Weight (% of exam) | Candidates must be able to:  | No. of questions | Category of questions            | Knowledge and Comprehension | Application | Analysis, synthesis and Evaluation |
|---|--------------------|--|------------------|----------------------------------|-----------------------------|-------------|------------------------------------|
| <b>ELO 1: Apply basic scientific knowledge to provide technical support in delivering pharmaceutical services.</b>  |                    |  |                  |                                  |                             |             |                                    |
| <b>1. Practice ethically, legally and professionally, within the scope of practice</b>  | 40%                | 1.1 Apply legislation related to the relevant scope of practice in pharmaceutical services in the South African context.                                 | 15               | General (35)<br>Calculations (5) | 18                          | 13          | 9                                  |
|   |                    | 1.2 Demonstrate ethical and professional conduct related to the relevant scope of practice in the provision of pharmaceutical technical support services | 10               |                                  |                             |             |                                    |
| <b>2. Perform basic calculations and apply basic pharmaceutical concepts</b>  |                    | 2.1 Apply basic pharmaceutical terms and concepts concerning non-sterile drug delivery systems and their routes of administration                        | 5                |                                  |                             |             |                                    |
|   |                    | 2.2 Apply basic scientific principles and perform basic scientific calculations  | 10               |                                  |                             |             |                                    |
| <b>SUB-TOTALS</b>   |                    |  | <b>40</b>        |                                  |                             |             |                                    |
| <b>ELO 2: Provide technical support for the receiving, storing, picking, packing and distributing orders. To perform stock counts and participate in stock-taking in compliance with cGMP, GWDP and GPP requirements.</b> |                    |  |                  |                                  |                             |             |                                    |
| <b>3. Assist in the distribution and control of stock of Schedule 1 to Schedule 6 medicines or</b>  | 25%                | 3.1 Conduct distribution and control of the stock of medicines, scheduled substances, and medical devices according to SOPs, and per cGMP, GPP and GWDP  | 8                | General (22)<br>Calculations (3) | 10                          | 11          | 4                                  |
|   |                    | 3.2 Pick, pack and secure orders for medicines or scheduled substances according to all  | 5                |                                  |                             |             |                                    |



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| Occupational Tasks   | Weight (% of exam) | Candidates must be able to:   | No. of questions | Category of questions | Knowledge and Comprehension | Application | Analysis, synthesis and Evaluation |
|--|--------------------|---|------------------|-----------------------|-----------------------------|-------------|------------------------------------|
| scheduled substances   |                    | requirements and check that orders are dispatched according to SOPs   |                  |                       |                             |             |                                    |
|  |                    | 3.3 Complete documents and maintain records following applicable legislation and SOPs   | 8                |                       |                             |             |                                    |
|  |                    | 3.4 Participate in stock counts   | 4                |                       |                             |             |                                    |
| <b>SUB-TOTALS</b>  |                    |   | <b>25</b>        |                       |                             |             |                                    |
| <b>ELO 3: Provide technical support for the manufacture, packaging and re-packaging of non-sterile medicines and scheduled substances in compliance with GMP guidelines under the supervision of a Pharmacist.</b>   |                    |   |                  |                       |                             |             |                                    |
| <b>4. Assist with the manufacturing, packaging and re-packaging of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist</b> | 15%                | 4.1 Apply pharmaceutical and cGMP principles and legislative requirements in the manufacture, packaging and/or repackaging of non-sterile medicines and scheduled substances        | 3                | General (15)          | 12                          | 2           | 1                                  |
|  |                    | 4.2 Organise and prepare resources, materials and equipment for the preparation of specific medicines following relevant SOPs and process documentation                             | 2                |                       |                             |             |                                    |
|  |                    | 4.3 Handle materials with due regard for environmental and storage conditions, transport and security requirements  | 3                |                       |                             |             |                                    |
|  |                    | 4.4 Participate in manufacturing processes for non-sterile medicines and scheduled substances   | 2                |                       |                             |             |                                    |
|  |                    | 4.5 Pack and re-package medicines and scheduled substances following GMP, ethical principles, relevant legislation, process documentation and SOPs, and authorised by a pharmacist. | 3                |                       |                             |             |                                    |

2024 External Integrated Summative Assessment (EISA) Manual for Pharmacist's Assistants (Basic)

| Occupational Tasks  | Weight (% of exam) | Candidates must be able to:   | No. of questions | Category of questions            | Knowledge and Comprehension | Application | Analysis, synthesis and Evaluation |
|---|--------------------|---|------------------|----------------------------------|-----------------------------|-------------|------------------------------------|
|   |                    | 4.6 Complete all documents and maintain records following cGMP guidelines   | 2                |                                  |                             |             |                                    |
| <b>SUB-TOTALS</b>   |                    |   | <b>15</b>        |                                  |                             |             |                                    |
| <b>ELO 4: Provide technical support for the compounding, manipulation and preparation of non-sterile medicines and scheduled substances (extemporaneous compounding) in compliance with standards as described in the GPP rules and GMP guidelines under the supervision of a Pharmacist.</b> |                    |   |                  |                                  |                             |             |                                    |
| <b>5. 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</b>   | 20%                | 5.1 Apply principles of GPP concerning the compounding of non-sterile medicines and substances  | 4                | General (12)<br>Calculations (8) | 10                          | 9           | 1                                  |
|   |                    | 5.2 Compound a simple solution, suspension and semi-solid following instructions (formulas), relevant SOPs and process documentation, using the principles of cGMP and/or GPP for specific patients | 8                |                                  |                             |             |                                    |
|   |                    | 5.3 Complete records for each of the preparations produced following legal requirements and organisational policies and procedures  | 2                |                                  |                             |             |                                    |
|   |                    | 5.4 Check and clean equipment, according to SOPs  | 2                |                                  |                             |             |                                    |
|   |                    | 5.5 Perform housekeeping activities according to SOPs   | 2                |                                  |                             |             |                                    |
|   |                    | 5.6 Operate a computer to generate documents and spreadsheets   | 2                |                                  |                             |             |                                    |
| <b>SUB-TOTALS</b>   |                    |   | <b>20</b>        |                                  |                             |             |                                    |
| <b>GRAND TOTALS:</b>  |                    |   | <b>100</b>       |                                  | <b>50</b>                   | <b>35</b>   | <b>15</b>                          |

**(a) Type of questions**

- (i) General questions will be formatted to test the general practice of pharmacy in community, institutional and manufacturing sectors.
- (ii) The types of calculation questions that may be included in the EISA are provided in Table 4.

**Table 4: Types of calculation questions for the EISA**

|              |  |  |
|--------------|--|--|
| <b>ELO 1</b> | <b>Perform basic calculations and apply basic pharmaceutical concepts</b>  | <ul style="list-style-type: none"> <li>• Basic conversions</li> </ul>  |
| <b>ELO 2</b> | <b>Assist in the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances</b>   | <ul style="list-style-type: none"> <li>• Stock consumption</li> <li>• Reconciliation calculations in stock management</li> <li>• Cost (value) of stock</li> </ul>  |
| <b>ELO 4</b> | <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</b> | <ul style="list-style-type: none"> <li>• Calculate quantities of ingredients according to a formula to prepare an extemporaneous formulation</li> <li>• Reconciliation calculations in repackaging operations</li> </ul> |

**(b) Reference material**

The **latest edition of any** reference including specified online references may be used during the assessment. **No previous assessment papers may be used in the assessment.**

The following references (the **latest editions of textbooks/documents**) are suggested:

- Anatomy & Physiology textbook
- Aulton's Pharmaceutics, The Design and Manufacture of Medicines (Kevin M.G. Taylor & Michael E. Aulton)
- Board Notices
- British Pharmacopoeia
- Calculations for Pharmaceutical Practice (A. J. Winfield & I. O. Edfiogho)
- Compendium of laws and regulations (electronic copies of the Pharmacy Act and Medicines and Related Substances Act available)
- ePharmaciae ([www.pharmaciae.org.za](http://www.pharmaciae.org.za))
- Essential Drug List and Standard Treatment Guidelines – PHC, Hospital and Paediatric (electronic copies provided)
- Good Pharmacy Practice (GPP) (electronic copy available)
- Guidelines for Good Wholesaling and Distribution Practices
- Handbook on Injectable Drugs (L. Trissel)
- Martindale: The Extra Pharmacopoeia (electronic copy provided)

- Martin's physical pharmacy and pharmaceutical sciences: Physical chemical and biopharmaceutical principles in the pharmaceutical sciences (Alfred N. Martin, P. Sinko, Y. Singh)
- Merck Manual or equivalent
- MIMS / MDR
- Pharmaceutical Calculations (H. C. Ansel)
- Pharmaceutical Practice (A. J. Winfield, et al.)
- Stock management handbook/textbook
- South African Guide to Good Manufacturing Practice (GMP) (electronic copy available)
- South African Medicines Formulary (SAMF)
- South African Pharmaceutical Journal (SAPJ)

The following websites may be accessed during the assessment:

- SAPC ([www.sapc.za.org](http://www.sapc.za.org))
- South African Health Regulatory Products Authority (SAHPRA) (<https://www.sahpra.org.za/>)
- EMGuidance (<https://emguidance.com/discover>)
- Merck Manual (<https://www.msdmanuals.com/professional>)

### (c) Policy for conducting Council assessments

#### (i) The following policy applies in relation to security measures and the invigilation of Council assessments:

- To improve the security of remote assessments, Council approved the implementation of live proctoring, i.e. live invigilation of candidates remotely via video and audio for assessments.
- The following parameters are monitored on proctoring:
  - ✓ physiological face biometry, i.e. face recognition, number of faces in the camera.
  - ✓ Identity verification, i.e. continuous face recognition, comparison with original photo.
  - ✓ Voice and noise detection.
  - ✓ Invigilators/proctors observe in real-time and will communicate with candidates via chat, audio and/or video.
- The invigilator is in control of the assessment and can be contacted on all matters pertaining to the assessment, e.g. via the chat functionality for candidates writing remotely or raising hands for candidates writing at a designated venue.
- Candidates must test their laptop and/or desktop for compatibility with the proctoring software prior to the assessment using the following link: <https://proctored.com/check>
- Candidates are only permitted to use one screen such as a laptop or a desktop computer to write the assessment. The assessment platform will not allow the connection of a second screen.
- Candidates will be required to **share the entire screen of the laptop/desktop**. Multiple tabs can only be opened from the **shared screen**.

- Candidates will be required to connect their smartphones via a QR code for a better view of their workspace and assessment room. The smartphone must be placed at an appropriate angle covering the full view of the workspace and assessment room.

**(ii) The following policy applies when conducting Council assessments remotely:**

- The remote invigilator is officially in control of the assessment and can be contacted via the chat functionality on all matters pertaining to the assessment.
- Candidates must log on to the SAPC assessment platform one (1) hour prior to the **assessment to register and gain access to the assessment**. Candidates can access the assessment using the latest versions of the following web browsers: Google Chrome, Microsoft Edge, Firefox or Safari.
- **Only candidates whose names appear on the official list of candidates who booked to write the assessment will be allowed access to the assessment.**
- Candidates must use their SAPC login details to access the assessment.
- Council will send a one-time password (OTP) to the candidate's cell phone number and email address registered on their SAPC profile, for authentication and access to the assessment. Candidates must, therefore, check both their cellphone and email for the OTP. The OTP will be valid for 10 minutes.
- **Laptops and/or desktops may be used** during the assessment, provided the device has a functioning camera. A cellular smartphone will be required as the second screen for a view of the assessment environment.
- Candidates **MUST** allow the SAPC to access their camera, location and laptop/desktop computer's entire screen when prompted by the assessment platform.
- Candidates are not allowed to refer to previous assessment papers during the assessment.
- Candidates must ensure they have read and understood the assessment guidelines prior to the start of the assessment.
- Candidates must ensure that their question paper for the assessment is correct.
- All questions are the same for that assessment but are randomised. Therefore, the **order of questions will not be the same between candidates**.
- There are **four (4) answer options per question**. There is **only one (1) correct answer per question**.
- The candidate must **use the mouse or relevant function for their device to select an answer option**. The selected option is then the candidate's answer for the question and is auto-saved by the system.
- **Clicking the "Submit" button completes the assessment** and the candidate cannot go back to the assessment questions.
- Candidates will not be allowed to exceed the time limit. If the allocated assessment time lapses without the candidate answering all the questions, the completed **answers**

**are automatically submitted** even if the candidate has not clicked the "Submit" button.

- **This is an open-book assessment. candidates may use textbooks, electronic references, and specified websites.**
- If a candidate is seen obtaining information from another person by any means during the assessment, or if any irregularities occur, the remote invigilator must report this to Council in writing.
- **Candidates are to adhere to assessment etiquette and code of conduct at all times.**
- **Candidates must ensure they are dressed appropriately as the assessment is invigilated using a video live stream and the platform randomly takes photographs of candidates during the assessment. Videos and photographs taken will form part of a permanent record.**

**(iii) The following policy applies when conducting Council assessments at designated venues:**

- **The invigilator is officially in control of the assessment** and must be obeyed on all matters pertaining to the assessment.
- Candidates must **present at the assessment venue at least an hour before the assessment and must be seated 30 minutes before the assessment.**
- **Only candidates whose names appear on the official list of candidates who booked to write the assessment** in that venue or who produce the written/electronic confirmation of the assessment booking in that venue will be admitted to that assessment venue.
- Each candidate must produce proof of their identity such as an **identity document, a valid passport or a driver's license.**
- Candidates must use their SAPC login details to access the assessment.
- Council will send a one-time password (OTP) to the candidate's cell phone number and email address registered on their SAPC profile for authentication and access to the assessment. Candidates must, therefore, check both their cell phone and email for a generated password. The OTP will be valid for 10 minutes.
- Candidates **MUST** allow the SAPC to access their camera, location and laptop/desktop computer's entire screen when prompted by the assessment platform.
- **This is an open-book assessment. Textbooks will be allowed** in the assessment room and candidates **may share these through the invigilator.** Personal notes are allowed but may not be shared between candidates. Previous assessment papers are **not allowed** in the assessment room.
- Candidates must ensure they have read and understood the assessment guidelines prior to the start of the assessment.
- Candidates must ensure that their question paper for the assessment is correct.

- All questions are the same for that assessment but are randomised. Therefore, the **order of questions will not be the same between candidates**.
- There are **four (4) answer options per question**. There is **only one (1) correct answer per question**.
- The candidate must **use the mouse to select an answer option**. The selected option is then the candidate’s answer for the question and is auto-saved by the system.
- **Clicking the “Submit” button completes the assessment** and candidates cannot go back to the assessment questions.
- Candidates will not be allowed to exceed the time limit. If the allocated assessment time lapses without the candidate answering all the questions, the completed **answers are automatically submitted** even if the candidate has not clicked the “Submit” button.
- If a candidate attempts to obtain information from another person by any means during the assessment, or if any irregularities occur, the invigilator must report this to Council in writing.
- **Candidates may not leave the assessment venue during the assessment without supervision**.
- **Candidates are to adhere to assessment etiquette and code of conduct at all times**.
- **Candidates must ensure they are dressed appropriately as the assessment is invigilated using a video live stream and the platform randomly takes photographs of candidates during the assessment. Videos and photographs taken will form part of a permanent record**.

**(d) Assessment declaration**

Candidates are required to complete a declaration agreeing to the Assessment Code of Conduct (Table 5). Failure to abide by the code of conduct and assessment rules may result in referral to the Professional Conduct Department for disciplinary action.

**Table 5: Pre- and post-assessment declaration**

|                                     |  |
|-------------------------------------|--|
| <b>PRIOR TO START OF ASSESSMENT</b> | <ul style="list-style-type: none"> <li>• I hereby declare that I am the candidate registered to write the assessment and agree to abide by the Assessment Code of Conduct.</li> <li>• I am completing the assessment in a suitable area with minimal anticipated distractions.</li> <li>• I am completing the assessment at the location/place stipulated in my booking confirmation.</li> <li>• I have procured the minimum required data for the purpose of the assessment, which is equivalent to three (3) gigabits per paper.</li> <li>• I am not sitting next to or in close proximity to any other candidates completing this assessment.</li> <li>• I will not receive any form of assistance from any person while writing this assessment.</li> <li>• I will not communicate (verbal/electronic/in-person) with any registered person during the assessment.</li> <li>• I will only use the reference material permitted in the assessment.</li> </ul> |
|-------------------------------------|--|

|                        |   |
|------------------------|---|
|                        | <ul style="list-style-type: none"> <li>• I will not access any other reference material that has been prohibited including websites.</li> <li>• I will not give any assistance to any person completing this assessment.</li> <li>• I will not retain and/or share the contents of the assessment via electronic, printed, written or verbal means with any person.</li> <li>• I will inform the South African Pharmacy Council if I am aware of any candidate (s) contravening the Assessment Code of Conduct.</li> </ul>                        |
| <b>POST-ASSESSMENT</b> | <ul style="list-style-type: none"> <li>• I confirm that I have completed the assessment without assistance from any person and adhered to the Assessment Code of Conduct.</li> <li>• I understand that if it is found that I have contravened the Assessment Code of Conduct, the SAPC will implement disciplinary action against me in terms of Chapter V of the Pharmacy Act.</li> <li>• I will not/have not retained and/or shared the contents of the assessment via electronic, printed, written or verbal means with any person.</li> </ul> |

In the event that the SAPC finds a candidate to have contravened the Assessment Code of Conduct, a case of misconduct will be opened and referred to the Committee of Preliminary Inquiry (CPI). This committee reviews the information and evidence submitted and will recommend one of the following:

- (i) refer the matter to the Committee of Informal Inquiry (CII) where-
  - (a) the candidate may admit guilt and pay the applicable fine plus a cost order, or
  - (b) the candidate may appeal the charges and defend the matter before the CII.
- (ii) refer the matter to the Committee of Formal Inquiry (CFI) where the candidate will appear before the CFI; or
- (iii) no further action may be taken, if the Committee is convinced that no evidence of unprofessional conduct exists.

If a candidate is found guilty by the CFI, in addition to the penalties imposed by the Committee, their names, summary of charges and the penalties imposed will be published in a Council report.

### (e) Tips for preparing for the EISA

Below are suggested approaches for preparing for and writing the EISA:

- **Become thoroughly familiar with the Exit-Level Outcomes, Associated Assessment Criteria and Occupational Tasks required for pharmacy support personnel.** Decide how you will learn about each aspect of the Exit-Level Outcomes and what learning resources you have or need to obtain. Discuss anything you are not sure about with your provider.
- **Decide on the reference texts that you will take into the assessment.** Decide on a few references you are familiar with and take only those into the assessment room instead of a suitcase of books you are unfamiliar with. A good rule of thumb is to take only as many books as you can carry comfortably.
- **Familiarise yourself with the content of your selected reference books.** Examine your selected references closely. Make sure you are aware of all the various types of information in the reference(s). Very often there are useful tables, etc., that you are unaware of if you have not inspected all the different sections of the reference.



- **Be familiar with the contents of your EISA manual.** Work through the manual and ensure that you have gained experience in all the activities relating to the occupational tasks of a learner included in the manual.
- **Read the *Pharmaciae* published by Council** (available online at [www.sapc.za.org/Publications\\_Pharmaciae](http://www.sapc.za.org/Publications_Pharmaciae)).
- Many current topics of relevance to the practice of pharmacy are discussed in the *Pharmaciae*.
- **Keep up to date with the latest research and information through reading appropriate journal articles.** This will create an awareness of current trends, thoughts, controversies or practices in the profession.
- **Think about what you did in your practical skills and workplace modules.** The entire period of your learning should serve as preparation for your assessment.
- **Think about the tasks you performed in your workplace.** Is the way in which you practise pharmacy ethical and legal? Are you aware of the legislation governing your actions? Are your recommendations/actions best practice – if so, why? If not, why not?
- **Attempt practice papers that are available on the secure site of the Council website (www.sapc.za.org)** for you to prepare for the assessment. Attempt the paper under strict assessment conditions. This will allow you to assess whether you are using the correct technique and to fine-tune your strategy for the assessment.
- **Calculations:** Do not memorise formulae or aids such as 'donkey triangles'. Rather understand the rationale behind the calculation and work from first principles. Practise doing calculations to develop your skills in performing calculations that are required regularly. Please note that no formulae will be provided/included in the assessment paper.
- **Test your laptop and/or desktop for compatibility with the proctoring software prior to the assessment using the following link:** <https://proctorededu.com/check>
- **Check your loadshedding schedule and arrange backup power if necessary.**

**(f) Tips for writing the assessment:**

- **Knowledge is in your head and references are for confirmation.** During an open book assessment, you do not have sufficient time to look up every aspect. If you try to do so you will not have time to fully complete the assessment. This is especially true if you search for the same small piece of information in more than one reference book. You must be able to understand and answer the question without using reference books for every question. Only use the reference books if you are unsure of the answer to a question, or if you need confirmation and/or fine detail.
- **Allocate the available time proportionally to questions.** This might seem to be a very basic concept, but it is an area where candidates often fall short. Prior to the assessment, calculate the time allowed per mark. If you have not completed a question within your allocated time allowance move on to the next question. You can come back to a question with which you are having difficulties. Rather complete those questions where you are

confident of the answers and then spend time on questions where you will have to search for information.

- **Read the questions carefully.** Read the entire question slowly and ensure that you understand the question fully before you select your answer. Candidates often see a phrase in a question, decide that they know 'all about that' and select an answer accordingly, whereas if they had spent time reading the entire question, they would have realised their answers were irrelevant.
- **Calculations – is your answer realistic?** On completion of a calculation look critically at your answer: Is it realistic? Ensure that you bring a working calculator to the exam.
- Finally – have a good night's sleep before the assessment and try to relax and enjoy the experience. Your performance will likely improve if your stress levels are low.

### (g) **Assessment results**

The following principles apply regarding assessment results:

- During the assessment, the answer option chosen by the candidate is auto-saved by the system as the candidate clicks on it.
- Once the assessment has been submitted by the candidate or invigilator (in a case where the assessment ends before the candidate presses submit), the assessment is marked electronically by the system and the results are moderated by Council's appointed moderators to ensure fairness of the assessment.
- The results are expressed as **successful** where the candidate has passed the assessment or **unsuccessful** where the candidate has failed the assessment. The candidate is deemed successful where a minimum of fifty percent (50%) overall mark is obtained for the assessment, and a subminimum of fifty percent (50%) is obtained for the calculation and the general section, respectively.
- Results are approved by Council's Pre-registration Committee or a person to whom Council delegates the function, e.g. the Registrar.
- The results are released to candidates only after their approval.
- Candidates unsuccessful in the assessment will be required to re-write both sections of the assessment even if they were unsuccessful in only one (1) section of the paper.

The assessment **results are released within eight (8) weeks of the assessment** or as determined by Council.

Candidates, who have not been successful in the assessment **may not be awarded the qualification or registered as qualified Pharmacist's Assistants** until they have completed their assessment successfully.

### (h) **Review of the assessment results**

Candidates who have not been successful in the assessment may apply for review of the assessment by submitting a duly completed application form (available at [www.sapc.za.org](http://www.sapc.za.org))

to the SAPC within a month of the date on which the results are released. A fee for the review of the assessment is published on the SAPC website.

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

**NB!!! The assessment review does not constitute a remark of the assessment as the assessment is marked electronically and the results are moderated and approved by the Pre-Registration Committee prior to release.**

**(i) Re-assessment**

Candidates who are unsuccessful in the assessment may re-attempt the assessment, provided they meet the necessary requirements. **The assessment is one (1) paper; therefore, candidates will be required to re-write both sections of the assessment even if they were unsuccessful in only one (1) section of the paper.**

Candidates may have a maximum of three (3) attempts at the assessment. The format of subsequent assessments following the second (2<sup>nd</sup>) attempt, including the supplementary assessment, as determined by Council, will be communicated to affected candidates.

Candidates unsuccessful after the second (2<sup>nd</sup>) attempt will be required to undergo remediation prior to the third (3<sup>rd</sup>) attempt.

## 3. South African Pharmacy Council

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

| <b>Objects of Council</b>                                  |   |
|--|---|
| The objects in terms of the Pharmacy Act, 53 of 1974, are: |   |
| 1.   | To assist in the promotion of the health of the population of the Republic  |
| 2.   | To advise the Minister or any other person on any matter relating to pharmacy   |
| 3.   | To promote the provision of pharmaceutical care which complies with universal norms and values, in both the public and the private sectors, with the goal of achieving definite therapeutic outcomes for the health and quality of life of a patient  |
| 4.   | To uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and private sectors  |
| 5.   | To establish, develop, maintain and control universally acceptable standards: <ul style="list-style-type: none"> <li>• in pharmaceutical education and training</li> <li>• for the registration of a person who provides one or more or all of the services which form part of the scope of practice of the category in which such person is registered</li> <li>• of practice of the various categories of persons required to be registered in terms of this Act</li> <li>• of professional conduct required of persons to be registered in terms of this Act</li> <li>• of control over persons registered in terms of this Act, by investigating in accordance with the Act, complaints or accusations relating to the conduct of registered persons</li> </ul> |
| 6.   | Promote transparency to the profession and the general public (corporate governance)  |
| 7.   | Maintain and enhance the dignity of the pharmacy profession   |
| 8.   | Coordinate the activities of Council and its Committees   |
| 9.   | Improve internal efficiency and effectiveness   |
| 10.  | Build a pipeline of highly skilled workers to meet Council's mandate  |

### Vision of South African Pharmacy Council

"Accessible quality pharmaceutical services for all"

### Council's Mission Statement

The mission statement of SAPC is:

The South African Pharmacy Council exists to promote universal health coverage through patient-centric pharmaceutical services.

This will be achieved by:

- protecting the rights and safety of the public;
- developing, enhancing and upholding acceptable norms and standards in pharmacy;

- safe-guarding and enhancing public health;
- promoting the dignity of the profession by ensuring ethical practice and conduct;
- ensuring ongoing competency of pharmacy professionals;
- creating an enabling environment to foster the adoption of technology and innovation; and
- create an enabling environment for proactiveness and responsiveness to emerging developments and challenges in pharmaceutical care.

## Council's Core Values

- (a) **People first** – we shall protect and empower people, treat everyone equally, and be inclusive in our approach.
- (b) **Accessibility** – we shall be accessible and transparent.
- (c) **Agility and Innovation** – we shall adapt to change, be flexible and relevant.
- (d) **Collaboration** – we shall collaborate with all stakeholders.
- (e) **Integrity** - we shall be ethical, accountable and honest in conducting our business.



## Functioning of Council

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

### COUNCIL COMMITTEES

#### Executive Committee

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

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

#### Pre-registration Committee

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

#### Education Committee

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

### **Practice Committee**

The Practice Committee considers all matters relating to the establishment, development, maintenance and control of universally acceptable standards of the practice of the various categories of persons required to be registered in terms of the Act, as well as the promotion of pharmaceutical care which complies with universal norms and values, both in the public and the private sector, the registration of pharmacies, as well as the issuing of permits in terms of the Act or medicine-related legislation. It may also deal with other matters delegated to it by the Council from time to time.

### **Committee of Preliminary Investigation**

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

### **Committee of Informal Inquiry**

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

### **Committee of Formal Inquiry**

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

### **Health Committee**

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

### **CPD Committee**

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

## 4. PROVIDERS OF THE PHARMACIST'S ASSISTANT QUALIFICATIONS

List of accredited providers of Pharmacist's Assistant courses.

| <b>CERTIFICATE OF QUALIFICATION: Occupational Certificate: Pharmacist's Assistant (Basic) - NQF Level 4 and the Occupational Certificate: Pharmacist's Assistant (Post-Basic) – NQF Level 5</b>   |   |
|---|---|
| <b>Provider</b>   | <b>Revised Qualifications</b>   |
| S Buys Academy (Pty) Ltd.<br>Ms J Meyer<br>Tel: +27 (0) 18 788 2102/03<br>Email: <a href="mailto:marketing@sbuys.co.za">marketing@sbuys.co.za</a><br>Email: <a href="mailto:training@sbuys.co.za">training@sbuys.co.za</a><br>Website: <a href="http://www.sbuys.co.za">www.sbuys.co.za</a>   | <ul style="list-style-type: none"> <li>Occupational Certificate: Pharmacist's Assistant (Basic) - NQF Level 4</li> <li>Occupational Certificate: Pharmacist's Assistant (Post-Basic) – NQF Level 5</li> </ul>   |
| <b>CERTIFICATE OF QUALIFICATION: Pharmacist's Assistant (Basic) - NQF Level 3 and Pharmacist's Assistant (Post-Basic) - NQF Level 4</b>   |   |
| <b>Provider</b>   | <b>Revised Qualifications</b>   |
|   | <ol style="list-style-type: none"> <li><b>NATIONAL CERTIFICATE: PHARMACIST ASSISTANCE (BASIC)</b> <ul style="list-style-type: none"> <li>Last date for new enrolments: 30 June 2024</li> <li>End of teach-out period: 30 June 2027</li> </ul> </li> <li><b>FURTHER EDUCATION AND TRAINING: PHARMACIST ASSISTANCE (LEARNER POST-BASIC)</b> <ul style="list-style-type: none"> <li>Last date for new enrolments: 30 June 2024</li> <li>End of teach-out period: 30 June 2027</li> </ul> </li> </ol> |
| Abaluleki Professional Consulting<br>cc/University of Fort Hare Consortium<br>Ms N Mbabama<br>Tel: +27 (0) 43 704 7581<br>Cell: +27 (0) 74 403 2754<br>Email: <a href="mailto:mbabamanr@mweb.co.za">mbabamanr@mweb.co.za</a>  | <ul style="list-style-type: none"> <li>National Certificate: Pharmacist's Assistant: Institutional (NQF Level 3)</li> </ul>   |
| Health Science Academy (Pty) Ltd.<br>Ms L Crause<br>Tel: 087 821 1109<br>Email: <a href="mailto:hsaenquiries@healthscience.co.za">hsaenquiries@healthscience.co.za</a><br>Website: <a href="http://www.hsa.co.za">www.hsa.co.za</a>   | <ul style="list-style-type: none"> <li>National Certificate: Pharmacist's Assistant: Community, Institutional, Manufacturing, Wholesale (NQF Level 3)</li> <li>Further Education and Training Certificate: Pharmacist's Assistant: Community, Institutional, Wholesale (NQF Level 4)</li> </ul>   |
| Pharmacy Healthcare Academy<br>Mr AC Malgas<br>Tel: +27 (0) 11 222 5731<br>Email: <a href="mailto:am85@clicks.co.za">am85@clicks.co.za</a><br>Email: <a href="mailto:Alphonso.Malgas@clicksgroup.co.za">Alphonso.Malgas@clicksgroup.co.za</a>   | <ul style="list-style-type: none"> <li>National Certificate: Pharmacist's Assistant: Community (NQF Level 3)</li> <li>Further Education and Training Certificate: Pharmacist's Assistant: Community (NQF Level 4)</li> </ul>  |
| Pharmacy Training and Development<br>Project: Sefako Makgatho Health Sciences University (previously University of Limpopo (Medunsa Campus))<br>Ms E Loock<br>Tel: +27 (0) 12 521 4997<br>Email: <a href="mailto:elmarie.loock@smu.ac.za">elmarie.loock@smu.ac.za</a>                         | <ul style="list-style-type: none"> <li>National Certificate: Pharmacist's Assistant: Community, Institutional, Wholesale (NQF Level 3)</li> <li>Further Education and Training Certificate: Pharmacist's Assistant: Community, Institutional (NQF Level 4)</li> </ul>   |
| S Buys Academy (Pty) Ltd.<br>Ms J Meyer<br>Tel: +27 (0) 18 788 2102 / 03<br>Email: <a href="mailto:marketing@sbuys.co.za">marketing@sbuys.co.za</a><br>Email: <a href="mailto:training@sbuys.co.za">training@sbuys.co.za</a><br>Website: <a href="http://www.sbuys.co.za">www.sbuys.co.za</a> | <ul style="list-style-type: none"> <li>National Certificate: Pharmacist's Assistant: Community, Institutional, Manufacturing, Wholesale (NQF level 3)</li> <li>Further Education and Training Certificate: Pharmacist's Assistant: Community, Institutional, Manufacturing, Wholesale (NQF Level 4)</li> </ul>  |

## 5. Pharmacy Professional Organisations and Others

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

The information was provided by the various organisations listed below. Please note that this is not a complete list of pharmaceutical organisations in South Africa.

Candidates are encouraged to contact these organisations for further information regarding membership or services offered.

| CONTACT DETAILS OF PHARMACY PROFESSIONAL ORGANISATIONS                  |  |
|---|--|
| Generic and Biosimilar Medicines of Southern Africa (GBM)               | Box 32361<br>Kyalami, 1684<br>Web: <a href="https://qbmsa.org/">https://qbmsa.org/</a>   |
| Independent Community Pharmacist Association (ICPA)                     | Unit 3, Mews 2 Rosmead Centre<br>67 Rosmead Avenue, Kenilworth<br>Cape Town, 7708<br>Web: <a href="http://www.icpa.co.za">www.icpa.co.za</a>   |
| Innovative Pharmaceutical Association South Africa (IPASA)              | Ballyoaks Office Park<br>Building D 1 <sup>st</sup> Floor, 35 Ballyclare Drive<br>Bryanston, 2191<br>Email: <a href="mailto:info@ipasa.co.za">info@ipasa.co.za</a><br>Web: <a href="https://ipasa.co.za/">https://ipasa.co.za/</a>   |
| National Association of Pharmaceutical Wholesalers (NAPW)               | PO Box 3069<br>Houghton, 2041<br>Email: <a href="mailto:napw@mweb.co.za">napw@mweb.co.za</a>   |
| National Department of Health   | Private Bag X828<br>Pretoria, 0001<br>Tel 012-395 9306<br>Web: <a href="http://www.health.gov.za">www.health.gov.za</a>  |
| Pharmaceutical Society of South Africa (PSSA)                           | PO Box 75769<br>Lynnwood Ridge, 0040<br>Tel 012 470 9550<br>Email: <a href="mailto:info@pssa.org.za">info@pssa.org.za</a><br>Web: <a href="http://www.pssa.org.za">www.pssa.org.za</a>   |
| South African Association of Community Pharmacists (SAACP)              | PO Box 95123<br>Grant Park<br>Johannesburg, 2051<br>Tell: 011 728 6668 / 012 348 1000<br>Email: <a href="mailto:execdir@saacp.co.za">execdir@saacp.co.za</a><br>Web: <a href="http://www.pssa.org.za">www.pssa.org.za</a> / <a href="http://www.saacp.org.za">www.saacp.org.za</a> |
| South African Health Products Regulatory Authority (SAHPRA)             | Private Bag X828<br>Pretoria, 0001<br>Tel: 012 501 0300<br>Email: <a href="mailto:enquiries@sahpra.org.za">enquiries@sahpra.org.za</a><br>Web: <a href="http://www.sahpra.org.za">www.sahpra.org.za</a>  |
| Southern African Pharmaceutical Regulatory Affairs Association (SAPRAA) | PO Box 2909<br>Randburg, 2125<br>Email: <a href="mailto:info@sapraa.org.za">info@sapraa.org.za</a><br>Web: <a href="http://sapraa.org.za">http://sapraa.org.za</a>   |
| South African Society of Clinical Pharmacy (SASOCP)                     | Web: <a href="http://www.sasocp.co.za/">www.sasocp.co.za/</a>  |



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## 6. Department of Health and the National Drug Policy

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health

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Department:  
Health  
REPUBLIC OF SOUTH AFRICA

### Mission of the Department of Health

To improve health status through the prevention of illnesses and the promotion of healthy lifestyles and to consistently improve the healthcare delivery system by focusing on access, equity, efficiency, quality and sustainability.

### Aims

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

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

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

### Structures

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

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

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

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

- foster community participation across the health sector
- improve planning in the health sector and the monitoring of health status and health services

### **The National Drug Policy**

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

**Some important issues addressed by the NDP are summarised below.**

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

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

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

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

### **Objectives**

#### **1. Health objectives**

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

#### **2. Economic objectives**

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

#### **3. National development objectives**

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

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

#### **4. The role of the pharmacist**

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

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

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

## 7. Heads of Pharmaceutical Services

| PROVINCE      | NAME & SURNAME          | POSTAL ADDRESS   | CONTACT DETAILS                        | E-MAIL ADDRESS   |
|---------------|-------------------------|--|--|--|
| FREE STATE    | <b>Ms NB Molongoana</b> | PO Box 227<br>Bloemfontein<br>9300                                   | Tel.051 411 0502<br>Fax.051 430 2208   | <a href="mailto:molongoanb@fshealth.gov.za">molongoanb@fshealth.gov.za</a>                 |
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## **ANNEXURE A: ASSOCIATED ASSESSMENT CRITERIA FOR THE EXIT-LEVEL OUTCOMES**

### **ELO 1: Apply basic scientific knowledge to provide technical support in delivering pharmaceutical services**

- 1.1 Explain legislation related to the relevant scope of practice in pharmaceutical services in the South African context.
- 1.2 Demonstrate ethical and professional conduct related to the relevant scope of practice in the provision of pharmaceutical technical support services.
- 1.3 Explain basic pharmaceutical terms and concepts concerning non-sterile drug delivery systems and their routes of administration.
- 1.4 Explain basic scientific principles and apply non-sterile pharmaceutical preparations.

### **ELO 2: Provide technical support for the receiving, storing, picking, packing and distributing orders. To perform stock counts and participate in stock-taking in compliance with cGMP, GWDP and GPP requirements**

- 2.1 Conduct distribution and control of the stock of medicines, scheduled substances, and medical devices according to SOPS, and per cGMP, GPP and GWDP.
- 2.2 Pick, pack and secure orders for medicines or scheduled substances according to all requirements and check that orders dispatched according to SOPS.
- 2.3 Complete documents and maintain records following applicable legislation and SOPs.
- 2.4 Perform stock counts accurately and render assistance in stock taking

### **ELO 3: Provide technical support for the manufacture, packaging and re-packaging of non-sterile medicines and scheduled substances in compliance with GMP guidelines under the supervision of a Pharmacist**

- 3.1 Comply with pharmaceutical and cGMP principles and legislative requirements in the manufacture, packaging and/or repackaging of non-sterile medicines and scheduled substances.
- 3.2 Organise and prepare resources, materials and equipment for the preparation of specific medicines following relevant SOPs and process documentation.
- 3.3 Handle materials with due regard for environmental and storage conditions, transport and security requirements.
- 3.4 Conduct relevant manufacturing processes for non-sterile medicines and scheduled substances according to procedures.
- 3.5 Pack and re-package medicines and scheduled substances following GMP, ethical principles, relevant legislation, process documentation and SOPs, and authorised by a pharmacist.
- 3.6 Complete all documents and maintain records following cGMP guidelines.

### **ELO 4: Provide technical support for the compounding, manipulation and preparation of non-sterile medicines and scheduled substances (extemporaneous compounding) in compliance with standards as described in the GPP rules and GMP guidelines under the supervision of a Pharmacist**

- 4.1 Comply with the principles of GPP concerning the compounding of non-sterile medicines and substances.
- 4.2 Compound a simple solution, suspension and semi-solid following instructions (formulas), relevant SOPs and process documentation, using the principles of cGMP and/or GPP for specific patients.
- 4.3 Generate records for each of the preparations produced following legal requirements and organisational policies and procedures.
- 4.4 Check and clean equipment, according to SOPs.
- 4.5 Perform housekeeping activities according to SOPs.
- 4.6 Operate personal computer to generate documents and spreadsheets.