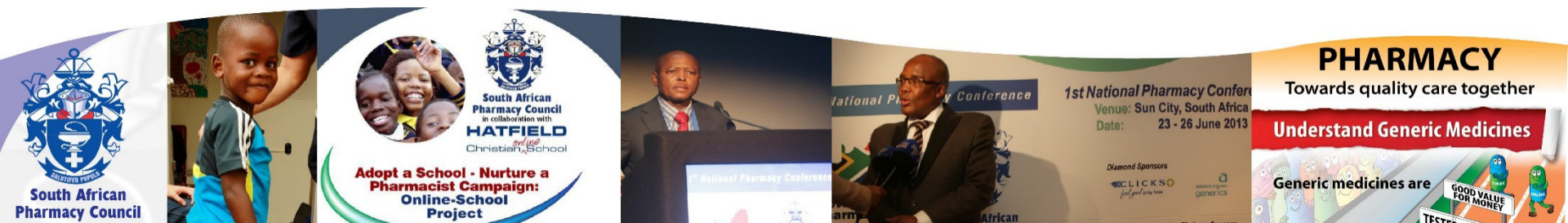


The Role of the Responsible Pharmacist (RP)

Pharmaceutical industry perspective

Vuyo Mokoena:

Senior Manager: Monitoring, Compliance and Professional Conduct (MCPC)



Overview

- Background
- Legislative provision
- Status quo
- Compliance requirements
- Council's vision of pharmacy



Background

- **Regulatory affairs pharmacist**
- **Role**
 - ➔ From conception to delivery
 - ➔ Including creating interest in the product from the market



OBJECTS OF COUNCIL

Prescribed in terms of Pharmacy Act, 1974

- Promotion of health of population
- Promotion of health of population
- Advice to Minister
- Promote provision of pharmaceutical care
- Uphold and safeguard rights of general public to acceptable standards of pharmacy practice in both the public and private sector



OBJECTS OF COUNCIL

Prescribed in terms of Pharmacy Act, 1974

- Establish, develop, maintain and control standards –
 - ➔ pharmaceutical education and training
 - ➔ registration
 - ➔ practice
 - ➔ professional conduct



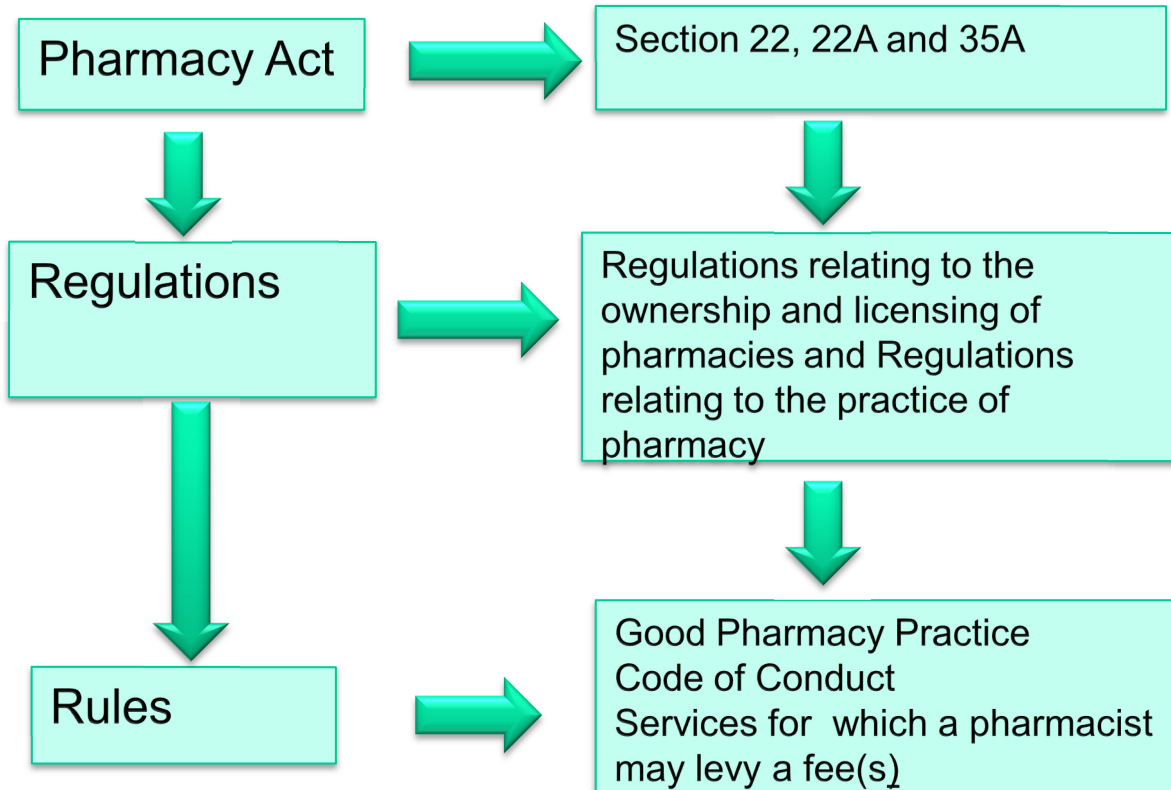
OBJECTS OF COUNCIL

Prescribed in terms of Pharmacy Act, 1974

- Transparent to profession
- Maintain and enhance dignity of pharmacy profession

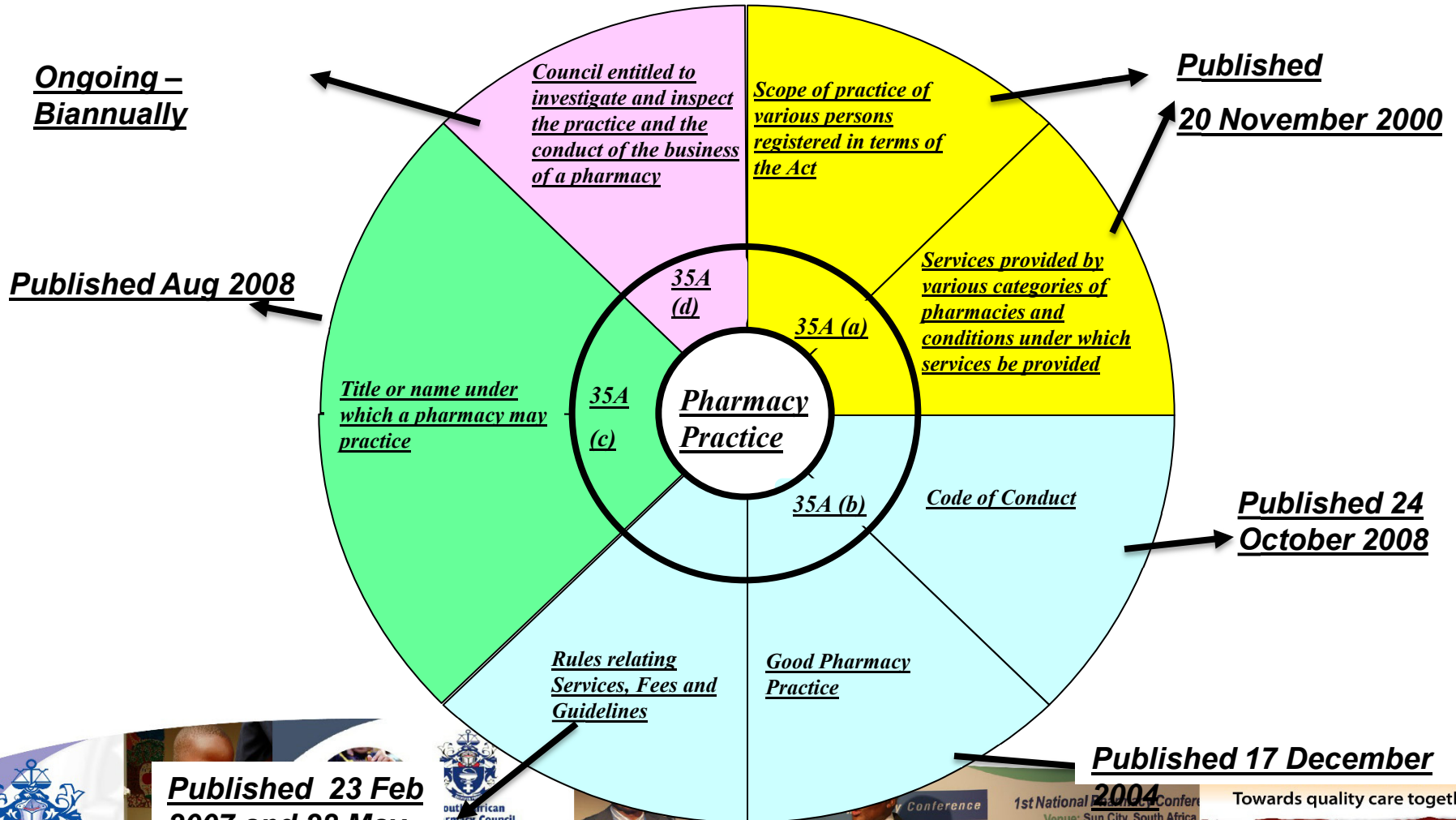


Pharmacy licensing legislative provisions

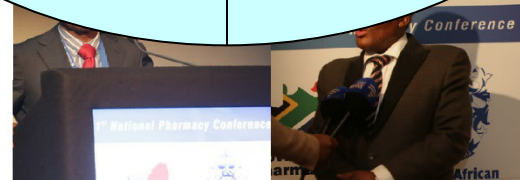


Section 35a of the Pharmacy Act, 1974

CONTROL OF PHARMACY PRACTICE



Published 23 Feb 2007 and 28 May 2009 for comment and implemented in 2010



Legislative provisions

- **Section 22 provides for the following:**
 - requirements for the application and issuing of the license;
 - recording of the pharmacy;
 - conditions under which pharmacy may be conducted;
 - right of Council to inspect such premises;
 - cancellation or suspension of a license by the DG;



Legislative provisions

- **Section 35A provides that Council may make rules:**
 - ➔ Services which may be provided in the various categories of pharmacies
 - ➔ Good pharmacy practice (license evaluation criteria)
 - ➔ Approve the trading title or name of the pharmacy



Conditions under which a pharmacy shall be conducted

(Ch VII Practice regulations)

- The services provided or acts performed in the various categories of pharmacy shall be performed in accordance with –
 - ➔ good pharmacy practice as published by council in rules; and the code of conduct as published by council in rules for pharmacists and other persons registered in terms of the Act; and the provisions of applicable legislation.
 - ➔ Only pharmacists or pharmacist interns and pharmacists' assistants under the direct personal supervision of a pharmacist, may handle scheduled substances in a pharmacy.
 - ➔ Every pharmacy shall, except in such circumstances and subject to such conditions as may be published in rules by the council, be conducted under the direct personal supervision of a **responsible pharmacist** whose name must be displayed conspicuously over the main entrance of such pharmacy.
 - ➔ The name of the pharmacist(s) on duty must be displayed conspicuously in the pharmacy for purposes of identification of such person(s) by the public.



RP as defined in the Pharmacy act (Act 53 of 1974)

- A responsible pharmacist means
 - ➔ a natural person who is a pharmacist and who shall be responsible to the council for complying with all the provisions of this Act and other legislation
 - ➔ applicable to services which specially pertain to the scope of practice of a pharmacist,
 - ➔ and the legislation applicable to the pharmacy which is under his or her personal supervision and who is registered as such in terms of the Act;



Why Responsible Pharmacist?

- Previously we had the owner of a pharmacy being a pharmacist
- The Managing Director of a body corporate conducting the business of a pharmacy being a pharmacist
- Later introduced licensing of pharmacies and a number of categories introduced viz: community, consultant, institutional, manufacturing & wholesale
- Introduced a “nominee”, manager of a close corporation and managing director of a company with specific duties under Regulation 25
- Ownership of pharmacies expanded to lay ownership
- Act binding to the State



Duties of an RP

- **The responsible pharmacist contemplated in regulation 25(3) must**
 - ➔ ensure that he or she in fact continuously supervises the pharmacy in which he or she has been appointed;
 - ➔ have appropriate qualifications and experience in the services being rendered by such pharmacy;
 - ➔ ensure that persons employed in such pharmacy and who provide services forming part of the scope of practice of a pharmacist are appropriately registered with council;
 - ➔ notify council immediately upon receiving knowledge that his/her services as responsible pharmacist have been or will be terminated;
 - ➔ take corrective measures in respect of deficiencies with regard to inspection reports of council or in terms of the Medicines Act; and



Duties of an RP

- in addition to the general responsibilities also:
 - ➔ ensure that unauthorized persons could not by lawful means obtain access to medicines or scheduled substances or the pharmacy premises outside of normal trading hours;
 - ➔ establish policies and procedures for the employees of the pharmacy with regard to the acts performed and services provided in the pharmacy;
 - ➔ ensure the safe and effective storage and keeping of medicine or scheduled substances in the pharmacy under his or her direct personal supervision; and
 - ➔ ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.



Current GPP requirements

- **Minimum standards for pharmacy premises, facilities and equipment (Section 1.2 GPP)**
 - ➔ Appearance of the pharmacy premises
 - ➔ Another business in a pharmacy or a pharmacy in another business
 - ➔ Security in a pharmacy
 - ➔ Control of access to pharmacy premises
 - ➔ Safety in pharmacy premises



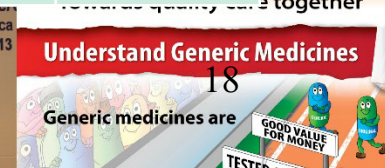
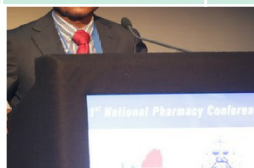
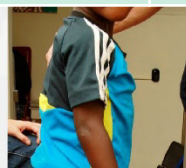
Current GPP requirements cont...

- Condition of pharmacy premises
- Construction of pharmacy premises
- Environment in pharmacy premises
- Hygiene in pharmacy premises
- Storage areas in pharmacy premises
- Dispensary
- Waiting area
- Areas for counselling and the furnishing of advice



Total number of pharmacies

	COMMUNITY PHARMACY	CONSULTANT PHARMACY	INSTITUTIONAL PRIVATE	INSTITUTIONAL PUBLIC	MANUFACTURING PHARMACY	WHOLESALE PHARMACY	Grand Total
EASTERN CAPE	230		22	92	7	20	373
FREE STATE	148		14	54	1	9	226
GAUTENG	1095	10	94	82	197	143	1623
KWAZULU NATAL	511	2	37	99	8	25	684
LIMPOPO	153		8	39		5	206
MPUMALANGA	228		15	43	1	3	290
NORTH WEST	201		23	53	8	3	289
NORTHERN CAPE	58		4	42		3	107
UNKNOWN	13		1	4	4		22
WESTERN CAPE	474	1	37	133	28	45	719
Grand Total	3111	13	255	641	254	256	4539



Pharmacy
Quality care together

Pharmacies with no RPs

	EASTERN CAPE	FREE STATE	GAUTENG	KWAZULU NATAL	LIMPOPO	MPUMAL ANGA	NORTH WEST	NORTHER N CAPE	UNKNOW N	WESTERN CAPE	Grand Total
COMMUNITY PHARMACY	50	24	284	99	42	57	43	7	2	73	681
CONSULTANT PHARMACY			3	1							4
INSTITUTIONAL PRIVATE	8		16	5	1	4	2	2		6	44
INSTITUTIONAL PUBLIC	43	12	24	28	11	15	24	28	1	32	218
MANUFACTURING PHARMACY	1		45	2						8	56
WHOLESALE PHARMACY	5	2	55	6	4					14	86
Grand Total	109	38	429	143	59	76	70	37	3	134	1098



Disciplinary powers of council

chapter v of the pharmacy act

- Dispensing practices
- Advertising and touting
- Relationship with colleagues and other health service professions
- General



Council's vision of pharmacy

- **Ensure that services supports primary health care initiatives and that pharmacy is part of the healthcare team**
 - ➔ APP and PCDT
 - ➔ Introduction of the mid-level worker
- **Pharmacy practice is patient centric**
 - ➔ Compliant and appropriate working conditions
 - ➔ Grading of pharmacy inspections



Council's vision of pharmacy

- **Ensure that pharmacy takes a leadership role in matters of pharmacy - Expand on Specialists**
 - ➔ Current
 - Pharmacokineticist
 - Radio Pharmacist
 - ➔ New
 - Clinical Pharmacist'
 - Public Health /Management pharmacist
 - Industrial Pharmacist



Conclusion

We are what we repeatedly do.
Excellence, then is not an act, but a habit
Aristotle

