

2nd National Pharmacy Conference

Moving to Pharmacy 2030 - **Shaping the Future**

21 - 24 October 2016 - Durban ICC

#2NPCSAPC



South African
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SAPC Update

SAPRAA

TA Masango

(Registrar/CEO)

8 April 2016



Overview

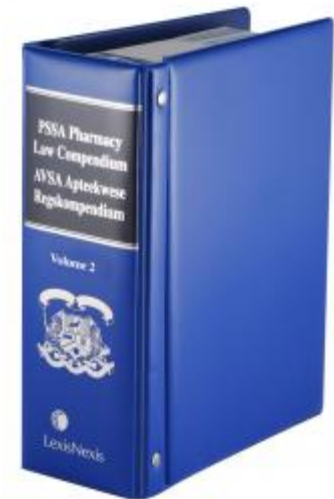
- Conditions under which a pharmacy shall be conducted
- Responsibilities of the RP
- Inspections
- Mid-level workers in pharmacy
- Competence standards for pharmacists
- Online processes





Conditions under which a pharmacy shall be conducted

- Acts / services performed in a pharmacy must be in line with (*Chapter VII of Practice Regulations 20-23*)-
 - ➔ Good Pharmacy Practice
 - ➔ Code of Conduct
 - ➔ Provisions applicable to legislation





Conditions under which a pharmacy shall be conducted (cont.)

- Scheduled medicines (S0 to S6) in a pharmacy may only be handled by (*refer to Reg. 20 of practice regs.*):
 - ➔ Pharmacist
 - ➔ Pharmacist intern under direct personal supervision by a pharmacist
 - ➔ Pharmacy support personnel under direct personal supervision by a pharmacist
- Hence, dispensary must not be accessible to unregistered people (public and private)
- S1/2 area must be under the continuous supervision of a pharmacist in the dispensary





Conditions under which a pharmacy shall be conducted (cont.)

- Every pharmacy must be conducted under direct personal supervision of responsible pharmacist (RP)
 - ➔ Exceptions determined by Council
 - ➔ Name of RP must be displayed conspicuously over the main entrance of the pharmacy
- Name of pharmacist(s) on duty must be displayed conspicuously in the pharmacy for purposes of identification of such person(s) by the public





Responsibilities of the RP

- RP must (*Chapter VIII of Practice Regulation 28*):
 - ➔ continuously supervise his/her pharmacy
 - ➔ have appropriate qualifications & experience
 - ➔ ensure that persons practising scope of practice in a pharmacy are appropriately registered with Council
 - ➔ notify Council on termination of his/her services as RP
 - ➔ take corrective measures re: inspection reports
 - ➔ ensure no unauthorised access to scheduled medicines
 - ➔ establish policies and procedures
 - ➔ ensure safe and effective storage/keeping of medicines
 - ➔ correct and effective record keeping of medicine sales, purchases, possessions, storage, safekeeping & returns





Trends in Disciplinary Action

- Dispensing errors by pharmacy support personnel as a result of no supervision or systems that promote insufficient supervision
- Pharmacies being operated without an RP or even a pharmacist present
- Pharmacists and locum pharmacists not knowing the registration status of pharmacy support personnel – so they are working outside of their registered Scope of Practice





Who will be held responsible?

- The RP is ultimately responsible to Council for the overall management of the pharmacy, however, in the absence of a registered RP with Council:
 - ➔ it will be the owner (private sector)
 - ➔ it will be the HOPS (public sector)
- RPs are being held accountable for GPP shortcomings (Grade C pharmacies) and failing to put systems in place that minimize or reduce transgressions by other pharmacists and pharmacy support personnel





2015 Community Pharmacy Inspections Report

Grading	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape	Grand Total
A	35	15	121	51	8	37	17	7	56	347
B	21	12	98	48	28	21	18	6	53	305
C	10	1	43	25	13	7	4	1	14	118
	70	29	275	128	50	73	42	14	135	816





2015 Hospital Pharmacy Inspections Report

Grading	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape	Grand Total
Institutional Private	5	2	16	9	3	5	6		6	52
A	5	1	15	7	1	5	3		5	42
B			1	2	2		1		1	7
D		1					2			3
Institutional Public	27	8	28	33	9	10	11	13	20	159
A	12	6	15	21	7	7	8	1	12	89
B	9		9	6	2	2	1	4	4	37
C	6	1	3	5				7	1	23
D		1	1	1		1	2	1	3	10



2015 Manufacturing Pharmacy Inspections Report

Grading	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape	Grand Total
Manufacturing Pharmacy	2		19	3		1			8	33
A	2		14	1		1			2	20
B			3	2					3	8
C			1						2	3
D			1						1	2





2015 Wholesale Pharmacy Inspections Report

Grading	Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape	Grand Total
Wholesale Pharmacy Private	5	1	21	7	2	1	1		12	50
A	3		6	2	1	1			6	19
B		1	9	5			1		1	17
C	1		1						4	6
D	1		5		1				1	8
Wholesale Pharmacy Public	1				1					2
B	1									1
C					1					1



Selling of HIV screening test kits

- HIV screening test kits that claims to be conclusive in diagnosing HIV may not be sold in pharmacies
- A pharmacist, pharmacist intern or pharmacy support personnel must have adequate training to properly counsel the caregiver/agent/patient before the sale of such HIV screening test kits
- The pharmacist must provide the caregiver/agent/patient with
 - ➔ information on how to conduct the test,
 - ➔ how to correctly interpret the test results; and
 - ➔ where to access follow-up and support services in the surrounding area





Mid-level workers in pharmacy

- Extension to offer qualifications for pharmacists' assistants is granted until 30 June 2018
- Council in July 2015 resolved that pharmacy support personnel are:
 - ➔ **Pharmacist's assistants (Basic) at NQF level 4**
 - ❖ Scope of practice to remain
 - ➔ **Pharmacist's assistants (Post-Basic) at NQF level 5**
 - ❖ Scope of practice to remain
 - ➔ **Pharmacy Technicians at NQF level 6**
 - ❖ Currently practising scope of practice of Post-Basic Pharmacist's Assistant until amended Regulations are published



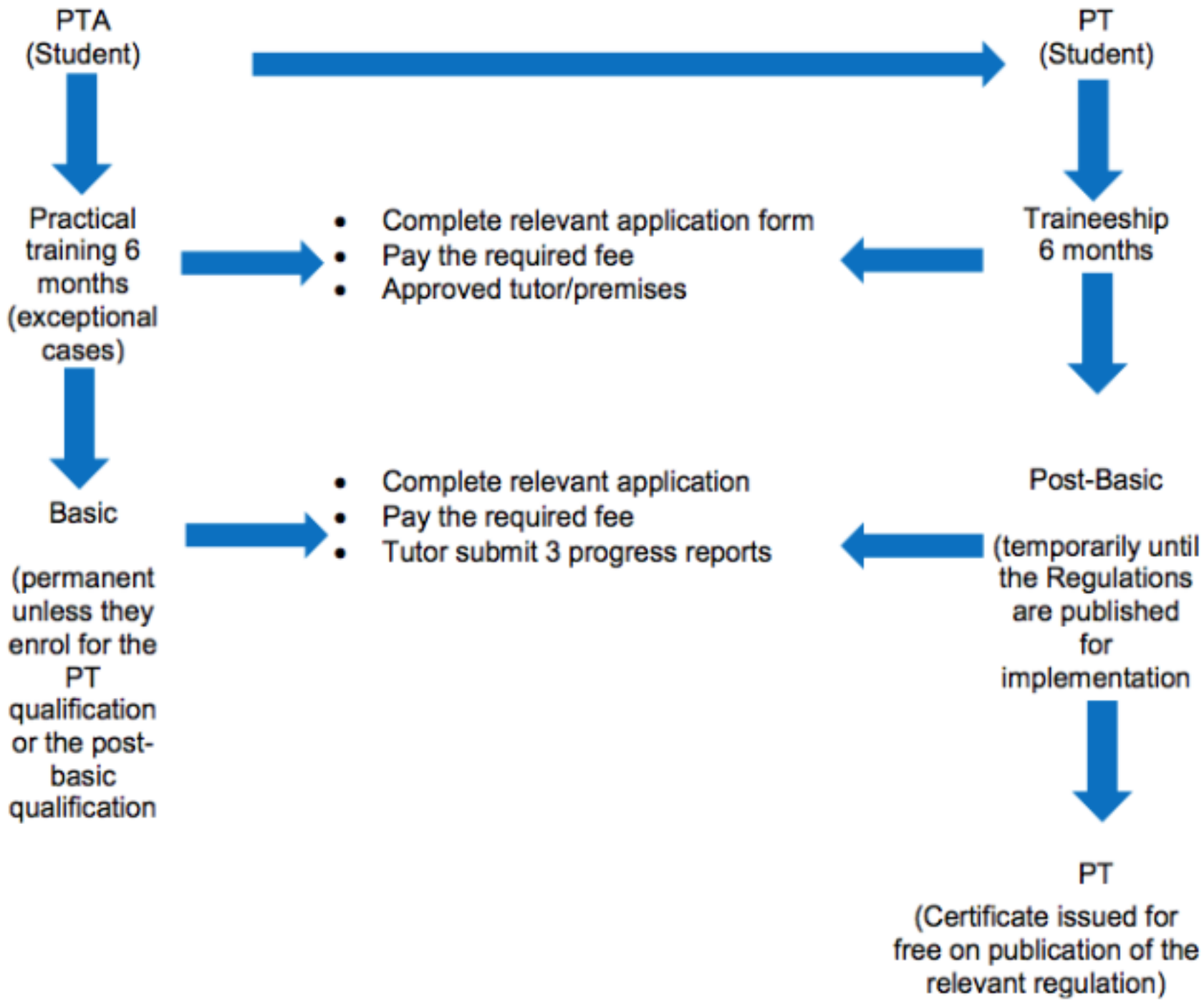


Training of mid-level workers

- Training of PTs will be in two ways:
 - ➔ CHE sub-framework
 - ➔ QCTO sub-framework
- CHE sub-framework
 - ➔ Current (*see flow chart in the next slide*): Higher Certificate / PTA (NQF 5) as prerequisite to Advanced Certificate / PT (NQF 6) as allowed by the education framework at that time
 - ➔ Proposed: 2-year diploma (NQF 6) to be developed (in progress)



May apply for RPL





Training of mid-level workers (cont.)

- Current PAB (NQF 3) & PAPB (NQF 4) qualifications
 - ➔ Expired on 30 June 2015
 - ➔ Extended (for accredited providers) until 30 June 2018 pending new qualification being developed in the QCTO format
- New qualification in QCTO sub-framework, i.e. occupational qualification, with 3 parts or exit points
 - ➔ PAB (NQF 4) = part qualification
 - ➔ PAPB (NQF 5) = part qualification
 - ➔ PT (NQF 6) = full qualification
 - ➔ Plan to finalise in 2016 and accredit providers in 2017





Review of Competence Standards

- The current competence standards (CS) for pharmacists were developed in 2006
- In 2010 and 2011, the BPharm qualification was revised
- Current qualification implemented in 2013
- BPharm qualification will expire in June 2018
- In 2015, Council resolved that the CS be reviewed
 - ➔ inline with the FIP CS used for pharmacists
 - ➔ to inform the *new curriculum* to be implemented in 2018
- The team to review the CS will include members from professional associations and pharmacy schools





Review of Competence Standards(cont.)

- The draft CS developed will follow the process:
 - ➔ presented to the Task Team approved by Council
 - ➔ presented to the CPD Committee
 - ➔ Approved by Council
 - ➔ Published for narrow consultation
 - ➔ Published for wider consultation
 - ➔ Published for implementation





Current Competence Standards

1. organise and control the manufacturing, compounding and packaging of pharmaceutical products
2. organise the procurement, storage and distribution of pharmaceutical materials and products
3. dispense and ensure the optimal use of medicines prescribed to the patient
4. provide pharmacist initiated care to the patient and ensure the optimal use of medicine
5. provide information and education on health care and medicine





Current Competence Standards (cont.)

6. promote community health and provide related information and advice
7. participate in the registration of medicine and research to ensure the optimal use of medicines
8. facilitate the development of pharmaceutical personnel
9. practise pharmacy professionally and ethically
10. manage the pharmacy/pharmaceutical service





Specialities in Pharmacy

- **2 Existing categories of specialities**
 - ➔ Radio Pharmacist (240 credits – new qualification)
 - ➔ Pharmacokineticist (will not be there in future as it is part of the clinical pharmacy speciality)
- **3 Additional categories approved by Council in 2011**
 - ➔ Public Health Pharmacist (240 credits)
 - ➔ Industrial Pharmacist (240 credits)
 - ➔ Clinical Pharmacist (360 credits)
- **3 qualifications were approved by Council – 13/14 May 2015**
 - ➔ Radio Pharmacist
 - ➔ Clinical Pharmacist
 - ➔ Public Health Pharmacist





Industrial Pharmacist

- Draft qualification- Council meeting in May 2016
- Narrow consultation
- Wider consultation
- Process of drafting regulations





Online registration processes

- Online applications are implemented for the following:
 - ➔ Pharmacist's assistant learner basic and post-basic registration
 - ➔ Pharmacist's assistant basic and post-basic registration
 - ➔ Pharmacist's assistant submission of progress report (4, 8 and 12 months)
 - ➔ Student registration (BPharm, PTA and PT)
 - ➔ Pharmacist intern registration
 - ➔ Pharmacist intern application to write pre-registration examination





Online registration processes (cont.)

- Online applications are implemented for the following:
 - ➔ Pharmacist intern submission of progress report
 - ➔ Pharmacist registration to perform remunerated community service(CSP)
 - ➔ Pharmacist – completion of remunerated community service
 - ➔ Pharmacist – voluntary removal from register
 - ➔ Responsible pharmacist application and resignation
 - ➔ Tutor application and resignation
 - ➔ Premises approval and recording of pharmacy





Online registration processes (cont.)

- Group owner pharmacy login
 - ➔ Update employee details
 - ➔ Make bulk payments
 - ➔ Recording of new pharmacy
 - ➔ Respond to inspection shortcomings
 - ➔ Respond to GPP shortcomings for license applications
 - ➔ View inspections, tutors, learners, RP
- Tracking your application status with Council
- License applications planned to go online from 1 May 2016





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to be submitted by:
1 July 2016



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Questions





Thank you



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