2015 Update: Pharmacy the Future – South Africa
SAPRAA

Vuyo Mokoena
Senior Manager: Professional Affairs (Practice)
South African Pharmacy Council

26 March 2015
Overview

• Status quo
• SAPC Website development
• Rules relating to Good Pharmacy Practice
• Good Education standards
• Specialists qualifications
• CPD
• Registrations of CSP
• Licensing and Recording of Pharmacies
• Midlevel workers in Pharmacy
• Online applications now mandatory
Status Quo

• Inspections 2014
• Inspection 2015
• Compliance issues
  ➔ No RP
  ➔ No Pharmacist
  ➔ Scope of practice
  ➔ No licensing
  ➔ No recording
## Compliance level 2013

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SAPC website development

- Individual member login and access
- Organization and provider (education) login and access
- Interactive functionality
Welcome

South African Pharmacy Council (SAPC) is the regulator established in terms of the Pharmacy Act, 1974 (Act 53 of 1974) to regulate pharmacists, pharmacy support personnel and pharmacy premises in South Africa. Our mandate is to protect, promote and maintain the health, safety and wellbeing of patients and the public ensuring quality pharmaceutical service for all South Africans.

Board Notice 49 of 2015 containing the GPP amendments for COMMENTS by 27 April 2015 click here

Welcome to the South African Pharmacy Council

Quick Links
- Contact us
- Complaints
- CPD
- Vacancies
- Documents
- Publications
- Rate our site
- Customer Survey

Registered persons click here Provider/Organisation Login Statistics

SAPC Register - Click here to search

Contact the SAPC

- 0861 7272 00 or 0861 SAPC 00
- +27(0)12 321 1492
- +27(0)12 321 1479
- customercare@sapc.za.org
- SAPC Building
  591 Belvedere St
  Arcadia
  0083
Rules relating to GPP

BOARD NOTICES

BOARD NOTICE 49 OF 2015

THE SOUTH AFRICAN PHARMACY COUNCIL

The South African Pharmacy Council intends to publish amendments and additional minimum standards to be added to Annexure A of the Rules relating to good pharmacy practice which was published on the 17 December 2004 Government Gazette No: 27112 in Board Notice 129 of 2004, in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974.

Interested parties are invited to submit, within 60 days of publication of this notice, substantiated comments on or representation regarding the amendments to the existing minimum standards and/or the additional minimum standards. Comments must be addressed to the Registrar, the South African Pharmacy Council, Private Bag 40040, Arcadia, or fax (012)326-1496 or email BN@sapc.za.org.
The following minimum standards were published for comment:

- Community or institutional pharmacy providing mobile pharmaceutical services;
- Community or institutional pharmacies operating internet sites;
- Collection and the delivery of medicines to patients from a community or institutional pharmacy; and
- Community or institutional pharmacy operating a remote automated dispensing unit (RADU)
Rules relating to what constitutes good pharmacy practice (Board notice 49 of 2015)

- **Amendments to Rule 1.4** - Minimum standards for community or institutional pharmacy providing mobile pharmaceutical services covers the following:
  - Purpose
  - General considerations
  - Pre-requisites for conducting mobile pharmaceutical services

- **Amendment to Rule 1.5** - Minimum standards for community or institutional pharmacies operating internet sites covers the following:
  - Introduction
  - Purpose
  - General considerations
Rules relating to what constitutes good pharmacy practice (Board notice 49 of 2015)

• **Insertion of Rule 1.10** - Minimum standards for a community or institutional pharmacy operating a remote automated dispensing unit (RADU)

• RADU standard covers the following:
  - Definitions
  - Purpose
  - General considerations
  - Specific considerations for a community pharmacy
  - Dispensing of medicines using a RADU
  - The responsibilities of a responsible pharmacist of the pharmacy from which the RADU is managed
  - Record keeping
  - Security, location, connectivity and features of a RADU
  - Documentation and information displayed conspicuously at the RADU
  - Information to be submitted in support of an application for installation and operation of a RADU
The following Rules relating to good pharmacy practice were published for implementation –

- Rule 1.2.1 paragraphs (d) and (e); and
- Annexure A to Rule 2.1.1.2.
- Minimum standards for the procurement, storage and distribution of thermolabile pharmaceutical products; and
- Minimum standards relating to automated dispensing units for the purpose of dispensing medicines and medical devices
Rules relating to what constitutes good pharmacy practice (Board notice 50 of 2015)

- Amendment to Rule 1.2.1 paragraphs (d) and (e) covers the following:
  - Names and surname of pharmacist on duty being conspicuously displayed in or outside the pharmacy
  - Pharmacist and pharmacy support personnel wearing name tags or name tags
  - Name tags or badges must indicate the designation (can be one badge or two badges)
- Amendment Annexure A to Rule 2.1.1.2 covers the circumstances and conditions under which a responsible pharmacist may be absent from pharmacy
  - Paragraph (i) is repealed, and paragraph (ii) is amended as follows:
    Schedule 1 to 6 substances are locked away in an area of which the key must be in the personal possession of the responsible pharmacist.
Rules relating to what constitutes good pharmacy practice (Board notice 50 of 2015)

- Amendment to Rule 2.3.5 - Minimum standards for the procurement, storage and distribution of thermolabile pharmaceutical products
  - Procurement
  - Storage
  - Distribution
  - Transportation
  - Receiving
  - Documentation
  - Personnel
Rules relating to what constitutes good pharmacy practice (Board notice 50 of 2015)

- Rule 1.9 Minimum standards relating to automated dispensing units for the purpose of dispensing medicines and medical devices
- ADUs in community pharmacies, institutional pharmacies, dispensaries in primary health care clinics and medicine rooms of licensed dispensers
- ADU - assist with Phase 2 of Dispensing
- ADU standard covers the following:
  - Dispensing of medicines using a ADU
  - The stocking and management of the ADU
  - The responsibilities of a responsible pharmacist of a pharmacy approved to operate an ADU
  - Security, location, connectivity and features of an ADU
  - Record keeping
  - Information to be submitted in support of an application for the installation of the ADU in a pharmacy
Rules relating to what constitutes good pharmacy practice

• Rule 4.3.6: Minimum standards for continuous supply of medicines not amended and read as follows:
   A community and institutional pharmacy must have a pharmacist available to provide a pharmaceutical service to the public on a 24-hour basis.
   If a pharmacy is not open on a 24-hour basis, a designated pharmacist(s) must be available for the emergency supply of pharmaceutical services.
   Contact details of the pharmacist-on-duty must be displayed conspicuously at the pharmacy premises

• Rule 4.2.3.2 Closure of pharmacies not amended and read as follows
• When a pharmacy is closed the following information must be made available to members of the public:
   the contact details of a pharmacist practising in the pharmacy in question;
   information as to alternate facilities where pharmaceutical services can be obtained in an emergency; and
   details relating to when the pharmacy will be opened/ closed.
Good Pharmacy Education Standards: Higher Education and Training (Board Notice 153)

• **Minimum standards for:**
  - vision, mission and planning
  - organisation and administration
  - work-integrated learning
  - facilities and financial, human and physical resources
  - quality assurance
  - short courses registered with council
Scopes of practice and qualifications for Specialist pharmacists - Board Notice 152 of 2014

- Three categories of specialists published
  - Clinical Pharmacy
  - Radio-pharmacy
  - Public Health Pharmacy and Management
- Industrial pharmacist the scope and qualification to be drafted
- 240 credits for Radio-pharmacy & Public Health Pharmacy and Management – based on inputs provided by profession
- 360 credits for Clinical Pharmacy
Scopes of practice and qualifications for Specialist pharmacists - Board Notice 152 of 2014

- Registration requirements
  - Professional masters degree
  - 2 year experience professional masters degree
- Recognition of prior learning is still to be determined by Council (consultation with profession to take place)
Wayfoward

• Publish amendments to the Regulations relating to the registration of persons and the maintenance of registers to make provision for specific categories for existing specialist pharmacists and new categories of specialist pharmacists:
  ✅ Radiopharmacist (existing);
  ✅ Pharmacokineticist (existing);
  ✅ Clinical Pharmacist (new);
  ✅ Public Health Pharmacy and Management (new).

• Publish amendments to the Regulations relating to the practice of pharmacy to make provision for the scopes of practice of the abovementioned specialist pharmacists; and

• Publish regulations in terms of Sections 33 and 49(mA) to provide the required qualifications for the specialist pharmacists.
Continuing Professional Development (CPD)

- CPD is currently obligatory for Interns and Tutors
- CPD regulations were published for comments in 2011 and comments were incorporated to the regulations
- Council has been requested to resubmit the CPD regulations with minor amendments to National Department of Health
Registrations of Interns and CSP

• Interns registrations is done online –
  ➤ Approved premises
  ➤ Approved Tutor
  ➤ Pay all applicable fees

• Community Service Pharmacist registrations is done online –
  ➤ Apply to DOH
  ➤ Can only be performed at gazetted sites
  ➤ Provincial and National Department of Health to sort the allocation of posts and placement
  ➤ SAPC annually provides National Department of Health with register of interns to assist in planning.
  ➤ SAPC to register compliant applicants
Licensing and recording of pharmacies

• Apply for license to the National Department of Health –
  ➢ NDOH do site inspection to verify need
  ➢ NDOH and SAPC Check compliance to ownership regulations
  ➢ SAPC issue GPP Certificate
  ➢ License issued by NDOH
  ➢ License holder to record with SAPC within 30 days

• New category of pharmacy to be added – Courier Pharmacy

• Draft MOU in progress with NDOH to handover admin functions to SAPC–
  ➢ DOH published the Guidelines relating to the criteria for issuing of pharmacy licence for comments and comments were reviewed and
  ➢ In light of some of the comments made it is foreseeable that the Guidelines will be published once more for comment before implementation
  ➢ Once Guidelines relating to the criteria for issuing of pharmacy licence published for implementation – administration of license will be done by SAPC
Midlevel workers in pharmacy

• SAPC has applied to Quality Council for Trade and Occupations (QCTO) for extension of current pharmacist’s assistant qualifications to 2018 and 2019 respectively
• Response is expected before end of April 2015
• Scoping of the following qualifications to take place in March and April 2015 according QCTO framework
  ➔ Pharmacy General Assistant
  ➔ Pharmacy Technical Assistant
  ➔ Pharmacy Technician
• New QCTO qualifications will allow for work integrated learning
• New midlevel worker cadres produced using CHE framework registered for traineeship for first time in 2015 i.e. Pharmacy Technical Assistant and Pharmacy Technician.
Why Online Processes?

- Improve service delivery by:
  - reducing turnaround times;
  - elimination of time delays if applications is submitted incomplete with outstanding documents;
  - elimination of risk of loss of posted or faxed forms
  - elimination of errors in data capturing
  - immediate updating of the register system.
  - system verifies applications – it is not done manually

- Council adopted ‘Go Green’ approach automating everyday business processes

- You can do business with council 24 hour per day, 7 days a week

- Comfortable and Convenient
Ensure:

- Your cell phone number and e-mail address is updated with Council
- Payments for P-number and Y-numbers are up to date
Online applications now mandatory

- No manual applications will be accepted for:
  - New Premises approval
  - Inspections (New Premises and Monitoring)
  - Submission of shortcoming letters
  - Tutor
  - Intern
  - Community Service Pharmacist
  - Pharmacist after CSP (Release online by HOPS)
  - Responsible Pharmacist
  - PT and PTA Trainee

- Provider/Organisation online submit:
  - Learner Basic
  - Learner Post Basic
  - PT and PTA Student
  - BPharm student
How Council communicate with you

**e-Pharmaciae** – council’s official e-publication distributed bi-monthly to every pharmacy professional. Ensure your e-mail address is updated to receive the latest e-edition carrying pharmacy information and council decisions.

**SAPC i-news / e-info** – bulletins dedicated to communicate urgent council information to pharmacy professionals that requires immediate action on their part.

**Bulk Sms’s** – Ensure your cell number is updated with council to receive instant messaging on application progress, exam results, exam dates, updates and other important information.

**SAPC website** – utilise SAPC website to check the latest news and information on the website banner (home page).

workshops, exhibitions, conferences etc.
Save the Date

The 2nd National Pharmacy Conference will be held in 2016 – the exact date and venue to be confirmed shortly.
Questions
Humility is a Strength
Arrogance is a Weakness