SCOPE OF PRACTICE FOR PHARMACY PROFESSIONALS - 2021



KINGDOM OF BHUTAN

BHUTAN MEDICAL AND HEALTH COUNCIL ROYAL GOVERNMENT OF BHUTAN

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Scope of Practice for Pharmacy Professionals

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Preamble

Under the power vested in the General Body by the Chapter VI Section (i) of the Medical and Health Council Act 2002, Kingdom of Bhutan, the General Body of the Council during its 14th General Body Meeting held on 25th August 2021 approved this document.

Short Title

Scope of Practice for Pharmacy Professionals (2021).

Commencement

This document shall come into effect from 1st January 2022.

Supersession

This document shall supersede the provisions of existing guideline, notifications and circulars that are inconsistent with this Scope of Practice.

Application

This document describes the scope of practice for all the pharmacy professionals (Specialist pharmacist, Clinical pharmacist, Pharmacist and Pharmacy Technician) registered with the Bhutan Medical and Health Council and practicing in the healthcare centres and community pharmacies (i.e. Competent Persons).

Statement

Medicines and medical supplies are one of the essential building blocks of the healthcare system. These products are vital for the prevention and treatment of diseases. However, without the proper management and use, the potential benefits of these products are often not realized. Pharmacy professionals are not only trained in the management of the distribution of medicines and medical supplies but also engage in efforts to ensure the safe and efficacious use of medicines. The pharmacy professionals are involved in all the processes of medicine use beginning with the receipt of the stock till consumption of medicines by the patients. Pharmacy professionals should be thorough with the pharmaceutical care processes involved in ensuring prescriptions for medications are appropriate to the patient's needs; instructions for use are clear; medicine–medicine and medicine– food interactions are prevented; and known and predictable adverse medicine reactions, including allergies and other contraindications, are avoided. Monitoring treatment outcomes to verify effectiveness and adverse medicine events is also an important part of the process of use of medicines. The patient-oriented role of pharmaceutical care should be complemented by the expertise in stock management of medicines, formulary management and formulation sciences.

Pharmacy professionals serve as a bridge between other healthcare professionals and patients through the provision of Good Pharmacy Practice. The practice of pharmacy should continually optimize patient safety and quality of services through effective use of emerging technologies and competency-based training.

Pharmacy professionals are also involved in public health functions through research, policy development, administering immunizations and work in partnership with hospitals, health systems and regulatory agencies to advance health and wellness thereby helping to reduce hospital admissions and readmissions.

2.1 The professional service framework for pharmacy professionals



Fig 1. The pharmacy service is considered to be effective if it satisfies all the three components which is by making the pharmaceutical product Safe, Available and Quality. In-order to achieve these components one must acquire the qualities of 1. Expert professional practice 2. Collaborative working relationship 3. Leadership 4. Management 5. Education and 6. Research.

Expert Professional Practice Provides specialized and professional expertise. Promotes reasoning and judgement. Harnesses professional autonomy.	Collaborative working relationship Communicates effectively. Builds teamwork and collaboration.
Leadership Sets strategic context and vision. Supports effective governance. Promotes innovation for service development. Provides motivational support.	Management Implements national priorities. Promotes proper resource utilization. Ensures standards of practice. Plans and manages risks.
Education, Training and Development Acts a role model. Provides mentorship. Conducts education & training. Enhances professional development. Develops educational policy.	Research and Evaluation Identifies gaps in the evidence base. Develops, evaluates and supervises research. Applies evidence-based practice. Establishes research partnerships.

Competency

To be able to practice effectively in diverse and challenging fields, pharmacy professionals must possess many key attributes, including subject knowledge, technical and practical skills, interpersonal skills and critical thinking. One must also possess a growth mindset, high emotional intelligence, be open-minded and inculcate lifelong learning habits. Pharmacy practitioners are expected to continually re-evaluate and upgrade their skills to cope with challenges in their day-to-day practice.

1. Expert professional practice - Pharmacy professionals must be able to meet the patients' health and drug-related needs to achieve the treatment goals. They must be able to apply basic and specialist

expertise to ensure responsible provision of drug therapy. Pharmacy professionals must practice within legal requirements, demonstrate professionalism, and uphold professional standards of practice, codes of ethics, conduct, etiquette and national policies.

2. Collaborative working relationships - Pharmacy professionals must be able to work in collaboration with healthcare teams to optimize patient safety and improve patient outcomes. Pharmacy professionals must communicate effectively with patients, within the pharmacy team, other health professionals and the general public in providing education to promote and support optimal patient care and wellbeing. Using the available resources they must be able to manage work issues and maintain interpersonal relationships with colleagues and caregivers.

3. Leadership - Pharmacy professionals must be able to set vision, strategic directions, foster teamwork and provide leadership to promote effective governance of pharmacy services. He/she must exhibit the highest level of integrity and be able to inspire others.

4. Management - Pharmacy professionals must be able to implement and evaluate standards of practice and align their activities with the national policies. There must also develop plans for resource mobilization and mitigation of risk.

5. Education, training & development - Pharmacy professionals must be up-to-date with evidence-based practice through continuous professional development. They should be able to impart training and education related to pharmacy service to pharmacy professionals and other healthcare professionals. They should continuously mentor their fellow colleagues and pharmacy students for professional development.

6. Research & evaluation - Pharmacy professionals must be able to carry out research related to pharmacy sciences independently and recommend policy interventions. They should be able to review, critically analyze and apply evidence into daily practice.

Roles and Responsibilities

Specialist Pharmacist

- Provide leadership in pharmaceutical governance.
- Set vision and strategic direction for pharmaceutical care and management.
- Enhance networking and partnership with the other professionals.
- Oversee the execution of all pharmaceutical services.
- Provide specialist pharmacy services and consultation.
- Provide expert input to the relevant programs/agencies on the areas of pharmaceutical management/pharmacoeconomic analysis/medicines regulation and control.
- Provide medication and practice related education and training of the pharmacy professionals and other healthcare workers
- Lead research in relevant areas.

Clinical Pharmacist

- Evaluate patient-specific pharmacotherapeutic regimens and recommend modification of dosage and schedule to prevent or resolve medication-related problems.
- Evaluate patient's therapeutic outcome based on patient's history and clinical laboratory test results.
- Conduct therapeutic drug monitoring for drugs with narrow therapeutic index.
- Coordinate antimicrobial stewardship activities to promote rational use of antimicrobials.
- Oversee pharmacovigilance activities in the healthcare facilities.
- Evaluate treatment outcome and provide follow-up services.
- Conduct medicine use evaluation (MUE) and recommend corrective interventions.

- Participate in pharmacoeconomic analysis.
- Coordinate hospital therapeutic committee (THC) meetings.
- Carryout education and training on rational use of medicine.
- Provide counseling to patients and/or caregivers about the proper use and effects of medications.
- Conduct research and promote evidence-based practices.
- Monitor compliance to Good Pharmacy Practices such as compounding, supplies management and dispensing practices.
- Implement Code of Conduct and professional standards.
- Comply with the national regulatory standards and requirements.

Pharmacist

- Interpret prescription and dispense medications.
- Detect and intervene to resolve medication-related problems.
- Collect and analyze information related to drug therapy.
- Provide patient education on appropriate use of medication.
- Review medication doses and dosage schedules for a specific patient.
- Advise specific patients on medication use to improve compliance.
- Promote public awareness on medication safety and rational use.
- Conduct prescription surveys and disseminate information to relevant stakeholders.
- Provide drug information to healthcare workers and patients. .
- Review prescriptions for errors, therapeutic appropriateness, and individual dose adjustment.
- Provide drug information to other healthcare professionals.
- Carry out pharmaceutical stock management and monitoring.
- Perform quality inspection of pharmaceutical products.

- Identify, record and report adverse drug reactions.
- Supervise and mentor Pharmacy Technicians.
- Prepare guidelines for drug use within the hospital and implement hospital regulations
- Monitor quality of extemporaneous preparation and specialized products.
- Participate in antimicrobial stewardship activities.
- Participate in hospital therapeutic committee activities and medicine use evaluation.
- Conduct research and promote evidence-based practices.
- Monitor compliance to Good Pharmacy Practices such as compounding, supplies management and dispensing practices.
- Implement Code of Conduct and professional standards.
- Comply with the national regulatory standards and requirements.

Pharmacy Technician

- Check the prescription for completeness, calculate dose, pack, label, record and dispense medication with proper counseling.
- Collect, compile and submit reports such as product quality issues, prescription, and morbidity
- Report adverse drug reaction to pharmacovigilance centre.
- Perform medication reconciliation in consultation with pharmacists.
- Assist pharmacists in investigational drugs studies.
- Administer injections in out-patient settings.
- Carry out extemporaneous compounding.
- Prepare sterile formulations in aseptic condition.
- Carry out pharmaceutical stock management as per Good Storage Practices.
- Refill medications in the wards.

- Carry out bedside dispensing in the wards.
- Comply with Good Pharmacy Practices.
- Comply with Ethical Code of Conduct and professional standards.
- Comply with the national regulatory standards and requirements.

Accountability

Accountability should be the cornerstone for every pharmacy professional and they should be accountable for the decisions they make in their practice. They should be accountable to the patient, the public, the regulatory body, employer and any relevant supervisory authority.

Continuous professional development

New research and developments are taking place rapidly in the field of pharmacy. Everyday new drugs and drug formulations are being discovered. Pharmacy professionals are required to update their skills and knowledge to attain development and advancement in career, role or professional duties. Continuing professional development (CPD) for pharmacy professionals is a statutory requirement demonstrate to (3). Professional safety to practice competence and ensure development and personal developments are required in order to maintain and enhance professional standards and to provide quality, competent and safe pharmaceutical care to patients. That encompasses the experiences, activities and processes contributing towards the development of pharmacy professionals as competent healthcare professionals. Continuing professional development is, therefore, a lifelong process of both structured and informal learning. It should consist of planned learning experiences which are designed to augment the knowledge, skills and attitudes of registered pharmacy professionals for the enhancement of practice, education, leadership and researchers.

Delegation and supervision

Pharmacy professionals as members of a multidisciplinary healthcare team may be required to delegate, supervise and educate pharmacy students in providing safe patient care. The pharmacy professionals who have the authority may delegate his/her responsibility or activity that is normally within the scope of practice provided necessary and appropriate level of supervision required by the delegate is provided. Delegation of responsibility and roles must be based on the level of knowledge and skills of the person to whom it is delegated. The senior pharmacy professionals must supervise the work conducted by the colleagues.

Practice setting

Practice settings can include outpatient pharmacy, inpatient pharmacy, compounding units, pediatric pharmacy and community pharmacy. In an outpatient setting, patient care is the most important responsibility. In line with the good dispensing practice, OPD pharmacy provides patient counseling and ensures that appropriate medicines are prescribed and dispensed appropriately so that patients can get maximum benefit with minimal side effects. This department involves all disciplines to provide a functional and accurate method of medication dispensing preparation, administration, proper storage, packaging, labeling, distribution and record keeping of medication.

Inpatient pharmacy has a direct role in bedside patient care partnering and collaborating with a multidisciplinary team. They play a vital role in providing drug information to healthcare professionals and caregivers. The pharmacist and pharmacy technician deliver pharmaceutical care in wards, identify drug related problems, report and monitor adverse drug reactions (ADRs), promote rational use of drugs, daily dosing in wards and dispense medication to seriously ill patients. Pharmacy professionals monitor drug charts and patient adherence to medicines in the wards to achieve maximum therapeutic benefits. Every patient has different therapeutic needs to improve their medication compliance. Modification of drug formulation improves patient adherence and reduces cost of medicines. Customizing the compounded medication is a vital part of quality healthcare.

Collaborative practice

Involving a caregiver and multidisciplinary team in decision-making for patient care is the key aspect of collaborative practice. It requires respect, effective communication and appropriate documentation – these are essential elements in providing safe, quality healthcare to patients and in identifying and managing risks.

Definitions

- 1. **Clinical Pharmacist** A pharmacist who possesses the additional qualification with master's degree in clinical pharmacy or post graduate residency program in Pharmacy.
- 2. **Competency** The Competency Development and Evaluation Group (CoDEG) defined competency as a distinct composite of knowledge, skill, attitude and value that is essential to the practice of the profession.
- 3. **Competent person -** Any qualified person who is competent to perform his duty in a government or community pharmacy after registering with the Bhutan Medical and Health Council or the Drug Regulatory Authority.
- 4. Form II medicines The system for procurement of vital medicines required for specific patients in low volumes.

- 5. Form III medicines The system for indenting medicines which are not available in the specific level of health facility but can be obtained from the higher level of healthcare facility as and when required.
- 6. **Expanded practice -** is a change in the role of pharmacy profession to include areas of practice that have not previously been within their scope of practice, but required to practice after undergoing certain levels of training recognized by the Bhutan Medical and Health Council and any other relevant regulatory body.
- 7. **Pharmacist -** A registered healthcare professional with a minimum qualification of bachelor's degree in pharmacy or Doctor of Pharmacy (Pharm D) from a recognized University by the Bhutan Medical and Health Council.
- 8. **Pharmacy Technician -** A healthcare professional with a minimum qualification of diploma in Pharmacy registered with Bhutan Medical and Health Council.
- 9. **Practice setting -** The practice setting refers to both the place in which pharmacy professionals are designated based on their nature of working environment. It includes the kind of service being offered and the complexity of care required by the patient.
- 10. **Specialist pharmacist -** A pharmacist possessing a master's degree or residency in pharmacy with research publication or specialized clinical practice recognized by Bhutan Medical and Health Council.

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Appendix A

Sl. No.	Pharmacy Services and Competencies	Clinical Pharmacist	Pharmacist	Pharmacy Technician
	TECHNI	CALROLE		
1.	Obtain patient consent, where required	Yes	Yes	No
2.	Protect patient confidentiality	Yes	Yes	Yes
3.	Respect diversity and social background of patient	Yes	Yes	Yes
4.	Accept responsibility and accountability for actions	Yes	Yes	Yes
5.	Accept written prescriptions	Yes	Yes	Yes
6.	Refill requests from the patient or the patient's representative	Yes	No	No
7.	Receive verbal prescriptions from prescribers; document immediately in the hospital setting.	Yes (With proper documenta- tio n)	Yes (With proper documenta- tio n)	Yes (With proper documenta- tion
8.	Receive verbal prescriptions from prescribers for controlled medicines and antibiotics.	No	No	No
9.	Prioritize prescription processing based on patients' profile/need	Yes	Yes	No
10.	Identify potential drug interactions and therapeutic duplications	Yes	Yes	Yes
11.	Review prescription/patient profile/health record	Yes	Yes	Yes
12.	Refer therapeutic issues and questions to the Clinical Pharmacist	N/A	Yes	Yes

13.	Ensure integrity and stability of product(s) including expiry dates and physicochemical properties	Yes	Yes	Yes
14.	Take the medication from the shelf to the working area	Yes	Yes	Yes
15.	Calculate, convert, and document the result of dosage calculations	Yes	Yes	Yes
16.	Perform count, measure and weighing of medications for compounding.	Yes	Yes	Yes
17.	Verify calculations with the pharmacist	Not applicable	Not applicable	Yes
18.	Reconstitute medications**	Yes (with relevant training recognized by the BMHC)	Yes (with relevant training recognized by the BMHC)	Yes (with relevant training recognized by the BMHC)
19.	Adhere to clean and aseptic techniques, where required	Yes	Yes	Yes
20.	Verify accuracy and appropriateness of ingredients and quantities, including weights and volumes	Yes	Yes	Yes
21.	Verify the accuracy and completeness of a pharmaceutical product prepared for release	Yes	Yes	Yes
22.	Label container, including relevant auxiliary labels	No	Yes	Yes
23.	Pre-package pharmaceuticals including replenishment of stock bottles	No	Yes	Yes
24.	Prepare non-sterile compounds	Yes	Yes	Yes

25.	Prepare sterile compounds (including IVs, TPNs) **	Yes (with relevant training recognized by BMHC)	Yes (with relevant training recognized by BMHC)	Yes (with relevant training recognized by BMHC)
26.	Handle and prepare hazardous medicinal products appropriately.	Yes (with relevant training recognized by BMHC)	Yes (with relevant training recognized by BMHC)	Yes (with relevant training recognized by BMHC)
27.	Fill unit dose carts from a drug chart in wards	No	No	Yes
28.	Check filled unit dose carts.	Yes	No	No
29.	Check and restock emergency boxes, nursing unit cupboards and carts and night cupboard supplies from an approved drug list.	No	Yes (Applicable only where inpatient services are available)	Yes (Applicable only where inpatient services are available)
30.	Assist the patient to make informed decisions regarding the selection and use of drugs.	Yes	Yes	Yes
31.	Comply with Acts, regulation policies and standards applicable to pharmacy practice.	Yes	Yes	Yes
32.	Follow procedures for the proper storage, handling, preparation, distribution, removal, and disposal of drugs.	Yes	Yes	Yes
33.	Ensure the cleanliness, functionality, and integrity of compounding, packaging, dispensing and storage equipment	Yes	Yes	Yes
34.	Perform routine equipment calibration/validation	Yes	Yes	Yes
35.	Store and transport pharmaceutical products appropriately	Yes	Yes	Yes

36.	Manage inventory/record keeping	No	Yes	Yes
37.	Question, report and assist in the resolution of potential and actual unsafe, illegal, unethical, or unprofessional actions or situations	Yes	Yes	Yes
38.	Use appropriate pharmacy reference material	Yes	Yes	Yes
39.	Act as a role model and mentor to new staff and students	Yes	Yes	Yes
40.	Collect and verify accuracy of patient demographics and known allergies	Yes	Yes	Yes
41.	Transferring and receiving prescriptions from other pharmacists or pharmacy technicians	Yes	Yes	Yes
42.	Checking pharmaceutical products prepared by unregulated personnel	Yes	Yes	Yes
43.	Perform quality assurance audits/checks on distribution functions and activities	Yes	Yes	Yes
44.	Packaging and labelling of medication	N/A	Yes	Yes
45.	Take medication history	Yes	Yes	Yes
46.	Medication reconciliation	Yes	Yes	Yes (in consultation with Pharmacist)
47.	Document drug distribution processes and outcomes i.e. medication errors, missing meds, ADR etc.	Yes	Yes	Yes
48.	Prepare reports and documents	Yes	Yes	Yes
49.	Manage workflow	Yes	Yes	Yes

	CLINICAL ROLES				
1.	Accountable to patients	Yes	Yes	Yes	
2.	Interprofessional collaboration	Yes	Yes	Yes	
3.	Call-back programs	N/A	Yes (For form II & III drugs)	Yes (For form II & III drugs)	
4.	Verifying written drug orders	Yes	Yes	Yes (in the absence of pharmacist)	
5.	Chronic disease management	Yes	No	No	
6.	Collaborate with primary health care teams	Yes	Yes	Yes	
7.	Distribution, dispensing, and administration of drug products with appropriate patient counseling	Yes	Yes	Yes	
8.	Documentation and communication of information and decisions	Yes	Yes	Yes	
9.	Ensure safe, accessible and cost-effective medicines are available	Yes	Yes	Yes	
10.	Contribute to the implementation and maintenance of safe and effective systems of drug supply and distribution	Yes	Yes	Yes	
11.	Health promotion and disease prevention requiring clinical knowledge	Yes	Yes	Yes	
12.	Identify and resolve drug- related problems	Yes	Yes	Yes	

13.	Recognize and respond to unusual patterns of drug distribution (including diversion, misuse, and fluctuations in utilization) Administration of drugs by injection and other routes	Yes Yes (with relevant training recognized by the	Yes Yes (with relevant training recognized by the	Yes (in the absence of pharmacist) Yes (with relevant training recognized by BMHC)
15.	Non-prescription drug selection and education	BMHC) Yes	BMHC) Yes	Yes
16.	Medication assessment for packaging compliance	Yes	Yes	Yes
17.	Medication adherence programs requiring clinical knowledge	Yes	Yes (With Clinical Pharmacist supervision in high-risk situations	No
18.	Carry out medication utilization reviews	Yes	Yes	Yes
19.	Minor ailment management **	Yes (with relevant training recognized by BMHC)	No	No
20.	Understand, participate in and promote patient safety initiatives	Yes	Yes	Yes

21.	Pharmaceutical care/ medication management	Yes	Yes	Yes (in consultation with Pharmacist or with prescriber)
22.	Prescriptive authority**	Yes (with relevant training recognized by BMHC)	No	No
23.	Carry out therapeutic drug monitoring	Yes (with relevant training recognized by BMHC)	No	No
24.	Perform pharmacogenomic based pharmacotherapy **	Yes (with relevant training recognized by the BMHC)	No	No
25.	Timely recognition of drug indication and other signs and symptoms relevant to drug use, along with accurate identification of underlying disease	Yes	Yes	No

****** Expanded practice.