

South African Pharmaceutical Regulatory Affairs

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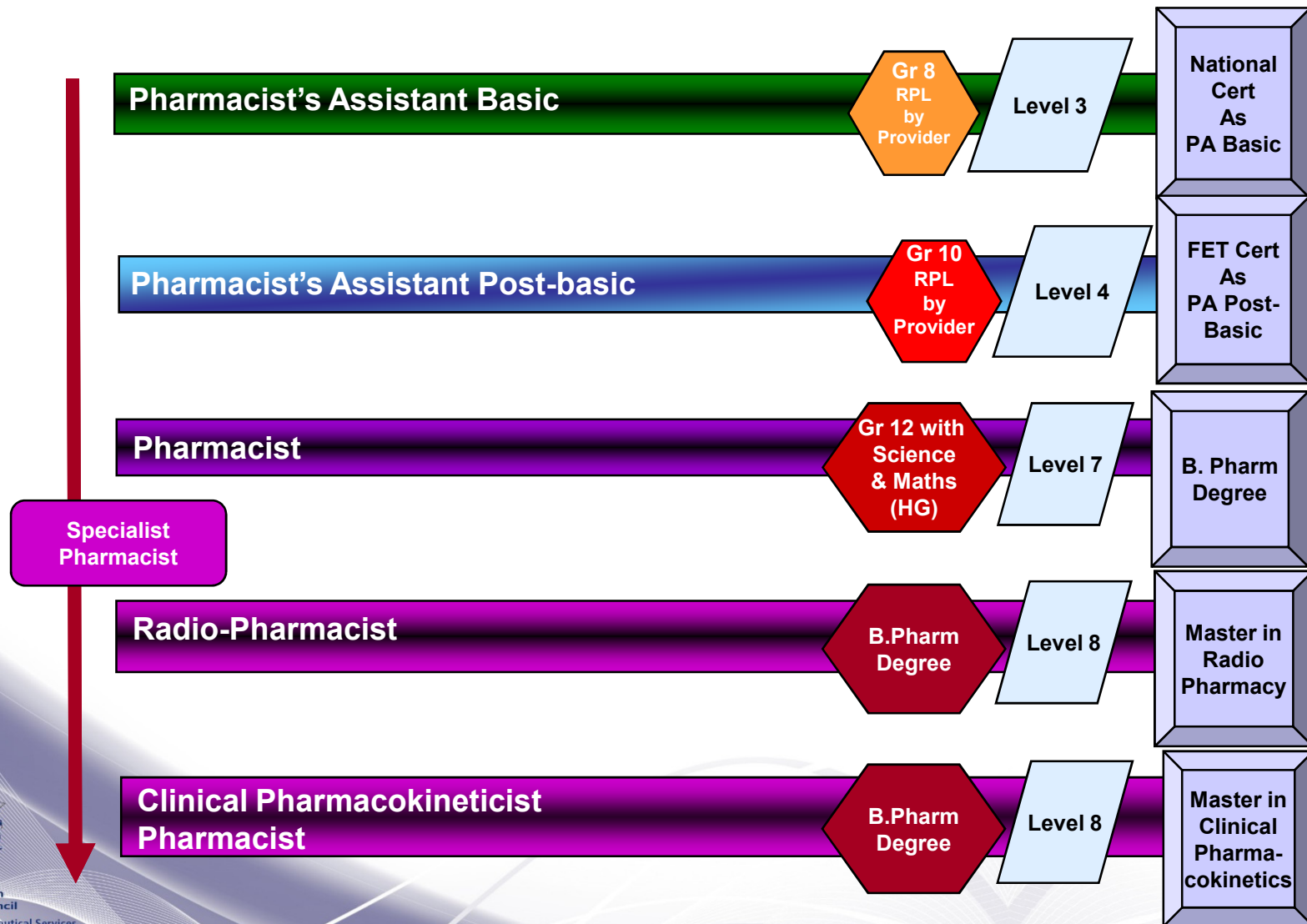
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Overview

- Category of registered persons – new cadre
- Career progression in pharmacy
- Rational for the new cadre
- Scope of Practice
- Exit level outcomes
- Bachelor of PharmacySpecialities in Pharmacy
- Registration requirements of new cadres



Categories of registered persons



- ***The NQF*** is a set of principles and guidelines by which records of learner achievement are registered to enable national recognition of acquired skills and knowledge, thereby ensuring an integrated system that encourages lifelong learning.



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Our decisions and practice models will influence the future practice of pharmacy

. . .

Any change, even a change for the better, is always accompanied by drawbacks and discomforts.

Arnold Bennett



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‘there is nothing permanent except change’

Lanning H. 2001

**“Change is the law of life and those who look only
to the past or present are certain to miss the
future”**

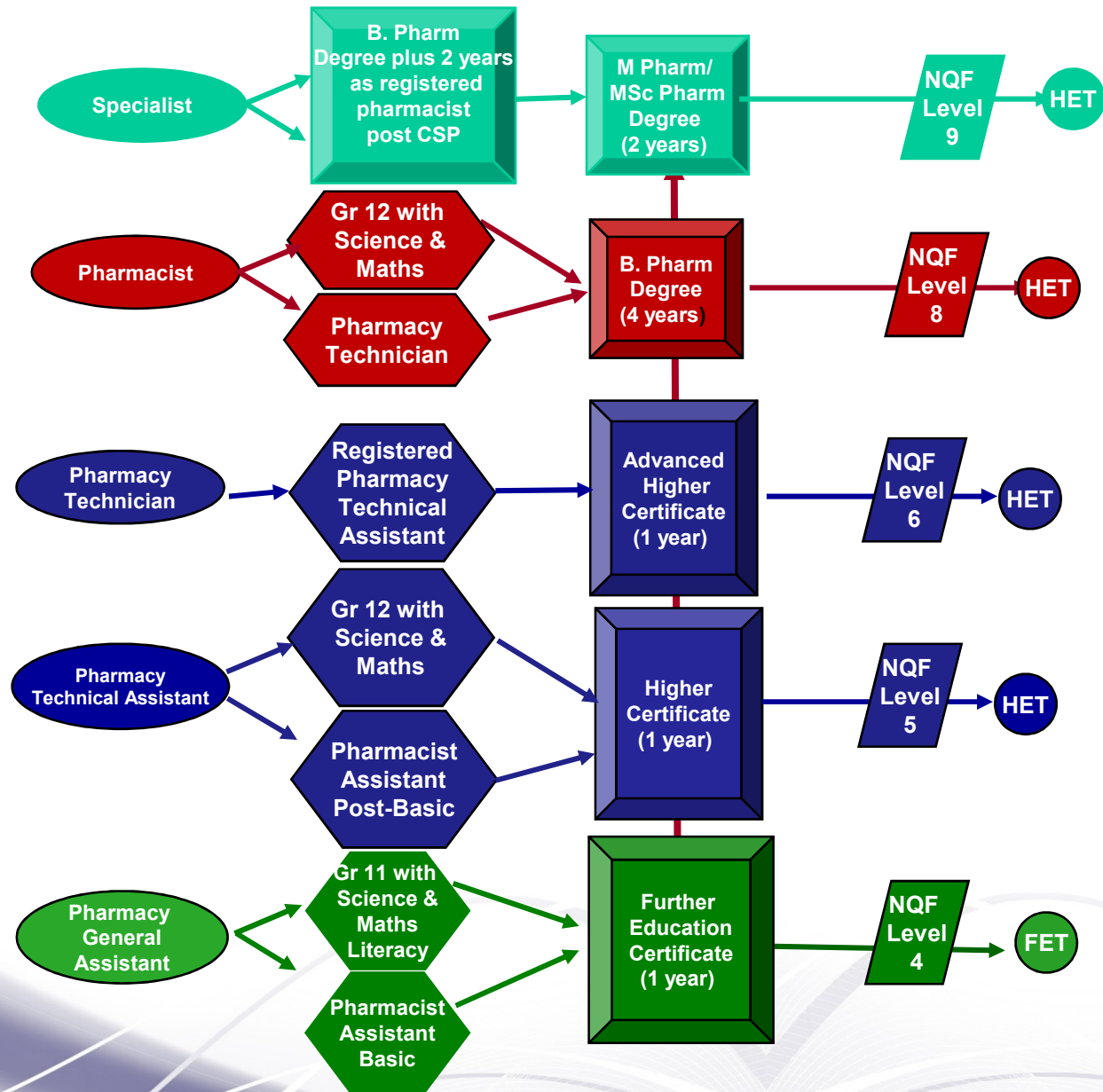
John F. Kennedy



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Career progression in pharmacy

My Pharmacy career



Rationale for the PT qualification

- The Advanced Certificate: was developed to meet the requirements of the National Human Resources for Health Plan, with specific reference to the need for mid-level workers in provision of pharmaceutical services to the people of South Africa.
- It is aimed at developing the core technical knowledge and personal skills acquired during qualification for the Higher Certificate: PTA thereby contributes towards development of a career path for mid-level workers



Why were the new cadres introduced?

- The extended scope of the PT will free the pharmacist from the more technical product oriented tasks and allow the pharmacist more time to be involved in research, innovation, operational effectiveness / efficiencies as well as providing strategic leadership



Manufacturing and Wholesale:

- Free the pharmacist for involvement in critical stages of the process.
- Responsible pharmacist must ensure that all is according to GMP/GWP.



How are pharmacists spending their time?

- Study in the USA in 1999:
 - ➔ 60% of time performing technical tasks which could be undertaken by technician
 - ➔ Only 31% of time spent on clinical activities



How are pharmacists spending their time?

- Study in the USA in 2000:
 - ➔ 56% of time performing technical dispensing tasks which could be undertaken by technician
 - ➔ Only 28% of time spent on clinical activities

(Schommer, J. 2010. Pharmacist contribution to the US Health care System. Innovations in Pharmacy. Vol 1(1))



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How are pharmacists spending their time?

- **In South Africa**

- ➔ Ratio of pharmacists to pharmacy support personnel
- ➔ 1 pharmacist to less than 1 Pharmacy support personnel (PSP)
- ➔ Council register 13 500 pharmacists and 6 000 PSP excluding those still learning

(SAPC Annual report 2012)

Purpose of the PT qualification

- In Institutional / Community: Able to work under supervision of a pharmacist who is physically present in a pharmacy or, **under specified circumstances**, under the supervision of a pharmacist who is physically not present in the dispensary of a PHC.
- All functions would have to be performed in accordance with standard operating procedures approved by the responsible pharmacist or supervising pharmacist.
- **In manufacturing and wholesale pharmacies:** PT will be able to perform certain defined functions without the direct oversight of a pharmacist. Such functions will be performed in accordance with the Batch Manufacturing Documents and standard operating procedures approved by the responsible pharmacist.



Scope of practice mid-level workers

Applies to PTA and PT

Scope	Community and Institutional	Manufacturing and wholesale
General housekeeping and administrative task in the pharmacy as specified by the responsible pharmacist	Yes	Yes
Assist with packaging and re-packaging of Schedule 0 to Schedule 5 (excluding Specified Schedule 5) medicines	Yes	Yes
Picking, packing and dispatching of orders for Schedule 0 to Schedule 5 medicines provided that orders that contain schedule 5 medicines are validated by a pharmacist prior to release thereof	Yes	Yes
Assist with the management of stock of Schedule 1 to Schedule 5 medicines : Provided that orders that contain medicines which fall into schedule 5 are validated by a pharmacist	Yes	Yes
Assist with the compounding, manipulation, preparation and manufacturing of non-sterile Schedule 1 to Schedule 5 medicines ; provided that the pharmacy general assistant is not involved in the planning of the production process, interpretation and evaluation, validation and quality assurance	Yes	Yes



Scope of practice mid-level workers

Applies to PTA and PT

Scope	Community and Institutional	Manufacturing and wholesale
The checking of orders containing Schedule 1 to 4 medicines in closed packs, prior to the packing and dispatch thereof, which have been picked by a pharmacist's assistant, as well as the supervision of such persons: Provided that this function may only be performed in a manufacturing pharmacy, wholesale pharmacy or bulk store of an institutional pharmacy	Yes	Yes
Assist with the manufacturing, compounding, manipulation or preparation of sterile medicine or scheduled substance, in accordance with the Medicines Act	Yes	Yes
Assist with the selection or preparation of a Schedule 1 to Schedule 5 medicine or scheduled substance prescribed by an authorized prescriber and the labelling of an appropriate container, following the interpretation and evaluation of the prescription by a pharmacist	Yes	No



Scope of practice mid-level workers

Applies to PT only

Scope	Community and Institutional	Manufacturing and wholesale
The provision of information to a patient, caregiver or the agent of a patient to optimize therapeutic outcomes resulting from the use of medicines which have been dispensed at a pharmacy and sent to the primary health care clinic for supply to the patient or the patient's agent or caregiver	Yes	No
The ordering and receipt of Schedule 1 to Schedule 5 medicines : Provided that orders that contain schedule 5 medicines are validated by a pharmacist;	Yes	Yes
The sampling, or supervision of the sampling of medicines in accordance with Good Manufacturing Practice	No	Yes
Supervision of pharmacy support personnel as specified by the responsible pharmacist	Yes	Yes
The provision of technical support in the provision of screening tests provided that where an interpretation of results is required this is done by a pharmacist	Yes	No



Exit level Outcomes (ELO): Pharmacist's Assistant Post Basic

ELO 1: Communicate effectively to provide assistance to the pharmacist and the community.

ELO 2: Utilise Mathematical Literacy skills in the workplace and in daily living.

ELO 3: Apply specific pharmaceutical skills and knowledge in the workplace.

ELO 4: Interact with patients/clients in a pharmaceutical environment.

ELO 5: Apply management functions in the workplace.

ELO 6: Apply personal development skills in the work environment.



Exit level outcomes: Pharmacists vs Pharmacy Technicians

- ELO 1: Integrate and apply foundational scientific principles and knowledge to pharmaceutical sciences;
 - ELO 2: Apply integrated knowledge of product development and formulation in the compounding, manufacturing, distribution and dispensing of pharmaceutical products;
 - ELO 3: Compound, manipulate and prepare medication in compliance with Good Pharmacy Practice (GPP) rules, Good Manufacturing Practice (GMP) and/or Good Clinical Practice (GCP) guidelines;
 - ELO 4: Manage the manufacture, packaging and registration of pharmaceutical products in compliance with GMP and GCP;
 - ELO 5: Manage the logistics of the selection, procurement, storage, distribution and disposal of pharmaceutical products;
- ELO1: Apply scientific knowledge to provide technical support in pharmaceutical services.
 - ELO 2: Provide technical support to compound, manipulate and prepare sterile and non-sterile medicines and scheduled substances in compliance with standards as described in GPP rules and GMP guidelines under the supervision of a pharmacist.
 - ELO 3: Provide technical support to manufacture, package and re-package sterile and non-sterile medicines and scheduled substances in compliance with GMP guidelines under the supervision of a pharmacist.
 - ELO 4: Provide technical support to order, manage, despatch and dispose of medicines, Scheduled substances, medical supplies and devices in compliance with GWDP and legal requirements.
 - ELO 5: Provide technical support to dispense prescriptions for patients in compliance with applicable legislation, including GPP.



Exit level outcomes: Pharmacists vs Pharmacy Technicians

- ELO 6: Dispense medication and ensure optimal pharmaceutical care for the patient in compliance with GPP and, where applicable, GCP;
 - ELO 7: Apply a pharmaceutical care management approach to ensure rational medicine use;
 - ELO 8: Initiate and/or modify therapy, where appropriate, within the scope of practice of a pharmacist and in accordance with GPP and GCP, where applicable;
 - ELO 9: Promote public health;
 - ELO 10: Integrate and apply management principles in the practice of pharmacy; an
 - ELO 11: Participate in research
- ELO 6: Provide schedule 1 and 2 medicines in accordance with legal requirements, including GPP.
 - ELO 7: Manage the dispensary in a Primary Health Care Clinic under the indirect supervision of a Pharmacist.
 - ELO 8: Demonstrate an understanding of the principles of management of common chronic conditions.
 - ELO 9: Demonstrate an understanding of principles of traditional African medicines.
 - ELO 10: Demonstrate an understanding of principles of complementary medicines.
 - ELO 11: Demonstrate an understanding of principles of nutraceuticals and functional foods.



Specialities in Pharmacy

- 2 Existing specialist on the register
- 3 Additional Categories of Specialists approved by Council
 - ➔ Clinical Pharmacist
 - ➔ Public Health / Management Pharmacist
 - ➔ Industrial Pharmacist
- Scope of practice of all 3 categories were approved



Industrial pharmacist

- The focus would be on product formulation, innovation, manufacturing storage and distribution and possible areas of interest:
 - ➔ Pharmaceutical research and development
 - ➔ Regulatory affairs
 - ➔ Warehousing and distribution of pharmaceuticals (inbound and outbound logistics)
 - ➔ GMP and Quality management systems in the manufacture of medicines



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Scope of practice for Industrial pharmacist

- Perform acts and services pertaining to the profession of a pharmacist
- Control both intrinsic and extrinsic quality of a product taking into account patient health and safety
- Manage knowledge and transfer of research evidence into practice
- Provide strategic leadership for manufacture of medicine, warehousing and supply chain management
- Design, develop and interpret quality systems for implementation of GMP



Scope of practice for Industrial pharmacist cont.

- Provide education and training relating to industrial pharmacy
- Provide pharmaceutical leadership and guidance in directing the business
- Take a leading role in pharmaceutical research and development
- Take a leading role in the development of and contribution to regulatory guidelines and relevant legislation
- Appraise pharmaceutical information, make informed decisions with the evidence available and be able to justify/defend the decisions



Registration requirements as a PTA trainee / PTA

- **To register with the SAPC as a Pharmacy Technical Assistant (PTA) trainee**

- Have achieved a higher certificate
- Have an approved tutor and a facility approved for traineeship
- Complete application form and pay the prescribed fees

- **To register with the SAPC as a Pharmacy technical assistant (PTA)**

- Have completed a minimum of 6 months at a facility approved for training and under the supervision of an approved tutor
- Submitted 3 progress reports (use online)



Registration requirements as a PT trainee / PT

- **To register with the SAPC as a Pharmacy Technician (PT) trainee**

- Have achieved an advanced certificate
- Have an approved tutor and a facility approved for traineeship
- Complete application form and pay the prescribed fees

- **To register with the SAPC as a Pharmacy Technician (PT)**

- Have completed a minimum of 6 months at a facility approved for training and under the supervision of an approved tutor
- Submitted 3 progress reports (use online)



Training of pharmacy technical assistants (PTA)

- Students will register with Council
- After completion they will either
 - ➔ Register as trainee with Council (6 months)
 - ➔ Register as pharmacy technician students
- After traineeship they will register as pharmacy technical assistants



Training of PTA and PT

- Full time programme - currently offered by NMMU (North-West and TUT are anticipated with the 2 new universities)
- Council approved the standard relating to the distance learning mode of delivery for the PTA and PT programmes
- Council and the NDoH are currently engaging all pharmacy schools including the Universities of technology as well as the current accredited FET providers to consider training of PTA and PT
- There is a need for all employers to create positions to absorb all the newly qualified mid-level workers.



Registration requirements: PTA studentsTrainee.....PTA

- **To register with the SAPC as a Pharmacy technical assistant (PTA) trainee**

- Have achieved a higher certificate in PTA
- Have an approved tutor and a facility approved for training
- Complete application form and pay the prescribed fees

- **To register with the SAPC as a Pharmacy technical assistant (PTA)**

- Have completed a minimum of 6 months at a facility approved for training and under the supervision of an approved tutor
- Submitted 3 progress reports (use online)



Registration requirements: PT studentTrainee.....PT

- **To register with the SAPC as a Pharmacy technician (PT) trainee**

- Have achieved an advanced certificate in PT
- Have an approved tutor and a facility approved for training
- Complete application form and pay the prescribed fees

- **To register with the SAPC as a Pharmacy technician (PT)**

- Have completed a minimum of 6 months at a facility approved for training and under the supervision of an approved tutor
- Submitted 3 progress reports (use online)



Training of Pharmacy Technical Assistants (PTA)

One year full time programme - Higher Certificate
(Students will register with Council)

PTA Trainee
(6 months
traineeship)

← Graduation →

PT
(Advanced Cert)

PTA

Graduation

PT Trainee
(6 months
traineeship)

PT



Training of Pharmacy Technicians

One year full time programme
Advanced Certificate



Graduation



Registered
Pharmacy
Technician



PT Trainee
(6 months)



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CONCLUSIONS (cont)

Training new Cadres

