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Review

Pharmaceutical Development in Nepal and a Comparative Critical Review of the Nepal Pharmacy Council Act (2000)

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Abstract

The Nepal Pharmacy Council (NPC) Act, 2057 BS (2000 AD), established the statutory body responsible for regulating pharmacy education, professional standards, and ethical practice in Nepal. Since its inception, pharmacy education has expanded significantly, from the initial PCL programs in 1972 to widespread Diploma, B. Pharm, M. Pharm, Pharm D, and Ph.D. programs across public and private institutions. Similarly, Nepal's pharmaceutical industry and hospital pharmacy services have grown, yet challenges remain, including workforce shortages, uneven professional distribution, limited clinical integration, and underdeveloped regulatory enforcement. This study critically analyzes the NPC Act using a qualitative, document-based approach, employing SWOT analysis and international comparisons with legal frameworks from countries including the USA, UK, Australia, India, Japan, South Korea, and EU nations. Key findings indicate that while the Act provides foundational regulation, it lacks provisions for modern pharmacy roles, continuing professional development (CPD), research promotion, digitalization, and integration of pharmacists into public health and clinical services. Suggested amendments include revising the Council's functions, enhancing merit-based governance, instituting mandatory CPD, clarifying roles of pharmacists and assistants, strengthening inspection and accreditation, and aligning with global standards. Implementing these reforms would modernize pharmacy regulation in Nepal, ensure high-quality education, strengthen healthcare integration, and enhance public safety.

Keywords: Nepal pharmacy council; pharmacy regulation; pharmaceutical education; clinical pharmacy; continuing professional development

1. Introduction

The *Nepal pharmacy council Act, 2057BS (2000 AD)* was established to manage a statutory body Nepal Pharmacy Council (NPC) with the aim of regulating the pharmacy profession, education and setting of quality standards for pharmacists in Nepal. The *Nepal Pharmacy Council Regulations* 2059 (2002) were framed in 2002. The *NPC Act* led to the formation of NPC, responsible for the registration of pharmacists and Assistant pharmacists in Nepal [1].

The council is entrusted with ensuring ethical pharmacy practice, maintaining professional standards, and upholding public health by guaranteeing the competency of pharmacy professionals throughout the country. There are currently 7430 pharmacists and 14507 Assistant pharmacists registered in Nepal Pharmacy Council, as of Sept. 9, 2025 [1].

Before critically analyzing act, it is important to first discuss the background that led to the establishment of the NPC. This includes the history of pharmacy education in Nepal, the progress of pharmaceutical development, and the role of different pharmacy-related organizations. With the increasing number of pharmacy graduates, the need for a regulatory body like the Pharmacy Council

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became essential. Therefore, outlining this background is crucial to framing any act amendments in line with both the national context and global practices.

1.1. History of Pharmacy Education in Nepal

Pharmacy education in Nepal formally began in 1972 with the introduction of a two-and-a-half-year Proficiency Certificate Level (PCL) program at the Institute of Medicine (IOM) under Tribhuvan University. Designed for students who had completed school-level education, this program laid the foundation for professional pharmacy training in the country. At the time, many students joined the PCL program as a stepping stone to medical studies, particularly MBBS, as it provided eligibility to sit for medical entrance examinations [2–4].

To address the widespread shortage of pharmacists in 1980s and to regulate the informal sale of medicines, a Drug Retailer's Training initiative was launched in 1981. This 45-hour course provided essential practical and theoretical instruction on pharmacology, ethics, storage practices, and relevant legal frameworks. By 1989, a total of 4,096 participants had completed the training, helping to fill the gap in pharmaceutical services across the country [2,5].

A significant milestone in pharmacy education came in 1994 with the launch of the Bachelor of Pharmacy (B. Pharm) program at Kathmandu University (KU). This marked the beginning of degree-level pharmaceutical education in Nepal. The university later expanded its academic offerings to include the Master of Pharmacy (M. Pharm) program in 2000, followed by the Ph.D. in Pharmaceutical Sciences in 2004. Additionally, KU introduced a Post-Baccalaureate Doctor of Pharmacy (Pharm D) program in 2010 [6], contributing to the diversification of advanced pharmacy education in the country [2].

The role of pharmacists has evolved globally from being primarily involved in compounding and dispensing to taking on broader responsibilities within multidisciplinary healthcare teams [7,8]. In many developing countries, pharmacies serve as critical points of access for healthcare information and services. Pharmacists, with their expertise in medicines and therapeutics, are well-positioned to contribute to areas such as clinical management and basic diagnostics. However, in the context of Nepal, pharmacists are still largely concentrated in the pharmaceutical manufacturing sector, with limited integration into clinical [9] and public health teams. This has led to low public awareness of the pharmacist's role and underutilization of pharmacy services in patient care [2].

By 2004, institutions affiliated with the Council for Technical Education and Vocational Training (CTEVT) began offering the Diploma in Pharmacy, a three-year program considered equivalent in structure and purpose to the earlier PCL [2,3]. As of 2025, a total of 116 institutions under CTEVT offer the Diploma in Pharmacy program, with an annual enrollment capacity of 4,640 students [10].

The B. Pharm program has also expanded significantly; as of the 2024/25 academic year, a total of 27 colleges affiliated with four federal universities (TU, PU, KU & Purbanchal U.), two provincial universities (GU & MTU), and two health science academies (KAHS & MBAHS) are offering the course, with a collective enrollment capacity of 755 students, as per MEC allocated quota. Out of 27 colleges only 7 are public. For details about each institution allocation of B. Pharm quota for year 2024 and 2025 see table 1 below [2,11].

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Table 1. B. Pharm program–offering institutes and MEC seat distribution for 2024 and 2025 batches [11].

SN	University/ Academy	Institute Name	College Type	Allocated seats 2024	Seats enrolled	Demand for 2025	Allocation for 2025
1	Purvanchal University	Asian Foundation of Education & Research Pvt. Ltd.	Private	30	30	40	30
2	Purvanchal University	Hope International College	Private	30	24	40	30
3	Purvanchal University	Kantipur Academy of Health Science	Private	10	8	40	10
4	Purvanchal University	Karnali College of Health Sciences	Private	15	7	30	15
5	Purvanchal University	Little Buddha College of Health Science	Private	20	10	30	30
6	Purvanchal University	Novel Academy, Pokhara	Private	10	9	30	10
7	Purvanchal University	Purbanchal University School of Health Sciences	**Public**	30	30	40	30
8	Purvanchal University	Shree Medical & Technical College	Private	30	27	40	30
9	Purvanchal University	Valley College of Technical Sciences	Private	10	8	30	10
10	Tribhuvan University	Chitwan Medical College	Private	40	33	50	40
11	Tribhuvan University	Gandaki Medical College	Private	10	10	40	20
12	Tribhuvan University	JF Institute of Health Science	Private	30	27	40	30
13	Tribhuvan University	KIST Medical College	Private	0	0	20	0
14	Tribhuvan University	Maharajgunj Medical Campus	**Public**	20	20	20	20
15	Tribhuvan University	Manmohan Memorial Institute of Health Sciences	Private	40	39	60	40
16	Tribhuvan University	National Model College for Advance Learning (NIST)	Private	40	40	50	40
17	Tribhuvan University	Universal College of Medical Sciences and Teaching Hospital	Private	40	34	40	40
18	Pokhara University	CIST College	Private	40	35	40	40
19	Pokhara University	Crimson College of Technology	Private	30	16	40	30
20	Pokhara University	Modern Technical College Ltd.	Private	20	15	40	20

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21	Pokhara University	Nobel College	Private	40	34	40	40
22	Pokhara University	School of Health and Allied Sciences (SHAS)	**Public**	40	38	40	40
23	Kathmandu University	KU School of Science (Department of Pharmacy)	Private	50	50	60	60
24	Gandaki University	Gandaki University (Department of Pharmacy)	**Public**	20	18	40	30
25	KAHS	School of Pharmacy, Karnali Academy of Health Sciences	**Public**	20	16	20	20
26	MBAHS	Madan Bhandari Academy of Health Sciences	**Public**	30	29	30	30
27	MTU	Manmohan Technical University, School of Medicine & Allied Health Sciences	**Public**	10	10	20	20
		Total		**705**	**617**	**1010**	**755**

Despite this progress, there remains a persistent shortage of pharmacists, especially in the public healthcare system. Many District Hospitals, District Public Health Offices, and even some provincial hospitals lack trained pharmacy professionals, which continues to hamper the delivery of quality pharmaceutical services. In the private sector, the growth has been more robust; the number of registered drug retail outlets increased from 16,640 in 2014 to 30,185 by 2025[12]. Registration data from the Nepal Pharmacy Council shows a steady increase in qualified personnel, with 3,761 pharmacists and 7,162 pharmacy assistants registered in 2010, rising to 7,430 pharmacists and 14,507 pharmacy assistants by 2025 [1,2].

In line with global efforts to advance pharmacy education, the International Pharmaceutical Federation (FIP) in October 2021 convened stakeholders from across all six WHO regions to co-develop roadmaps aimed at enhancing the quality and scope of pharmacy and pharmaceutical sciences education worldwide [13]. These initiatives serve as a guiding framework for countries like Nepal in strengthening their pharmacy workforce and integrating pharmacists more fully into national health systems [2].

1.2. History of Pharmaceutical development in Nepal

The roots of pharmaceutical practices in Nepal can be traced back to the Licchavis era, particularly during the reign of King Amshuverma (605–621 CE), when an ancient Ayurvedic hospital, referred to as "Aarogyashala," is believed to have existed. Although historical evidence is limited, it indicates the early presence of organized healthcare rooted in traditional medicine. During King Pratap Malla's rule (1641–1674 AD), an Ayurvedic medicine production unit was initiated in Hanuman Dhoka, which was later relocated to Thapathali by Prime Minister Jung Bahadur Rana in 1846. This facility eventually became known as the Singh Durbar Vaidyakhana. Initially reserved for the royal family, the medicines were later made available to the general public under King Tribhuvan's reign [14].

The introduction of modern (**allopathic**) medicine began after the Sugauli Treaty in 1816 AD with the establishment of the British Residency in Nepal. A small clinic set up within the residency compound marked the beginning of western medical practice, later followed by the establishment of

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Bir Hospital in 1889. As the popularity of modern medicine grew, the pharmaceutical trade expanded, leading to the formation of wholesale and retail drug businesses [14–17].

In 1964, the **Royal Drug Research Laboratory** (RDRL) was founded to initiate drug research and production. This laboratory evolved into Royal Drug Limited (RDL) in 1972, under the Nepalese government, marking the start of institutionalized allopathic drug manufacturing. Around the same time, Chemidrug Industries Pvt. Ltd. became the first private pharmaceutical company in Nepal, beginning operations in Kathmandu in 1970 [14].

The formal regulation of pharmaceuticals began with the enactment of the **Drug Act in 1978,** followed by the establishment of the Department of Drug Administration (DDA) in 1979 under the Ministry of Forest and Soil Conservation. This act was designed to prevent the misuse and misrepresentation of pharmaceuticals, ensure safety and efficacy, and regulate production, marketing, distribution, and use [3,14]. Several regulatory instruments followed, including:

- Drug Consultative Council and Advisory Committee Regulation (2037 BS),
- Drug Registration Regulation (2038 BS),
- Interrogation and Inspection Regulation (2040 BS),
- Drug Manufacturing Code (2041 BS), and
- Drug Standard Regulation (2043 BS).

The **National Medicines Laboratory**, formerly RDRL, now serves as the national body for drug testing and quality control. Two key advisory bodies under the Ministry of Health and Population-Drugs Advisory Council and Drugs Advisory Committee-were also established to guide policy and ensure scientific development and regulation of pharmaceuticals [14].

The **National Drug Policy** was introduced in 1995 with the objective of promoting the availability of safe, effective, and quality medicines [18]. It also aimed to strengthen coordination among governmental, non-governmental, and private sectors engaged in drug-related activities, including production, regulation, distribution, and information dissemination [14].

From an industrial perspective, the pharmaceutical sector saw significant growth in the 1980s and 1990s, with the establishment of major domestic companies such as Manoj, Everest, Lomus, and NPL. However, several large-volume parenteral manufacturers-including Pashupati Chemical and BHK Pharma-eventually ceased operations. The adoption of Good Manufacturing Practice (GMP) guidelines, including certification by the World Health Organization (WHO), has improved the quality standards of domestic pharmaceutical products. As of Sept. 9, 2025 there total 194 pharmaceutical companies among which 114 are allopathic, 66 are ayurvedic and 14 are veterinary company [12]. And of them only 58 are GMP certified companies running in Nepal [19].

The **Association of Pharmaceutical Producers of Nepal** (APPON), founded in 1990, plays a crucial role in advocating for the pharmaceutical industry. It represents approximately 45% of the domestic market share and supports technical and regulatory advancement to enhance the competitiveness of Nepalese pharmaceuticals in both local and international markets. Several companies have already received Certificates of Pharmaceutical Products (CoPP) to facilitate exports [20].

Hospital pharmacy services in Nepal began with the establishment of Patan Hospital (formerly Santabhavan) in 1956, followed by Tansen Mission Hospital in 1959. In the 1970s and 1980s, government hospitals commonly prepared basic medicinal formulations such as cough mixtures, ointments, and antiseptic solutions. However, there was a lack of trained pharmacy professionals, with most dispensing duties carried out by assistant health workers. In 1979, the Ministry of Health created the first posts for assistant pharmacists at Mechi Zonal Hospital and Bharatpur Hospital. Despite these early efforts, by 2007, fewer than 8% of registered pharmacists and 37% of pharmacy assistants were employed in hospital or community settings. Even today, many hospitals lack proper pharmacy services, although a few institutions-such as Manipal Hospital (Pokhara), Dhulikhel Community Hospital, and Model Hospital-have established exemplary systems [14].

The **Nepal Pharmacy Council**, established through an act passed in 2000, serves as the regulatory and professional body for pharmacists in Nepal, ensuring academic standards and

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professional conduct [21]. The MEC currently oversees quota allocation for pharmacy colleges and conducts regular annual inspections.

The **Nepal Chemists and Druggists Association** (NCDA, https://ncda.org.np/), founded in 1973, represents the interests of pharmaceutical retailers and wholesalers. Its primary aim has been to enforce uniform pricing and represent the trade profession in national forums.

The **Nepal Pharmaceutical Association** (NPA) is a professional body established in 1972 to promote the development, regulation, and quality advancement of the pharmacy profession in Nepal (https://npa.org.np/).

Recently, Dr. Dirgha Raj Joshi founded the **Association of Faculties of Pharmacy of Nepal** (AFPN) on 1st Baishakh 2082 BS with the vision of uniting pharmacy educators across the country. (https://dirghajoshi.com.np/afpn/).

In Nepal, pharmacists are predominantly engaged in roles within pharmaceutical industries, whereas globally, pharmacists are increasingly involved in community-based services and direct clinical care to patients. However, there is a growing recognition and advocacy for expanding the role of clinical pharmacy in Nepal [22–25].

Given this historical and contextual background, the objective of this article is to critically analyze the Pharmacy Council Act of Nepal (2000) in light of the nation's evolving pharmaceutical education, professional practice, and regulatory needs. While the Act was a landmark step in establishing a statutory body to regulate pharmacy practice and education, its provisions now appear limited when compared to the dynamic global role of pharmacists, the rapid expansion of pharmacy education, and the growing pharmaceutical industry in Nepal. This article seeks to assess whether the Act adequately addresses the challenges of uneven professional distribution, limited integration of pharmacists into clinical and community health systems, and the need for stronger alignment with international standards such as those promoted by the International Pharmaceutical Federation (FIP). By situating Nepal's Pharmacy Council Act within both its historical context and a comparative global framework, this analysis aims to identify gaps, highlight opportunities for reform, and propose ways to strengthen the role of pharmacists in safeguarding public health and advancing the nation's healthcare system.

2. Methods

This study used a qualitative, document-based, and analytical approach to critically examine the Nepal Pharmacy Council (NPC) Act, 2000 (2057 BS). The primary source was the official text of the Act from the Nepal Law Commission, supplemented by secondary sources including scholarly articles, government reports, regulatory websites, and pharmacy acts from other countries. The analysis was guided by a SWOT (Strengths, Weaknesses, Opportunities, Threats) framework, with emphasis on the Act's administrative, legal, and educational provisions, their relevance to contemporary pharmacy practice (hospital, community, and clinical), and their implications for professional development, academic institutions, and public health in Nepal.

3. NPC act and Amendment Suggested

Table 2 shows chapters and sections of NPC act 2000. Table 3 shows analysis of the NPC Act in SWOT form.

Preamble of NPC act: "Whereas, it is expedient to manage the Nepal Pharmacy Council to make effective the Pharmacy Profession through systematic and scientific operation" [1].

Amendment suggested: Whereas, it is expedient to regulate and strengthen the pharmacy profession in Nepal by ensuring the competency, ethical conduct, and continuous development of pharmacy professionals; to safeguard public health through the promotion of safe, effective, and quality use of medicines; to advance pharmacy education and practice in alignment with international standards; and to integrate pharmacists as vital members of the healthcare system for the service of society.

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Current Functions, Duties, and Powers of NPC [1]

NPC Act (2000) currently assigns the Council the following core responsibilities:

1. Policy and Program Management: Prepare and implement plans for systematic and scientific management of the pharmacy profession.
2. Education Recognition: Grant recognition to institutions offering pharmacy education and validate their certificates and degrees.
3. Curriculum and Standards: Determine curricula, admission requirements, and examination systems; ensure compliance and revoke recognition if standards are not maintained.
4. Registration of Professionals: Determine qualifications to practice pharmacy and maintain a register of pharmacists and pharmacy assistants.
5. Disciplinary Actions: Remove names from the register for professional misconduct or violation of the prescribed code of conduct.

While these provisions establish the foundation of professional regulation, they primarily focus on administrative, educational, and disciplinary functions. Moreover *number 1 and 2 are mostly taken now by MEC this limits the role of NPC.* The current Act does not explicitly address public health integration, continuing professional development, research promotion, or equitable access to pharmacy services, which are emphasized in global pharmacy council practices.

So, here are some suggested **amendment** for functions, duties, and powers of the Council:

(a) Policy and Planning: To formulate, implement, and periodically review policies, plans, and programs for the advancement of the pharmacy profession, ensuring alignment with national health priorities, public health needs, and international standards.

(b) Education Recognition and Accreditation: To recognize, accredit, and periodically inspect educational institutions providing pharmacy education, ensuring that the certificates and degrees awarded meet internationally accepted standards of competence, quality, and ethical training. [For this council may need to discuss with MEC to share authorities]

(c) Curriculum and Examination Standards: To prescribe and periodically review curricula, admission criteria, training requirements, and examination systems for pharmacy education. To ensure compliance with these standards through inspections, audits, and evaluation, and to suspend or revoke recognition of institutions or programs failing to meet established standards after due process. [For this council may need to discuss with MEC to share authorities]

(d) Registration and Licensing: To determine qualifications and competencies required to practice as a pharmacist or pharmacy assistant. To maintain and update a National Register of pharmacists and pharmacy assistants, granting licenses only to those meeting prescribed standards.

(e) Professional Conduct and Disciplinary Actions: To establish, publish, and enforce a code of professional and ethical conduct for pharmacists and pharmacy assistants. To initiate investigations and disciplinary actions, including suspension or removal from the register, in cases of professional misconduct, negligence, or violation of ethical standards, ensuring due process and transparency.

(f) Continuing Professional Development (CPD) [26]: To promote and regulate continuing professional development programs for registered pharmacists and pharmacy assistants to ensure ongoing competency, knowledge update, and alignment with evolving healthcare practices.

(g) Integration in Healthcare System: To promote the participation of pharmacists in clinical, community, and public health services, ensuring that pharmacy practice contributes effectively to patient care, rational medicine use, and overall health system strengthening.

(h) Research and Policy Advisory Role: To encourage research and innovation in pharmacy practice, pharmaceutical sciences, and medicine use. To advise the government and stakeholders on pharmaceutical policies, public health programs, and professional standards.

(i) Public Awareness and Advocacy: To increase public awareness of the role of pharmacists, the safe and rational use of medicines, and the availability of pharmacy services, including advocacy for equitable access to pharmacy education and professional services across all regions of Nepal.

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Current **Constitution of the Council:** Mostly government-nominated pharmacists, plus association (NPA) and DDA representative. This lacks fair selection, so proposed new amendment is:

(a) Chairperson: The Chairperson of the NPC shall be selected through an **open, transparent, and merit-based process**. A public call for applications shall be issued for eligible candidates who are registered pharmacists with a minimum of ten years of professional experience and demonstrated leadership in pharmacy education, practice, or research. Applicants shall submit a detailed action plan and vision statement for advancing the NPC's mandate. A **Selection Committee**, comprising representatives from the MEC or UGC, the Ministry of Health & Population, and a public health representative, shall evaluate the applications and shortlist three candidates. These shortlisted candidates shall present their strategic plans and undergo interviews before the committee. Based on the committee's recommendation, the Government shall appoint one candidate as Chairperson for a fixed term of five years, renewable once, ensuring a merit-based, transparent, and visionary leadership for the NPC. The candidate must hold a minimum of a Master's degree in Pharmacy (Preferred PhD) and have at least ten years of professional experience in the pharmacy field.

(b) Four senior academic pharmacists nominated by universities (through UGC or MEC) offering pharmacy programs – **Member**

(e) One senior hospital or clinical pharmacist nominated by the Council – **Member**

(f) One representative of community pharmacists, nominated by their professional body – **Member**

(g) One representative of the Department of Drug Administration – **Member**

(h) One public representative (not being a pharmacist) with experience in public health, patient rights, or consumer advocacy – **Member**

(i) **Registrar**: The Registrar of the NPC, serving as the **Member-Secretary**, shall be selected through a transparent and merit-based process similar to that of the Chairperson.

***Note**: At least three female members among the above nominees to ensure gender balance. All of the members should hold minimum master's degree in pharmacy. The Council may, if necessary, invite relevant experts or observers to its meetings.*

To understand other relevant things; Table 4 shows global pharmacy regulation- legal frameworks, key features, strengths, and weaknesses. Table 5. Shows comparative overview of pharmacy education, licensing, and renewal requirements across countries (including Nepal) and Table 6. Shows recommendations for modernizing the NPC act based on global practices.

Table 2. NPC Act 2000, Chapters and Sections [1].

Chapter Number and Title	Section Number
1. Preliminary	1-2
2. Establishment, functions, duties and powers of Council	3-10
3. Provisions relating to registration of name	11-20
4. Recognition to educational degree and certificate	21-24
5. Provisions relating to functions, duties and powers of chairperson and registrar	25-26
6. Fund of Council	27-28
7. Miscellaneous	29-36

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Table 3. Analysis of the Act: Below table summarize Act in SWOT form.[1].

Strengths	Weaknesses
1. Inclusion of Hospital Pharmacy as a profession (Ch.1, Sec.2) – promotes patient-centered care. 2. Legal recognition of pharmacy profession through establishment of NPC (Ch.2, Sec.3). 3. Structured representation of multiple stakeholders in Council composition (Ch.2, Sec.4). 4. Standardization of pharmacy education and institutional recognition (Ch.2, Sec.9). 5. Clear role in pharmacist registration, renewal, and removal (Ch.3, Sec.15–19). 6. Professional ethics and discipline provisions (Ch.3, Sec.20). 7. Public protection by prohibiting unqualified practice (Ch.7, Sec.29). 8. Power to dissolve the Council in cases of misuse or ineffectiveness (Ch.7, Sec.31).	1. Outdated provisions – excludes modern roles (clinical, community, telepharmacy, pharmacovigilance). 2. Registration limited to pharmacists & assistants, excluding technicians/entrepreneurs. 3. Council composition bias – automatic inclusion of NPA chair (Ch.2, Sec.5). 4. No compulsory CPD requirements. 5. Financial dependence on government grants, aid, and loans (Ch.6, Sec.27). 6. Weak enforcement, especially in rural areas. 7. Limited institutional capacity for inspection and monitoring. 8. Several pharmacy colleges reportedly not meeting minimum standards. 9. Lack of transparency between pharmacist and assistant pharmacist roles. 10. Ineffective control of illegal dispensing practices.
Opportunities	**Threats**
1. Aligning functions with global pharmacy standards (WHO/FIP). 2. Expanding registration categories to include technicians, clinical and community pharmacists, and entrepreneurs. 3. Digitalizing registration processes (Ch.3, Sec.15–16).	1. Persistence of unregulated traditional/informal practice (Sec.11, 29). 2. Political interference in council appointments (Sec.4, 5). 3. Brain drain of pharmacists seeking opportunities abroad.

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4. Promoting research and fostering global collaborations (WHO, FIP, FDA, EMA). 5. Introducing CPD and online learning to strengthen professional competence. 6. Pharmacists' role in Universal Health Coverage (UHC) and rational medicine use. 7. Strengthening pharmacovigilance by linking NPC to WHO Uppsala Monitoring Centre.	4. Low public awareness about licensed vs. unlicensed practitioners. 5. Slow amendment of the outdated Act compared to global standards (WHO, FDA, EMA). 6. Limited enforcement capacity and monitoring mechanisms at provincial/local levels 7. Overlapping jurisdiction and lack of coordination among regulatory bodies and some power of NPC overtaken by MEC.

Table 4. Global Pharmacy Regulation: Legal Frameworks, Key Features, Strengths, and Weaknesses.

Country & Legal Framework	Key Features, Strengths, and Weaknesses
India – Pharmacy Act, 1948 (Pharmacy Council of India, PCI) [27]	Registration at state level; approval of pharmacy institutions; minimum D.Pharm (B.Pharm preferred). **Strengths:** Long-established council, unified curriculum, moving toward National Pharmacy Commission Bill. **Weaknesses:** Allegations of corruption, slow updates, CPD not enforced [27,28].
Bhutan – Bhutan Medicines Act (Drug Regulatory Authority, Pharmacy Division) [29]	Licensing of pharmacists, inspections, emphasis on traditional medicine integration. **Strengths:** Unified regulation, incorporation of traditional medicine. **Weaknesses:** Limited training infrastructure, small workforce [29].
USA – State Boards of Pharmacy; NABP (NAPLEX) [30,31]	PharmD required; mandatory CPD [26]; state registration; strong ethical and clinical standards; telepharmacy in practice. **Strengths:** High autonomy, clinical integration, telepharmacy regulation. **Weaknesses:** Fragmented oversight, complex state licensing [30].

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UK – Medicines Act 1968 (General Pharmaceutical Council, GPhC) [32,33]	MPharm + 1-year pre-reg + GPhC exam; mandatory CPD; online pharmacy regulation. **Strengths:** Strong safety/ethics standards, robust online regulation. **Weaknesses:** Bureaucratic licensing [33].
Australia – Pharmacy Board of Australia (AHPRA) [34,35]	CPD compulsory; registration exam + English proficiency; recency of practice rules. **Strengths:** Integrated national system, clear professional standards. **Weaknesses:** Rural access challenges [34,35].
Ghana – Pharmacy Act 1994[36] & Health Professions Regulatory Bodies Act 2013 [37]	Licensing, inspections, and ethical standards by Pharmacy Council Ghana. **Strengths:** Strong enforcement powers, public awareness campaigns. **Weaknesses:** Resource limitations.
Nigeria – Pharmacy Council of Nigeria Act, 2022 [38]	Licensing of pharmacists, technicians, and PPMVs; inspections; public health initiatives. **Strengths:** Broad regulatory scope, modernized Act. **Weaknesses:** Implementation challenges.
South Africa – South African Pharmacy Council (SAPC) [39]	BPharm + internship + pre-reg exam; CPD compulsory; roles in primary care. **Strengths:** Strong CPD & licensing system. **Weaknesses:** Healthcare system disparities.
Japan – Pharmaceutical & Medical Device Act (MHLW) [40,41]	Six-year pharmacy program; national exam; strong focus on clinical pharmacy. **Strengths:** Robust education, clinical emphasis. **Weaknesses:** Limited community pharmacy role [40].
South Korea – Pharmaceutical Affairs Act (Ministry of Health & Welfare / Korean Pharmaceutical Association) [42]	Six-year pharmacy program; national licensing exam; roles in hospitals, community, and industry; strong pharma industry links. **Strengths:** Strong academic–industry integration, advanced hospital pharmacy practice, research support. **Weaknesses:** Limited clinical pharmacy roles vs. Western systems; uneven workforce distribution [42].
France & Germany (EU Directive 2005/36/EC –	≥5 years pharmacy education; CPD and internship mandatory; pharmacists central to public health. **Strengths:** EU-wide

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National Health Authorities) [43]	recognition, strong clinical pharmacy integration. **Weaknesses:** Administrative burdens [43].

Table 5. Comparative Overview of Pharmacy Education, Licensing, and Renewal Requirements Across Countries (Including Nepal).

Country	**Degree Requirement**	**Licensing Exam / Credentialing**	**Internship / Practical Training**	**License Validity**	**Renewal / Continuing Education (CE/CPD)**
USA [31]	Pharm.D (entry-to-practice)	NAPLEX + state law exam (often MPJE)	~1,500 hrs (varies by state)	Renewal every 1-2 yrs (varies by state)	State-mandated CE hours (varies by state)
Canada [44]	B.Pharm or Pharm.D (entry-to-practice often Pharm.D)	Pharmacy Examining Board of Canada (PEBC) Qualifying Exam	~1,000 hrs+ (varies by province)	Annual or as set by province	CE/CPD mandatory (e.g., 15 hrs/yr in some provinces)
Australia [45]	B.Pharm / M.Pharm	Written + oral board (varies by state)	~1 yr practical	Annual renewal (varies)	CPD required (e.g., ~20 hrs/yr)
United Kingdom [46]	M.Pharm (entry-to-practice)	General Pharmaceutical Council (GPhC) registration assessment	~1 yr foundation training	Active practice + annual registration	Annual renewal + CPD (as defined by GPhC)

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Germany [47]	≈ 5-year pharmacy degree	State exam	1-2 yrs practical training	Generally lifetime licence unless revoked	CPD recommended
Japan [48,49]	6-year pharmacy degree	National Pharmacist Examination	Practical/ internship component integrated in degree (≈1 yr)	Licence issued for life	Optional/encouraged lifelong learning via e.g. Japan Pharmacists Education Center
South Korea [50]	6-year pharmacy degree	National Pharmacy Exam	Intern/ practical training (need verification)	Generally lifetime licence	CPD optional/varies by region
China [51,52]	≈ 5-year pharmacy (or equivalent)	National Exam	Practical training required (details vary)	Licence renewal every 5 yrs (approx)	CE required (details vary)
India [27,53,54]	D.Pharm / B.Pharm	State Registration via Pharmacy Council of India (PCI)	Practical training included in diploma/ degree	Lifetime licence (in many states)	CPD recommended (not uniformly mandatory)
Nepal [1]	D.Pharm / B.Pharm	Name registration exam by Nepal	Practical training as part of degree;	Name registration valid (non-Nepali	No mandatory CPD identified

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		Pharmacy Council (NPC)	separate internship N/A	up to 2 yrs), Nepali citizen every 3 yrs renewal	

Table 6. Recommendations for Modernizing the NPC Act Based on Global Practices.

Recommendation	Global Example & Detailed Expected Benefit for Nepal
Mandatory CPD [55,56] for license renewal	Systems in the USA [57], UK [58], Australia [59], and EU [60,61] require Continuing Professional Development (CPD) for license renewal. Implementing mandatory CPD in Nepal will ensure pharmacists maintain competency, stay updated with clinical, technological, and pharmaceutical advances, enhance patient safety, and align professional standards with global practice.
Clarify roles of pharmacists vs. assistant pharmacists	In countries like Japan, South Korea, and EU nations [43], the roles and responsibilities of pharmacists and assistant pharmacists are clearly defined. Clarifying these roles in Nepal will reduce overlaps, enhance accountability, ensure proper delegation, and strengthen professional practice standards.
Strengthen inspection and accreditation mechanisms [62,63]	USA (state boards of pharmacy) and India (PCI) implement systematic inspections of educational institutions and practice sites. Adopting similar mechanisms in Nepal will guarantee the quality of pharmacy education, improve compliance in community and hospital pharmacy practice, and enforce professional and ethical standards effectively.
Digitalization and telepharmacy integration [64,65]	Countries such as South Korea and EU members use online registration systems, electronic documentation, and telepharmacy to modernize practice. Nepal can adopt these technologies to streamline licensing, improve access to pharmacy services in remote areas, support telehealth initiatives, and collaborate with health ministries and international agencies for technical guidance and training.

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Alignment with international standards [66,67]	Adopting frameworks from WHO [68], FIP [13], EMA, and FDA ensures adherence to global best practices. For Nepal, this will improve pharmacy education and practice quality, facilitate international recognition of pharmacists, and enable workforce mobility while maintaining patient safety and service quality.
Regular review and amendment of the Act	Countries like India and EU nations [43] periodically review and amend pharmacy legislation. Implementing a review cycle every 5–10 years in Nepal will ensure the Act remains current with emerging pharmacy roles, technological advancements, and evolving healthcare system needs.
Inclusion of modern pharmacy roles [8,69]	Modern pharmacy roles such as clinical pharmacy, community pharmacy with prescribing role [70,71], and pharmacovigilance are formally recognized in USA, Japan, and South Korea. Including these roles in Nepal's Act will strengthen patient-centered care, enhance pharmacists' contribution to public health, and ensure pharmacy education and practice meet contemporary healthcare demands.

4. Conclusions

The NPC Act 2000 was a landmark initiative that formally recognized pharmacy as a regulated profession in Nepal and established the Council to oversee education, registration, and professional conduct. Over the past two decades, pharmacy education and the pharmaceutical industry have grown substantially, yet gaps in workforce distribution, professional roles, and regulatory enforcement persist. The current Act primarily addresses administrative, educational, and disciplinary functions, with limited focus on clinical integration, public health involvement, CPD, research, or digital modernization. Comparative analysis with global regulatory frameworks highlights the importance of mandatory CPD, clear role differentiation between pharmacists and assistants, telepharmacy integration, periodic legislative review, and inclusion of contemporary pharmacy roles such as clinical, community, and pharmacovigilance practices. Proposed amendments emphasize merit-based leadership, enhanced governance, expanded responsibilities, and alignment with international standards to strengthen the NPC's capacity. Modernizing the NPC Act will not only ensure competent and ethical pharmacy practice but also enhance pharmacists' contribution to healthcare delivery, rational medicine use, and patient safety. By bridging historical context, current challenges, and global best practices, Nepal can build a robust, dynamic pharmacy profession capable of meeting national health needs and achieving alignment with international standards.

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References

1. *Nepal Pharmacy Council*. [cited 2025 Sept. 9]; Available from: www.nepalpharmacycouncil.org.np.
2. Khanal, D.P. and S. Karki, *History of pharmacy education in Nepal.* Journal of Manmohan Memorial Institute of Health Sciences, 2023. **8**(1): p. 6-10.
3. KC B, P.S., et al., *History and evolution of pharmaceutical education in Nepal: education versus practice.* J Nepal Pharamaceut Assoc, 2017. **28**(1): p. 12-15.
4. Saha, D., *Glimpse of pharmaceutical education in Nepal.* Int J Pharm Teach Pract, 2013. **4**(1): p. 438-441.
5. Kafle, K.K., et al., *Drug retailer training: experiences from Nepal.* Social science & medicine, 1992. **35**(8): p. 1015-1025.
6. Bhuvan, K., P. Subish, and M.M. Izham, *PharmD education in Nepal: the challenges ahead.* American journal of pharmaceutical education, 2011. **75**(2).
7. Chowdhury, N., *Pharmacists as integral members of multidisciplinary teams: Improving Hospital Care.* Journal of Pharmacist and Hospital Pharmacy, 2024. **1**(1): p. 04-06.
8. Felemban, E.J., et al., *The Evolving Role of Pharmacy Professionals in Modern Healthcare Systems.* Journal of International Crisis and Risk Communication Research, 2024. **7**(S8): p. 3048.
9. Shrestha, S., D. Shakya, and S. Palaian, *Clinical pharmacy education and practice in Nepal: a glimpse into present challenges and potential solutions.* Advances in Medical Education and Practice, 2020: p. 541-548.
10. *CTEVT*. [cited 2025 August 15]; See page no. 73]. Available from: https://ctevt.org.np/public/uploads/kcfinder/files/CTEVT%20Annual%20Report_80_81_final.pdf.
11. *Medical Education Comission Notice*. [cited 2025 August 5]; Available from: https://drive.google.com/file/d/1ZKT7IHWM0I9K4fww5fPUuhZzGurocpBB/view.
12. *DDA-Domestic manufacturer companies*. Sept. 9, 2025]; Available from: https://dda.gov.np/pages/domestic-mfc/.
13. *FIP*. [cited 2025 Oct. 29]; Available from: https://www.fip.org/fip-unitwin-pathfinder-toolkit.
14. Khanal, D.P., *History of pharmaceutical development in Nepal.* Journal of Manmohan Memorial Institute of Health Sciences, 2017. **3**(1): p. 86-93.
15. Shah, R.K., *Historical aspects of cardiovascular services in Nepal.* Nepalese Heart Journal, 2000. **1**: p. 2-5.
16. Heydon, S., *Death of the King: The Introduction of Vaccination into Nepal in 1816.* Medical History, 2019. **63**(1): p. 24-43.
17. Heydon, S., *Mountains and medicines: history and medicines use in rural Nepal.* 2011.
18. *National Drug Policy 1995*. [cited 2025 Oct. 16]; Available from: https://www.opmcm.gov.np/wp-content/uploads/npolicy/Health/National-Drug-Policy-2005.pdf.
19. *GMP*. [cited 2025 Sept. 9]; Available from: https://giwmscdntwo.gov.np/media/pdf_upload/WHO%20GMP%20updated%20as%20of%2002.03.2082_pbujzqa.pdf.
20. *Association of Pharmaceutical Producers of Nepal (APPON)*. [cited 2025 Aug. 2]; Available from: https://appon.org.np/.

 doi:10.20944/preprints202511.1019.v1

21. https://nepalpharmacycouncil.org.np. Nepal Pharmacy Council. (2022). Minimum standards for Bachelor of Pharmacy (BPharm) programs in Nepal. Retrieved from].
22. Ranjit, E., *Pharmacy practice in Nepal.* The Canadian journal of hospital pharmacy, 2016. **69**(6): p. 493.
23. Kokane, J.V. and P.S. Avhad, *Role of pharmacist in health care system.* J Community Health Manag, 2016. **3**(1): p. 37-40.
24. Sahera, S. and D.S. Kumar, *Role of clinical pharmacist in healthcare system.* Journal of Research in Pharmaceutical Science, 2020. **6**(01): p. 08-23.
25. Bates, I., et al., *Pharmacy Workforce Intelligence: Global Trends Report 2018.* 2018.
26. Wheeler, J.S. and M. Chisholm-Burns, *The benefit of continuing professional development for continuing pharmacy education.* American journal of pharmaceutical education, 2018. **82**(3).
27. *Pharmacy Council of India*. [cited 2025 Oct. 31]; Available from: https://www.pci.nic.in/.
28. *CBI probe into PCI chief reignites push for pharmacy commission bill*. [cited 2025 Oct. 31]; Available from: https://timesofindia.indiatimes.com/city/ahmedabad/cbi-probe-into-pci-chief-reignites-push-for-pharmacy-commission-bill/articleshow/122327121.cms?
29. *Bhutan Food and Drug Authority (BFDA)*. [cited 2025 Oct. 31]; Available from: https://bfda.gov.bt/.
30. *National Association of Boards of Pharmacy (NABP)*. [cited 2025 Oct. 31]; Available from: https://nabp.pharmacy/.
31. Scott, D.M., *United States health care system: a pharmacy perspective.* The Canadian Journal of Hospital Pharmacy, 2016. **69**(4): p. 306.
32. *Medicine Act 1968*. [cited 2025 Oct. 30]; Available from: https://www.legislation.gov.uk/ukpga/1968/67.
33. *General Pharmaceutical Council (GPhC)*. [cited 2025 Oct. 29]; Available from: https://www.pharmacyregulation.org/.
34. *Pharmacy Board of Australia*. [cited 2025 Oct. 25]; Available from: https://www.pharmacyboard.gov.au/.
35. *Australian Health Practitioner Regulation Agency (Ahpra)*. [cited 2025 Oct. 29]; Available from: https://www.ahpra.gov.au/.
36. *Ghana PHARMACY ACT - 1994*. [cited 2025 Oct. 14]; Available from: https://www.moh.gov.gh/wp-content/uploads/2016/02/Pharmacy-Act-1994-Act-489.pdf.
37. *Health Professions Regulatory Bodies ACT, 2013*. [cited 2025 Oct. 15]; Available from: https://gsmpghana.org/wp-content/uploads/2022/04/Health-Profession-Regulatory-Bodies-Act-2013.pdf.pdf.
38. *PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT)*
39. *ACT, 2022*. [cited 2025 Oct. 12]; Available from: https://pcn.gov.ng/wp-content/uploads/2024/09/Pharmacy-Council-of-Nigeria-Act-2022-publication.pdf.
40. *South African Pharmacy Council (SAPC)* [cited 2025 Oct. 10]; Available from: https://www.pharmcouncil.co.za/.
41. *Pharmacists Act (Act No. 146 of 1960)* . Available from: https://www.japaneselawtranslation.go.jp/en/laws/view/2596/en?utm_source=chatgpt.com.
42. *National Pharmacist Examination*. [cited 2025 Oct. 15]; Available from: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/yakuzaishi-kokkashiken/index.html.
43. *PHARMACEUTICAL AFFAIRS ACT*. [cited 2025 Oct. 30]; Available from: https://elaw.klri.re.kr/eng_service/lawView.do?hseq=40196&lang=ENG.

 doi:10.20944/preprints202511.1019.v1

44. *Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications* [cited 2025 Oct. 18]; Available from: https://eur-lex.europa.eu/eli/dir/2005/36/oj/eng.
45. Austin, Z. and M.H. Ensom, *Education of pharmacists in Canada.* American journal of pharmaceutical education, 2008. **72**(6): p. 128.
46. Sudeshika, T., et al., *General practice pharmacists in Australia: A systematic review.* PLoS One, 2021. **16**(10): p. e0258674.
47. Sosabowski, M.H. and P.R. Gard, *Pharmacy education in the United Kingdom.* American journal of pharmaceutical education, 2008. **72**(6): p. 130.
48. Müller, M.A., et al., *Pilot survey on continuing education for pharmacists in Germany.* Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen, 2022. **172**: p. 78-91.
49. Dolder, C., et al., *Changes in Japanese pharmacy education and practice.* American Journal of Health-System Pharmacy, 2008. **65**(3): p. 201-202.
50. Nakagawa, S. and N. Kume, *Pharmacy practice in Japan.* The Canadian Journal of Hospital Pharmacy, 2017. **70**(3): p. 232.
51. Kim, E. and S. Ghimire, *Career perspectives of future graduates of the newly implemented 6-year pharmacy educational system in South Korea.* American journal of pharmaceutical education, 2013. **77**(2): p. 37.
52. Wang, H.-C., L.-Y. Chen, and A.H. Lau, *Pharmacy practice and education in the People's Republic of China*. 1993, SAGE Publications.
53. Li, J., et al., *Clinical pharmacy undergraduate education in China: a comparative analysis based on ten universities' training programs.* BMC Medical Education, 2023. **23**(1): p. 83.
54. Deshmukh, P. and S. Paliwal, *Pharmacy education 2.0 with special reference to digital India.* Multidisciplinary Reviews, 2024. **7**(4): p. 2024065-2024065.
55. Salahudeen, S.M., et al., *Bridging Competency Gaps in Indian Pharmacy Education: Student perspectives from five states of Southern India.* Research Journal of Pharmacy and Technology, 2025. **18**(7): p. 3221-3227.
56. Rouse, M.J., *Continuing professional development in pharmacy.* Journal of Pharmacy Technology, 2004. **20**(5): p. 303-306.
57. Ballaram, S., V. Perumal-Pillay, and F. Suleman, *A scoping review of continuing education models and statutory requirements for pharmacists globally.* BMC medical education, 2024. **24**(1): p. 343.
58. Owen, J.A., J.B. Skelton, and L.L. Maine, *Advancing the adoption of continuing professional development (CPD) in the United States.* Pharmacy, 2020. **8**(3): p. 157.
59. Karas, M., et al., *Continuing professional development requirements for UK health professionals: a scoping review.* BMJ open, 2020. **10**(3): p. e032781.
60. Main, P.A.E. and S. Anderson, *Evidence for continuing professional development standards for regulated health practitioners in Australia: a systematic review.* Human resources for health, 2023. **21**(1): p. 23.
61. Micallef, R., I. Huet, and R. Kayyali, *Current reality and preferences for continuing professional development of pharmacists in England–supporting pharmacists to achieve their CPD requirements.* Pharmacy Education, 2020. **20**(1): p. 103-115.
62. Silva, H., et al., *Continuing medical education and professional development in the European union: evolution and implications for pharmaceutical medicine.* Pharmaceutical Medicine, 2012. **26**(4): p. 223-233.
63. Zarembski, D.G., M.J. Rouse, and P.H. Vlasses, *Quality Assurance in Pharmacy Education*, in *Clinical Pharmacy Education, Practice and Research*. 2019, Elsevier. p. 381-387.
64. Fathelrahman, A.I. and M.J. Rouse, *Quality and Accreditation in Pharmacy Education*, in *Pharmacy Education in the Twenty First Century and Beyond*. 2018, Elsevier. p. 213-269.

 doi:10.20944/preprints202511.1019.v1

65. Abdelmonem, R., et al., *A Comprehensive Review of Improvements in Clinical Pharmacy: Integration of AI, Pharmacovigilance, Telepharmacy, Legalization, and Multidisciplinary Collaboration for Enhanced Healthcare Delivery.* Journal of Pharmaceutical Sciences and Drug Manufacturing-Misr University for Science and Technology, 2025. **2**(1): p. 89-99.
66. Alhur, A.A., et al., *Pharmacists in the digital era: Opportunities and challenges in telepharmacy implementation.* Modern Phytomorphology, 2025. **19**(1).
67. Sharif, S., et al., *A comparative analysis of the ACPE accreditation standards and the FIP developmental goals and impact on pharmacy education.* Pharmacy Education, 2025. **25**(1): p. 353-358.
68. Bader, L., Z. Kusynová, and C. Duggan, *FIP Perspectives: Realising global patient safety goals requires an integrated approach with pharmacy at the core.* Research in Social and Administrative Pharmacy, 2019. **15**(7): p. 815-817.
69. Organization, W.H., *The legal and regulatory framework for community pharmacies in the WHO European Region*, in *The legal and regulatory framework for community pharmacies in the WHO European Region*. 2019.
70. Ahmad, S., *FIP VIRTUAL 2020: Pharmaceutical Practice: Academic Pharmacy.*
71. Law, M.R., et al., *Independent pharmacist prescribing in Canada.* Canadian Pharmacists Journal/Revue des Pharmaciens du Canada, 2012. **145**(1): p. 17-23. e1.
72. Zhou, M., et al., *Barriers to pharmacist prescribing: a scoping review comparing the UK, New Zealand, Canadian and Australian experiences.* International Journal of Pharmacy Practice, 2019. **27**(6): p. 479-489.