2025, Volume 5, Issue 2, Page No: 139-158
ISSN: 3108-4850

Society of Medical Education & Research

Annals of Pharmacy Education, Safety, and Public Health Advocacy

Investigating the Roles and Mandates of National Pharmaceutical Service Agencies: Evidence from Global Trends and the Cases of Côte d'Ivoire, Kenya, and Nepal

Wei Zhang[1]*, Chen Hui[2], Michael Tan[1]

[1]Department of Pharmaceutical Policy and Health Systems, Faculty of Pharmacy, University of Melbourne, Melbourne, Australia.
[2]Department of Global Health and Medicines Supply Chain, Faculty of Pharmacy, National University of Singapore, Singapore.

***E-mail** ✉ wei.zhang@unimelb.edu.au

Abstract

National pharmaceutical services units (NPSUs) are central government entities, typically embedded within ministries of health, that oversee the pharmaceutical system. Recently, their scope appears to have narrowed considerably. Observational evidence suggests a growing concentration on logistics and supply chain activities, while responsibilities related to pharmaceutical care, regulation, and policy leadership have become fragmented across different structures. This study assessed the current mandates and roles of NPSUs and outlined the essential functions these units should assume in the future. This research drew on comparative case studies from Côte d'Ivoire, Kenya, and Nepal, supported by a comprehensive literature review and qualitative in-depth interviews. Data were triangulated and synthesized to map NPSUs by their hierarchical placement within ministries of health, reporting structures, formal mandates, and operational functions. Across the cases, four broad functional areas were commonly associated with NPSUs: regulation of medicines, procurement and supply chain management, selection and rational use of medicines, and oversight of pharmacy practice. Effective performance of these units depended on three key elements: a clearly defined position within the Ministry of Health hierarchy, an explicit legal or administrative mandate, and supportive national pharmaceutical policies and regulatory systems. A formal legislative framework is necessary to designate at least one NPSU as the steward of pharmaceutical governance. This stewardship role involves system-wide coordination, administrative oversight, and responsibility for designing, implementing, and evaluating policies related to governance, financing, regulation, monitoring, and performance of the pharmaceutical system. Based on these findings, we propose that NPSUs should, at minimum, be responsible for four core areas: pharmaceutical policy and governance, medicine regulation, regulation of pharmacy practice, and procurement and supply chain management. The findings highlight the importance of establishing a dedicated pharmaceutical policy and governance function that provides leadership for the pharmaceutical system, ensures coordination across stakeholders, and strengthens monitoring and evaluation mechanisms to improve overall system performance.

Keywords: Pharmaceutical service, Pharmaceutical policy, Governance, Medicine regulation, Pharmacy practice, Health supply chain management

Introduction

Medicinal products represent a major and steadily increasing component of global health expenditure [1], requiring structured coordination within ministries of health to support universal health coverage (UHC) and related Sustainable Development Goals. At the national level, specific departments or divisions are typically assigned responsibility for managing pharmaceutical system functions to improve access to essential medicines and contribute to UHC goals. These central governmental structures—responsible for areas such as medicine regulation, supply chain coordination, and pharmaceutical service delivery—are referred to as national pharmaceutical services units (NPSUs). Such units function as administrative bodies overseeing

Access this article online https://smerpub.com/

Received: 29 September 2025; **Accepted:** 14 December 2025

Copyright CC BY-NC-SA 4.0

How to cite this article: Zhang W, Hui C, Tan M. Investigating the Roles and Mandates of National Pharmaceutical Service Agencies: Evidence from Global Trends and the Cases of Côte d'Ivoire, Kenya, and Nepal. Ann Pharm Educ Saf Public Health Advocacy. 2025;5(2):139-58. https://doi.org/10.51847/dndoYaLPXT

multiple components of the pharmaceutical system, which comprises the interconnected structures, actors, resources, and processes within the health system designed to ensure equitable access to safe, effective, quality-assured medical products and their appropriate and cost-efficient use to improve health outcomes [2]. In this context, NPSUs play a critical role in advancing UHC by supporting access to essential, safe, and affordable medicines and related services.

Existing literature has largely focused on pharmaceutical care and the role of pharmacists at the facility level [3-6]. In contrast, relatively limited attention has been given to NPSUs as system-level coordinating entities. Nevertheless, several high-level policy discussions over the past decade—often centred on rational medicine use—have indirectly highlighted systemic challenges and the potential functions of these units [6-8]. These include involvement in the development of national medicines policy, essential medicines lists, and standard treatment guidelines, as well as the coordination of human and financial resources supporting the implementation of pharmaceutical policy. There is also growing recognition of the importance of pharmacists engaging in policy formulation and implementation rather than being limited to clinical service delivery [7]. However, weak political commitment, lack of dedicated champions, and poor integration of national medicines policies into broader health strategies have hindered effective implementation [9]. A key unresolved issue is whether essential functions such as policymaking, administration, implementation, monitoring, and technical support are embedded within pharmaceutical units or distributed across multiple divisions within ministries of health, and how these functions interact with one another.

NPSUs must also be able to respond to evolving health system priorities. For example, in Brazil, the absence of a clearly defined pharmaceutical services structure at the municipal level created barriers to the implementation of decentralized pharmaceutical services within primary healthcare systems [10, 11]. The global movement toward UHC requires additional technical capabilities, including health technology assessment and the design of reimbursement systems. At the same time, emerging challenges such as antimicrobial resistance (AMR) and pandemic preparedness demand strengthened antimicrobial stewardship and more rational use of medicines. Addressing these issues requires strong integration between policy development, clinical expertise, pharmaceutical sciences, pharmacology, and related disciplines such as infection prevention and control. Broader global shifts—including reduced reliance on external aid, increased private-sector participation, and epidemiological transitions from infectious to noncommunicable diseases—further reinforce the need for coordinated pharmaceutical governance structures. In addition, the growing emphasis on quality in health service delivery underscores the importance of ensuring appropriate medicine use and strengthening the implementation of pharmaceutical services.

We propose that NPSUs are public-sector entities responsible for coordinating the structures, actors, resources, and processes required to ensure equitable, timely, and affordable access to safe, effective, and quality medical products and services, while promoting their rational use. Their functional scope includes medicine regulation, supply chain management, pharmaceutical policy development and execution, and monitoring and evaluation. These responsibilities may be distributed differently across countries depending on institutional arrangements and governance structures. However, due to the absence of a clear conceptual framework and limited attention in the literature, this study examines the current status of NPSUs regarding their mandates, roles, and functional responsibilities within health systems (**Table 1**).

Table 1. Framework for document review

Element	Reformulated description
Purpose of review	The aim was to gather and consolidate available information describing the responsibilities, mandates, and functional roles of central government bodies (such as departments, divisions, or directorates) involved in national medicines policy, regulation of medical products, pharmaceutical services, supply chain systems, and pharmacy practice.
Key research questions	(1) Which organizational forms or categories of national pharmaceutical service units (NPSUs) exist that oversee policy development, implementation, medicine regulation, supply chain operations, pharmacy

	practice, and pharmaceutical services? (2) What duties, responsibilities, and formal mandates are assigned to these units?
Eligibility criteria for inclusion	Included sources comprised official government and regulatory materials such as legal statutes, policy frameworks, Ministry of Health organisational charts, strategic plans, standard operating procedures, and other relevant institutional documents, as well as published reports.
Search terms	A broad combination of keywords was applied, including: national, health ministry, pharmaceutical, pharmacy, medicines, services, practice, department, division, directorate, policy, mandate, function, structure, organogram, governance, regulation, procurement, supply chain, selection, access, and rational use.
Language and time coverage	Only English-language publications were included, and no restrictions were applied to publication dates or time periods.
Exclusion criteria	Peer-reviewed publications not written in English were excluded. For official government documentation, French-language sources were additionally retrieved and reviewed by team members fluent in French.
Information sources	Data were obtained from Google Scholar, PubMed, official Ministry of Health websites, WHO databases, International Pharmaceutical Federation resources, USAID portals, and other relevant grey literature repositories.

Côte d'Ivoire, Kenya, and Nepal were deliberately chosen as case study settings based on the established presence of the MTaPS programme in these countries, which enabled easier engagement with relevant stakeholders. In addition, the selected countries provide representation across Asia and both anglophone and francophone regions of Africa. Using insights from the document review together with inputs from in-country programme teams, a stakeholder mapping exercise was undertaken to identify suitable key informants. Following this, country teams applied purposive sampling to recruit participants based on predefined criteria guiding informant selection.

In total, 44 interviews were completed: 16 in Kenya, conducted in English between September and October 2022; 10 in Côte d'Ivoire, conducted in French from November 2022 to January 2023; and 18 in Nepal, conducted in Nepali between May and June 2023. A semi-structured interview guide was developed in line with the study objectives. It included questions addressing the current status of NPSUs, including their organisational structure, roles, responsibilities, historical changes, and perceived future priorities and functions. The interview tool was translated into French for Côte d'Ivoire and into Nepali for Nepal by the respective country teams.

Ethical clearance for the case studies was obtained from the Comité National d'Ethique des Sciences de la Vie et de la Santé (reference number 109-22/MSHPCMU/CNESVS-kp) in Côte d'Ivoire, the Institutional Scientific and Ethical Review Committee of Strathmore University in Kenya (reference number SU-ISERC1414/22), and the Nepal Health Research Council (reference number 986).

In Côte d'Ivoire and Kenya, interviews were audio-recorded and later transcribed verbatim; all transcripts were then de-identified. In Nepal, participants declined audio recording; therefore, interview data were captured in real time through Nepali note-taking. All Nepali notes and French transcripts were subsequently translated into English for analytical purposes. Each participant was assigned an anonymised identifier consisting of a country code and a numeric label (e.g., KIK13 refers to the 13th respondent from Kenya).

The dataset was analysed using thematic analysis guided by the framework method to examine NPSU configurations in each country, their institutional positioning within government structures, and their respective mandates and functions. The analysis further explored political and policy-level factors that enable or limit their effectiveness. The framework approach involved six iterative stages: transcription, data familiarisation, initial coding, development of an analytical framework, application of the framework to the dataset, data charting into a matrix, and interpretation of findings [12]. Transcription and initial data handling were undertaken jointly by the lead researcher and country team leads. In contrast, the remaining analytical stages were primarily led by the lead researchers with input from the wider team. Preliminary results were shared with the technical working group (TWG) on April 19, 2023, for review and discussion before finalisation.

Results and Discussion

The findings begin with a synthesis of evidence from the literature review, focusing on the classification of NPSUs by hierarchical placement within ministries of health and reporting structures, as well as the broad functional categories identified in the literature. This is followed by the presentation of the three-country case studies, detailing the number and types of units identified, their mandates and functions, and their associated strengths and limitations.

NPSU position in the hierarchy

The institutional placement of an NPSU within government structures influences its authority, reporting relationships, access to resources, and involvement in decision-making within the health ministry. Based on a review of government organograms and policy documents from 16 countries, three distinct categories of NPSUs were identified according to their hierarchical position and degree of autonomy (**Figure 1**).

Type I NPSUs are positioned at a high administrative level within the Ministry of Health and report directly to the minister. Type II NPSUs occupy a mid-level position in the hierarchy and report to the minister indirectly through intermediary units. Type III NPSUs are structured as semi-autonomous or fully autonomous agencies operating under the ministry or department as independent or quasi-independent entities. Examples corresponding to each category are presented in **Table 2**.

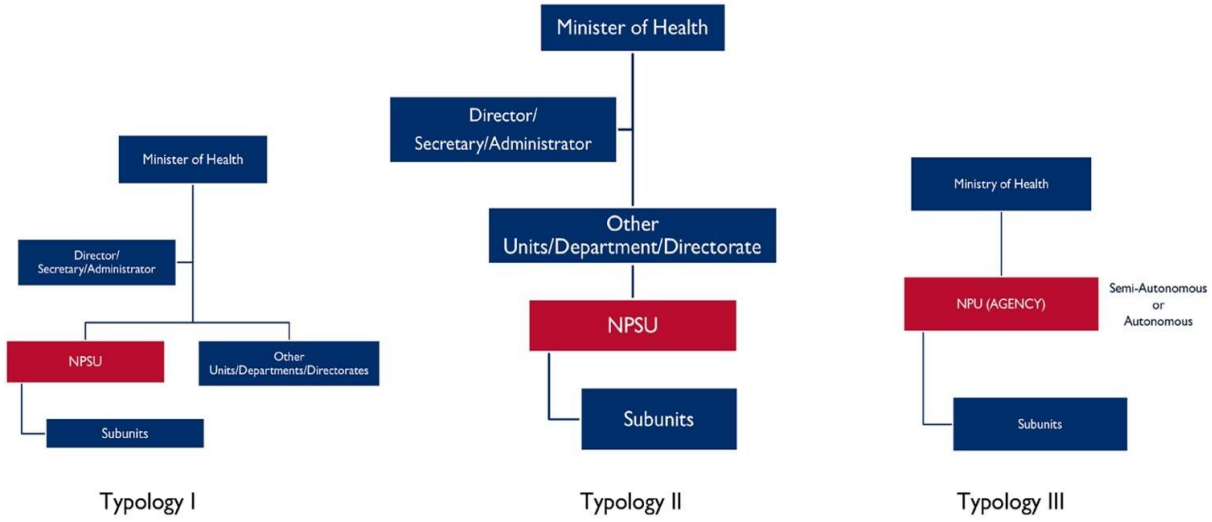


Figure 1. NPSU typology based on position in the health ministry's organisational hierarchy.

Table 2. National pharmaceutical service structures grouped by typology III-I

Country	Typology III functions/agencies	Typology II functions/units	Typology I functions / units
Australia	—	—	Therapeutic Goods Administration [6]
Brunei Darussalam	—	Brunei Pharmacy Board [13]	[14]
Côte d'Ivoire	Regulatory body for pharmaceuticals; National professional pharmacists' order; Public pharmaceutical service initiative;[15]	Pharmaceutical operations unit within the Directorate General of Health and Public Hygiene [16]	National Public Health Laboratory system [15]
Democratic Republic of Congo	—	—	National pharmaceutical regulatory authority [17]
Finland	Medicines regulatory agency; drug pricing authority; former medicines agency structure [18, 19]	—	—

Ghana	—	National drug regulatory authority; professional pharmacy council [20, 21]	Supply chain and procurement directorate; pharmaceutical coordination unit under technical services [22, 23]
Kenya	—	Medicines regulator; national supply agency; quality control laboratory system [24]	Department overseeing health products and technologies [25]
Lao PDR	—	—	Central food and drug administrative department [6]
Malaysia	—	—	National Pharmaceutical Services Division under the Ministry of Health [26]
Nepal	—	Professional Pharmacy Council [27]	Drug regulatory department; standards and compliance division; logistics management section [17]
New Zealand	—	Pharmaceutical management agency [28]	Medicines regulatory control unit; device and medicines safety authority [28]
Nigeria	National food and drug regulatory authority [26]	—	Government drug service unit; procurement administration division [26]
Philippines	National food and drug regulatory agency [20]	—	Government pharmaceutical services division [29]
Rwanda	National food and drug authority [30]	—	Pharmaceutical services desk; production oversight unit; procurement coordination office [30]
Senegal	—	—	Medicines and pharmacy directorate; public procurement coordination unit [31]
Uganda	National medicines regulatory authority [32]	—	Pharmaceutical and natural medicines department; national medicines supply system [32]

NPSU mandate and functions

The analysis revealed four primary functional areas commonly assigned to these units: oversight of medicine regulation, management of procurement and supply chains, processes for medicine selection and promotion of rational use, and regulation of pharmacy practice (**Table 3**).

Table 3. Four categories of NPSU functions identified from the literature.

Medicine regulation	Selection and rational use of medicines	Procurement and supply chain management	Pharmacy practice regulation
Registration and marketing authorisation	Selection	Supply and distribution	Regulation of pharmacists and other pharmaceutical support staff
Vigilance	Medicine policy and administration	Distribution	Regulation of wholesale and retail medicine sale
Market surveillance and control	Access programmes design and implementation	Supply chain strategic planning and logistics management	Control the location of licensed pharmacies

Licensing establishments	Essential medicines list and standard treatment guideline updates	Logistics data collection and analysis	Regulation of education and training
Regulatory inspection	Pharmaceutical policy implementation	National procurement and supply chain policies and frameworks	
Laboratory testing	Strategic monitoring of the availability and accessibility of medicines	Central procurement coordination and central medical stores management	
Clinical trial oversight	Regulation of compulsory stockpiling and medicine reimbursement	Quantification, procurement, formulation of national medicines policies, and control of medicines prices	
National regulatory authority lot release	Pharmaceutical services		
	Pharmaceutical care		
	Emergency preparedness for medicines and medical technologies		

A national medicines regulatory authority is a type of National Pharmaceutical Services Unit (NPSU) primarily responsible for overseeing the regulation of medical products. These institutions are generally classified within typology I or typology III, reflecting their central importance in the health system architecture. Their institutional independence differs across countries, and their responsibilities may be restricted solely to medicines regulation, as illustrated by Uganda's National Drug Authority and Zambia's Medicines Regulatory Authority. In other jurisdictions, their scope is broader and may include regulation of pharmacy practice or even food safety. For example, Laos' Food and Drug Department, Ghana's Food and Drugs Authority (FDA), and Rwanda's FDA are mandated to oversee both food and pharmaceutical products. At the same time, Kenya's Pharmacy and Poisons Board (PPB) additionally has authority over pharmacy practice regulation.

The establishment and authority of national medicines regulatory agencies are defined through formal legal frameworks, including acts of parliament, statutes, and other legislative instruments. For instance, Ghana's Public Health Act 2012 (Act 851), which created the FDA, requires it to "provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances" [33].

Case I: Kenya

In Kenya's devolved governance system, responsibility for health service delivery is shared between national and county levels. The national government, through the Ministry of Health (MoH), is responsible for policy formulation, regulation of the health sector, supervision of national referral hospitals, and provision of technical guidance to county governments. County administrations manage local health facilities and ambulance services. They are also responsible for primary health care delivery, disease surveillance and outbreak response, public health and sanitation services, disaster preparedness, veterinary public health, and waste disposal functions [34, 35].

At the national level, four main National Pharmaceutical Services Units (NPSUs) operate: the Directorate of Health Products and Technologies (DHPT), the Pharmacy and Poisons Board (PPB), the Kenya Medical Supplies Authority (KEMSA), and the National Quality Control Laboratory (NQCL) (**Table 4**). The DHPT is categorized under typology I, while the PPB, KEMSA, and NQCL are categorized under typology III because they function as semi-autonomous or autonomous agencies within the Ministry of Health.

Table 4. Kenyan NPSUs: organizational structures, typologies, roles, mandates, and legal foundations.

NPSU name and typology	Functions	Mandate
Directorate of Health Products and Technologies (DHPT), typology I	• Maintains a coordinated national system covering the full cycle of health products and technologies, including selection, forecasting, procurement, distribution, and rational use • Supervises nationwide logistics and delivery of health products and technologies • Leads development and implementation of key pharmaceutical policy instruments and standards such as essential medicines lists, treatment guidelines, and supply lists for medicines, laboratory items, and other technologies • Provides expert advisory and technical guidance on health products and technology services • Produces standards and frameworks for non-pharmaceutical commodities such as laboratory supplies, nutritional products, and medical devices • Works to guarantee uninterrupted, fair, and cost-efficient availability of health products across all levels of care in the country • Strengthens county-level capacity through training programs, technical support, and coordination between national and subnational supply chain systems • Collaborates with monitoring and evaluation units to track availability, distribution, and utilization patterns of health commodities • Encourages research development, supports domestic manufacturing initiatives, and promotes use of international trade flexibilities (TRIPS) for improved access • Builds strategic partnerships to support financing, coordination, and execution of supply chain and health product initiatives	Functions under the legal and policy framework of the Kenya Health Policy, the Health Act (2017), and the Constitution of Kenya [25]
Pharmacy and Poisons Board (PPB), typology III	• Oversees regulation of the pharmacy profession, including education, licensing, and practice standards for pharmacists and allied personnel • Controls licensing and inspection of pharmaceutical premises such as wholesale and retail outlets • Authorizes certification and quality confirmation of tested pharmaceutical products • Grants approval for marketing and distribution of medicinal products • Issues permits for pharmaceutical manufacturing activities • Ensures compliance with manufacturing standards through inspections and enforcement of GMP requirements • Monitors medicine safety and effectiveness through pharmacovigilance and post-market surveillance systems • Regulates importation, trade, production, and circulation of medicines and controlled substances • Maintains regulatory lists for poisons used in agriculture and related sectors	Operates under the Pharmacy and Poisons Act (Cap 244, 2012 amendment), which provides legal authority for regulating pharmacy practice and control of medicines and poisons in Kenya [24]
Kenya Medical Supplies Authority (KEMSA), typology III	• Handles procurement, storage, and nationwide distribution of medicines and health commodities for public health services, emergency reserves, and referral facilities • Develops and maintains logistics infrastructure including warehouses and distribution networks for medical supplies • Works jointly with county governments in sourcing, storing, and delivering essential health commodities • Evaluates efficiency, performance, and cost implications of procurement and supply chain operations across health facilities	Created under the Kenya Medical Supplies Authority Act No. 20 of 2013, establishing KEMSA as an independent state agency under the Ministry of Health [36]

	• Provides technical guidance to counties to strengthen and sustain supply chain management systems	
National Quality Control Laboratory (NQCL), typology III	• Carries out laboratory-based verification of pharmaceutical quality and compliance • Performs extensive scientific testing including chemical, biological, biochemical, physiological, and pharmacological analyses of medicinal products • Assesses both domestically produced and imported medicines for safety, quality, and compliance with regulatory standards • Conducts ongoing post-market surveillance focused on laboratory testing of medicines in circulation	Legally established under Section 35D of the Pharmacy and Poisons Act (Cap 244, 2012), designating it as a Ministry of Health institution responsible for ensuring quality assurance of medicines and related products [24]

Function and mandate

Established as an independent state corporation through the Kenya Medical Supplies Authority Act No. 20 of 2013, KEMSA is charged with the procurement, storage, and nationwide distribution of health commodities, as well as offering technical support to county governments in setting up and sustaining effective pharmaceutical supply chain systems [36]. The Pharmacy and Poisons Board (PPB), functioning as a semi-autonomous regulator under the amended Pharmacy and Poisons Act (Cap 244, 2012), is responsible for overseeing pharmacy practice and controlling the manufacture, distribution, and trade of medicinal products. The National Quality Control Laboratory (NQCL), also provided for under the same Act, is assigned the role of ensuring quality assurance of medicines and related pharmaceutical substances [24]. It conducts systematic testing and evaluation of medicinal products to confirm their safety, efficacy, and compliance with quality standards. **Table 5** presents a consolidated overview of the functions of the four units.

Table 5. Ivorian NPSUs: institutional names, typologies, roles, mandates, and legal foundations.

NPSU name and typology	Functions	Mandate
Directorate of Pharmaceutical Activity (DAP), typology II	• Acts as the central coordinating body for pharmaceutical operations within the Ministry of Health and Public Hygiene • Serves as the ministry's principal technical unit for pharmaceutical service delivery • Oversees and tracks execution of the National Pharmaceutical Policy framework • Leads strategic planning related to medicine supply chain systems • Develops national essential medicines lists and defines their categorization across different levels of care in the public health sector • Prepares and submits technical pharmaceutical documentation to the Minister of Health • Continuously monitors availability and access to medicines and key health commodities nationwide • Supports strengthening of supply chain systems across both central and decentralized public institutions, including distribution processes, electronic stock tracking, and rehabilitation of pharmacy services • Follows up on regulatory instruments developed by the AIRP and ensures their alignment within the Ministry of Health	Established under Law Order No. 0220/MSHP/CAB (15 November 2020), the DAP is mandated to improve population health outcomes through leadership of pharmaceutical functions defined in the National Pharmaceutical Policy [16]

Ivorian Pharmaceutical Regulatory Authority (AIRP), typology III	• Oversees regulation of imported and exported pharmaceutical products • Manages authorization procedures for medicines, including licensing, inspection, and market entry control • Supports implementation of national pharmaceutical policy while ensuring legal and regulatory compliance within the sector • Regulates promotion and advertising of medicines and pharmaceutical products • Supervises pharmacies as well as clinical and medical analysis laboratories • Conducts post-market monitoring and pharmacovigilance activities • Carries out inspections across pharmaceutical services and laboratory facilities	Established through Act No. 2017–541 (3 August 2018), Decree No. 2018–926 (12 December 2018), and subsequent implementing decree issued in February 2019, which collectively define its regulatory authority [37]
New Public Health Pharmacy (NPSP), typology III	• Manages national-level pharmaceutical supply chain operations • Oversees distribution of medicines and health commodities from central warehouses to regional, district pharmacies, and hospitals • Functions as the central procurement and distribution hub for essential medicines within the public health system • Implements contractual performance-based agreements with health facilities • Conducts forecasting and planning for essential medicines and consumables across the public sector • Ensures continuous availability and accessibility of essential medicines within public health services	Operates under the State–NPSP agreement (2018–2023), functioning as a semi-autonomous public procurement and distribution body [15]
National Public Health Laboratory (LNPS), typology I	• Verifies compliance of products intended for human consumption and public use • Performs quality control across a wide range of products including medicines, medical devices, veterinary products, herbal derivatives, dietary products, para-pharmaceutical goods, drinking water, food items, and beverages • Works jointly with AIRP in monitoring pharmaceutical market quality and safety • Provides forensic and anti-fraud expertise related to medicines and other regulated consumables under applicable legal provisions • Conducts toxicological analyses for industrial and medico-legal purposes • Organizes, evaluates, and develops external quality assurance systems for medical laboratory testing • Contributes to formulation of hygiene and analytical standards in public health • Undertakes research and analytical work aimed at protecting public health	Authorized under Order No. 198/MSHP (2009) to monitor and evaluate quality standards of medicines and related products [15]

National Order of Pharmacists, typology III	• Governs professional pharmacy practice in accordance with the profession's ethical code • Ensures adherence to professional obligations and standards among pharmacists • Safeguards the integrity, independence, and ethical standing of the profession • Organizes continuing professional development and evaluates professional practice standards • Contributes to broader public health promotion efforts	Established under Act No. 60–272 (2 September 1960) and governed by the Code of Ethics introduced via Act No. 62–249 (31 July 1962), which collectively regulate pharmacy practice in Côte d'Ivoire

Kenya's National Pharmaceutical Services Units (NPSUs) demonstrate three key deviations from conventional arrangements. First, as in other contexts, the Department of Health Products and Technologies (DHPT) is responsible for setting the overall direction of pharmaceutical policy, particularly regarding the selection, safeguarding, and appropriate use of health products and technologies (HPT). However, unlike many systems where distribution responsibilities are clearly separated, both DHPT and the Kenya Medical Supplies Authority (KEMSA) jointly oversee the distribution of medicines and related commodities. Although overlapping institutional roles are often associated with coordination problems in other settings, this does not appear to be the case in Kenya. One interviewee noted that collaboration between the two institutions is structured and information-driven, emphasizing shared planning platforms such as commodity security committees that align stakeholders and ensure coordinated decision-making (KIK6).

Second, the function of ensuring the quality of medicine, which is typically integrated within a national regulatory authority elsewhere, is carried out in Kenya by a distinct body, the National Quality Control Laboratory (NQCL). Despite institutional separation, the NQCL operates closely with the Pharmacy and Poisons Board (PPB) under the Pharmacy and Poisons Act, Cap 244 [24]. One respondent described NQCL as a technical extension of the regulator, explaining that it performs laboratory testing on behalf of the PPB and actively participates in technical committees that develop post-market surveillance protocols (KIK13).

Third, unlike many countries where regulatory oversight of medicines and pharmacy practice is divided between separate institutions, Kenya consolidates both responsibilities within the Pharmacy and Poisons Board (PPB). However, reform discussions have sought to distinguish regulatory functions from broader policy and administrative roles. A proposed reform in 2019 aimed at converting the PPB into an FDA-style agency faced opposition due to concerns that restructuring would require repealing key legislation, including the Pharmacy and Poisons Act Cap 244, and could potentially weaken regulatory effectiveness [38]. Despite this, national policy directions still envision a more autonomous regulatory framework in which both PPB and NQCL operate with increased independence, with PPB ultimately evolving into an FDA-like institution [38].

Coordination

The study indicates strong functional coordination among the four NPSUs. DHPT, PPB, KEMSA, and NQCL routinely collaborate through technical exchange and operational support across both internal structures and Ministry of Health programmes. For example, DHPT contributes technical expertise to PPB in areas such as registration of health products, oversight of clinical trials, vaccine procurement processes, and logistics management. It also works jointly with the Division of Reproductive and Maternal Health to estimate demand, determine commodity quantities, and support procurement planning for family planning products.

One participant highlighted their involvement in multi-agency coordination structures, noting that they participate in post-market surveillance activities that bring together officers from DHPT, PPB, and other stakeholders, as well as national therapeutic governance structures involving multiple programmes (KIK5).

Beyond internal government coordination, these institutions maintain partnerships with development agencies, academic institutions, and other external actors to strengthen technical capacity and support broader health system goals. Improved collaboration among DHPT, donors, and PPB has, for instance, contributed to the National Quality Control Laboratory achieving international recognition through WHO prequalification and ISO certification.

At the subnational level, NPSUs play an active supportive role in county health systems. DHPT has led the establishment of HPT units across all 47 counties and continues to support the implementation of national pharmaceutical policies, the coordination of pharmaceutical services, the rational use of medicines, and supply chain management.

Several county HPT units—five in total—have been formally recognized by the Public Service Commission, allowing them access to national human resource structures. DHPT also strengthens county systems through capacity-building initiatives, including ongoing professional training and technical support. One respondent explained this role by emphasizing that capacity building and coordination between the national and county levels are part of their institutional mandate, particularly to strengthen HPT supply chains and service delivery systems while ensuring multi-stakeholder collaboration across levels of government (KIK14).

At the operational level, counties use the national essential medicines list when procuring commodities through DHPT and KEMSA channels. Additionally, the PPB has trained county pharmacists to improve regulatory monitoring, enhance patient safety, and strengthen product quality assurance systems. These interventions have contributed to improved pharmaceutical service delivery in both inpatient and outpatient care settings (KIK2, KIK6).

Strengths

Kenya is currently implementing the HPT Supply Chain Strategy 2020–2025 under DHPT leadership. This strategy has led to the creation and dissemination of multiple policy instruments, including updated guidance on pharmaceutical management, therapeutic committee frameworks, supervision tools, county-level HPT operational guidelines, essential commodity lists, and other supporting regulatory documents.

One respondent described the impact of the strategy as the generation of a wide range of policy and implementation tools, including frameworks for quantification, therapeutic committee operations, and supervisory checklists that strengthen pharmaceutical governance systems (KIK14).

In addition, NPSUs promote inclusive participation in policy development processes. DHPT collaborates with PPB and other stakeholders to identify, orient, and train members of national committees such as the National Medicines and Therapeutics Committee, which plays a key role in developing standard treatment guidelines. The Pharmaceutical Society of Kenya, in collaboration with PPB, also contributes to strengthening professional standards and enforcing regulatory compliance. Ongoing reforms aim to further consolidate fragmented regulatory components into a more unified and effective system.

Weaknesses

Despite support from government and development partners, all four NPSUs continue to face significant financial limitations. These constraints are largely attributed to broader economic pressures and additional fiscal demands arising from the COVID-19 pandemic. As a result, institutions face multiple operational challenges that affect the implementation of their mandates.

For example, DHPT lacks sufficient funding to consistently ensure uninterrupted access to safe, high-quality medical products (KIK1). At the same time, NQCL struggles to procure the essential laboratory equipment and testing reagents required for quality assurance activities (KIK13). Overall, limited financial resources have shifted institutional focus toward commodity supply chain functions at the expense of broader pharmaceutical care responsibilities.

One respondent explained that current priorities disproportionately emphasize supply chain and product-related activities, while pharmaceutical care functions receive comparatively less attention and visibility. They noted that areas such as inventory management, quantification, and regulation dominate institutional focus, whereas pharmaceutical care components remain relatively underemphasized (KIK14).

Financial constraints have also significantly affected staffing structures. Following devolution, NPSUs lost direct mechanisms to replace retiring staff through transfers from county systems, resulting in persistent human resource gaps. Consequently, vacancies often remain unfilled as staff retire or leave for alternative opportunities (KIK3, KIK14).

One respondent described this situation by explaining that national-level recruitment has become constrained due to institutional separation between national and county governments. Unlike in the past, where staff transfers were straightforward, current arrangements limit replacement options, leading to a gradual decline in workforce numbers as attrition is not matched by new recruitment (KIK14).

In addition, remaining staff are often burdened with multiple competing responsibilities, including

obligations to development partners, which contribute to delays in implementing policies and operational tasks (KIK4, KIK12). Limited funding for continuous professional development further restricts opportunities to build technical expertise in areas such as supply chain management, quality assurance, and clinical pharmacy. This has resulted in shortages in both the number and skill level of personnel. In the case of the PPB, these constraints have contributed to delays in product registration, inspection backlogs, and slower pharmacovigilance processes (KIK8).

Case II: Côte d'Ivoire

Côte d'Ivoire's pharmaceutical governance system includes five principal NPSUs: the Directorate of Pharmaceutical Activity (DAP), the Ivorian Pharmaceutical Regulatory Authority (AIRP), the New Public Health Pharmacy (NPSP), the National Public Health Laboratory (LNSP), and the National Order of Pharmacists (**Table 5**). These institutions are positioned at different levels within the Ministry of Health and Public Hygiene [39]

The Ministry is responsible for implementing, supervising, and evaluating national policies related to health and public hygiene [39]. Within this structure, the DAP operates under the General Directorate of Health. Both the DAP and AIRP currently perform functions previously managed by the former Department of Pharmacy, Medicines, and Laboratories, which oversaw the regulation of medicines and controlled substances, as well as food products, cosmetics, and hygiene-related products.

In terms of classification, the LNSP and DAP correspond to typology I and II, respectively, while the AIRP, NPSP, and the National Order of Pharmacists fall under typology III due to their semi-autonomous or independent institutional arrangements.

Functions and mandate

The Directorate of Pharmaceutical Activity (DAP) is legally mandated under Law Order No. 0220/MSHP/CAB of November 15, 2020, to improve population health outcomes by steering pharmaceutical sector activities as outlined in the National Pharmaceutical Policy [16]. As two respondents explained, this mandate mainly covers:

[…] formulating and shaping national pharmaceutical policy, including regulatory elements related to pharmacy practice, medicines, and aspects of medicine supply systems. KICD1

[…] developing pharmaceutical policy and strategic frameworks, while ensuring security of health commodities, continuous monitoring of supply systems, and strengthening the overall supply chain for health products. KICD5

The Ivorian Pharmaceutical Regulatory Authority (AIRP) is an independent regulatory body established under Act No. 2017–541 of August 3, 2018, supported by Decree No. 2018–926 of December 12, 2018, and its implementing decree issued in February 2019. Its primary role is to oversee regulation of the pharmaceutical sector, including inspection activities, surveillance functions, and monitoring of pharmaceutical establishments and industries.

The New Public Health Pharmacy (NPSP) operates as a semi-autonomous public procurement entity under the agreement "Convention entre l'Etat et la Nouvelle PSP 2018–2023." It functions on a non-profit basis and reports directly to the Minister of Health and Public Hygiene. The NPSP began operations on June 21, 2013, replacing the former Public Health Pharmacy of Côte d'Ivoire, which had managed public pharmaceutical services since 1958 [15]. Describing this transition, two respondents stated:

The management of pharmaceutical supplies was previously handled by the National Pharmaceutical Development Program (PNDAP). In contrast, the current NPSP, operating as a non-profit entity, is responsible for procurement, storage, and distribution of medicines to public health facilities. KICD2 and KICD8

The National Public Health Laboratory (LNSP) is governed by Order No. 198/MSHP of 2009. It is responsible for monitoring the quality of medicines and related health products under the technical oversight of the Ministry of Health and Public Hygiene. The National Order of Pharmacists is an autonomous professional body established in 1960 under Act No. 60–272 of September 2, 1960, and regulated through a professional code of ethics defined in Act No. 62–249 of July 31, 1962. It is responsible for regulating pharmacy practice in the country.

Overall, the core responsibilities of the DAP (policy formulation and implementation), AIRP (regulatory oversight), NPSP (procurement and supply chain operations), and the National Order of Pharmacists (professional regulation) closely align with internationally observed NPSU functions. However,

similar to Kenya's NQCL, Côte d'Ivoire's LNSP operates as a separate stand-alone quality assurance institution, whereas this function is typically integrated within national regulatory authorities. The LNSP works in coordination with AIRP to ensure the safety and quality of medicines in the market. One respondent explained:

The LNSP maintains a strong working relationship with AIRP regarding the certification, evaluation, and laboratory testing of medicines. It provides quality control reports to AIRP to support market surveillance and ensure the quality of medicines. KICD2

Coordination

Findings show extensive collaboration among the five NPSUs: DAP, AIRP, NPSP, LNSP, and the National Order of Pharmacists. These institutions jointly contribute to pharmaceutical policy development, quality assurance, and supply chain management.

For example, DAP works closely with NPSP to plan medicine requirements, including forecasting and quantifying health commodities [KICD1]. It also shares responsibilities with NPSP in managing the national supply chain [KICD6]. In addition, DAP engages with regional health authorities and district structures to support training initiatives and collaborates with the National Institute of Public Health in capacity-building programmes for health personnel [KICD9]. Development partners also play a role; for instance, USAID MTaPS supports DAP in antimicrobial resistance (AMR) activities and policy integration. As one respondent described:

DAP collaborates with several units within the Ministry of Health and Public Hygiene, including the Expanded Programme on Immunization and the National Institute of Public Health. It also maintains close coordination with NPSP to ensure efficient pharmaceutical management. KICD1

The NPSP collaborates with LNSP to ensure product quality assurance during procurement processes. Both DAP and NPSP also work with public health programmes, such as immunization services, to forecast and estimate vaccine needs [KICD1]. The importance of such coordination was emphasized by respondents who noted that procurement decisions depend on joint quantification and laboratory verification processes:

Without collaboration between DAP, NPSP, and national health programmes during quantification, it is impossible to determine accurate procurement needs. Likewise, distribution cannot proceed without laboratory verification of product quality. KICD5

Another respondent highlighted formalized collaboration mechanisms:

There is an established agreement between NPSP and the national laboratory that governs medicine testing and quality control procedures, including sampling methods and timelines for reporting results. KICD3

AIRP also plays a role in supporting NPSP with legal authorization for medicine importation [KICD2]. Furthermore, it works with law enforcement and judicial bodies, including the Ministry of Justice, gendarmerie, anti-counterfeit agencies, and drug enforcement units, to combat counterfeit medicines [KICD3]. One respondent further explained:

DAP and AIRP jointly participate in central medicine procurement processes. NPSP and national health programmes collaborate within procurement committees coordinated by DAP. AIRP and the national laboratory ensure quality control, while NPSP also relies on laboratory verification systems. KICD8

DAP and AIRP also interact with the National Order of Pharmacists, where DAP holds representation on the council, and AIRP participates in an advisory capacity [KICD6].

Strengths

Four key enabling factors were identified across Côte d'Ivoire's NPSUs. The first is institutional autonomy. For instance, AIRP operates with a high degree of independence from ministerial interference. However, it still depends on government funding, indicating partial rather than full financial autonomy, partly due to its relatively recent establishment in 2019.

The second strength is effective collaboration between public and private sector actors, which has supported national price harmonization for medicines. Côte d'Ivoire has implemented a unified pricing system coordinated through AIRP's marketing authorization framework. As one respondent noted:

The pharmaceutical system is highly organized in terms of pricing. Through the established equalization mechanism, medicine prices remain consistent nationwide. KICD10

Third, the country benefits from an efficient distribution system that ensures medicines move smoothly from manufacturers to wholesalers, retailers, and end users. One respondent highlighted that geographical access is not a major challenge:

Medicines can reach even remote areas within 48 hours, ensuring strong geographical access. However, financial accessibility remains the main limitation. KICD10

To address affordability, several national policies have been introduced, including generic substitution regulations, repackaging policies, and universal health coverage reforms. Explaining their impact, one respondent stated:

Access to medicines has improved due to three key reforms: the generic substitution policy, which allows pharmacists to replace branded medicines with generics; the repackaging policy, which permits redistribution of medicines in smaller units; and universal health coverage, which has expanded financial protection for the population. KICD10

Fourth, strong political commitment was identified as a major driver of progress. One respondent emphasized:

Political commitment is crucial. Without government support, pharmaceutical sector initiatives cannot advance effectively; therefore, political will remains a key determinant of success. KICD6

Weaknesses

Several structural and operational challenges were identified. For example, the LNSP has not yet achieved WHO prequalification status. One respondent attributed this partly to administrative complexity and procedural rigidity within the system:

The laboratory has not yet attained WHO prequalification, possibly due to procedural delays. The administrative system can be quite rigid at times. KICD2

Within AIRP, the pharmaceutical inspection unit faces resource shortages, particularly a limited number of inspectors, which weakens efforts to combat illicit medicine markets. One respondent explained:

While progress has been made in pharmacovigilance, the system has not yet reached its full potential. The inspectorate remains understaffed, limiting enforcement capacity and weakening efforts to control illegal pharmaceutical trade. KICD8

Coordination challenges also exist between DAP and AIRP, partly due to overlapping institutional mandates inherited from the former centralized pharmaceutical authority. One respondent noted ongoing but unsuccessful efforts to improve coordination:

Collaboration between DAP and AIRP remains difficult. Attempts have been made to establish regular coordination meetings, but these have not been effective in resolving the issues. KICD10

Decision-making processes also present challenges. In some cases, the Ministry of Health does not consistently consult the National Order of Pharmacists on professional matters, whereas earlier decisions were made through council-level validation. Currently, ministerial ratification is required, which limits professional autonomy.

Continuous professional development is also insufficient despite being mandatory. To address this gap, the National Order of Pharmacists is working to establish training partnerships with national institutions so that participation in continuous education becomes a requirement for license renewal. KICD4

Funding constraints remain a major limitation. The DAP, in particular, relies heavily on government allocations and external partners. One respondent noted that this dependence creates administrative burdens due to multiple reporting requirements:

DAP remains underfunded and relies heavily on external partners, which adds additional reporting layers and administrative complexity. KICD8

Another respondent highlighted the broader impact of financial shortages:

Limited government funding and budget constraints make it difficult to recruit and retain qualified staff, especially given low civil service salaries. KICD8

Case III: Nepal

In Nepal, four institutional entities within the Ministry of Health and Population collectively perform functions equivalent to those of NPSUs: the Department of Drug Administration (DDA), the Quality Standard and Regulation Division (QSRD), the Logistics Management Section (LMS), and the Nepal Pharmacy Council (NPC) (**Table 6**). The DDA and QSRD correspond to typology I, while the NPC aligns with typology III and the LMS with typology II.

Table 6. NPSUs in Nepal: Name, typology, mandate and function, and legal framework

NPSU name and typology	Functions	Mandate
Department of Drug Administration (DDA), typology I	• Works jointly with the National Medicines Laboratory to ensure pharmaceutical products meet required quality standards through testing activities • Develops and maintains national benchmarks for	Operates under legal authority

	pharmaceutical laboratories and evaluates the performance of drug-testing facilities across the country; also delivers training on laboratory best practices and conducts compliance audits in coordination with the NML • Handles registration of foreign drug manufacturers and authorizes importation of their products, including issuing permits for import and export of medicines • Reviews proposals for establishing pharmaceutical manufacturing units and grants or renews production licenses • Manages licensing processes for pharmacies operating at wholesale and retail levels and authorizes individuals permitted to dispense medicines • Provides approval for clinical research activities and regulation of medicine promotion and advertising • Organizes capacity-building sessions for medicine retailers and disseminates safety-related drug information such as risks, contraindications, interactions, and storage guidance • Produces and distributes the Nepal Drug Bulletin and provides technical recommendations for the import of controlled substances • Oversees national systems for monitoring adverse drug reactions and pharmacovigilance reporting • Carries out inspections of pharmaceutical companies and enforces corrective actions when violations of the Drug Act 2035 are identified • Prepares documentation required for initiating legal action against non-compliant pharmacies and pharmaceutical manufacturers • Ensures enforcement of pharmaceutical legislation and regulates medicine import-export integrity; also serves as the national WHO pharmacovigilance contact point • Encourages appropriate and rational use of medicines • Periodically revises the national essential medicines list and formulary • Regulates medicine pricing mechanisms	granted by the Drug Act 2035 (1978) [40]
Quality Standard and Regulation Division (QSRD), typology I	• Responsible for developing regulatory policies and defining quality assurance standards for the pharmaceutical system • Designs regulatory guidelines covering pharmacy services, Ayurvedic medicine outlets, and measurement systems used in healthcare • Establishes rules for the appropriate use of medical devices across government agencies, ministries, and health institutions • Sets standards for healthcare service delivery across facilities • Carries out periodic monitoring and evaluation of programmes implemented by governmental bodies, NGOs, semi-government agencies, and committees • Develops and enforces standards for medical equipment and healthcare infrastructure • Implements responsibilities aligned with the International Health Regulations issued by WHO	Functions under the Drug Act 2035 (1978) [17]
Logistics Management Section (LMS), typology II	• Responsible for coordinating and strengthening national systems for supply chain data and information management • Formulates policies, regulatory frameworks, operational guidelines, and technical protocols related to pharmaceutical procurement and logistics • Maintains and updates national specifications, standards, and reference documents for health commodities and equipment • Oversees procurement of essential health goods such as vaccines, contraceptives, and medical equipment, and ensures their distribution across national and local levels	Functions under the Department of Health Services mandate [17]
Nepal Pharmacy Council (NPC), typology III	• Develops and oversees implementation of policies and programmes guiding the pharmacy profession • Accredits pharmacy schools and recognizes academic qualifications while ensuring compliance with national standards • Defines educational structures including curriculum requirements, admission rules, and examination systems for pharmacy training institutions • Establishes minimum standards for quality assurance in pharmacy education	Operates under the Nepal Pharmacy Council Act, 2057 (2000) [27]

Functions and mandate

The Department of Drug Administration (DDA) operates under the authority of the Drug Act 2035 (1978), which empowers it to prevent the dissemination of misinformation and the misuse of medicines and other pharmaceutical products, and to reduce the circulation of unsafe, ineffective, or substandard drugs [40]. In addition, the DDA serves as the national focal point for WHO pharmacovigilance activities, promotes rational antibiotic use, and periodically updates the national drug formulary and essential medicines list [KIN32].

One respondent summarized the DDA's responsibilities as follows:

The DDA is responsible for registering pharmaceutical companies, issuing operating licenses, and enforcing legal action against entities that violate drug laws, regulations, and standards. It also conducts both routine and targeted inspections of pharmaceutical industries and pharmacies to verify compliance with regulatory requirements. KIN3

The Quality Standard and Regulation Division (QSRD) holds responsibility for pharmaceutical regulatory oversight in Nepal, as defined under the Drugs Act 2035 (1978) [KIN61]. Its functions include coordination at the ministry level, development and revision of policies, and inspection and supervision of health facilities and pharmaceutical-related programmes [KIN21, KIN32, KIN52, KIN54, KIN63–KIN65].

However, there is some debate regarding the scope of QSRD's authority. One respondent highlighted differing interpretations of its role:

Some stakeholders do not fully recognize QSRD as the main authority for pharmaceutical regulation. Instead, some experts argue that this responsibility lies primarily with the DDA, while QSRD is seen more as a supporting or coordinating entity. KIN32

The Logistics Management Section (LMS) is tasked with managing pharmaceutical supply chains, including procurement systems and health logistics information management [KIN65]. Two respondents described its responsibilities as:

It is responsible for the distribution of medicines and health commodities to government health facilities, operating through central and regional warehouses that supply provinces, districts, and municipalities. KIN31

Its core responsibilities include procurement processes such as tendering and contracting, as well as distribution of medicines and health-related commodities after procurement. KIN63

The Nepal Pharmacy Council (NPC) is mandated to ensure the quality and regulation of the pharmacy workforce in line with national requirements. It was established under the Nepal Pharmacy Council Act 2057 in 2001 (Humagain, n.d.; [27].

Both the DDA and QSRD are involved in pharmaceutical regulation. The DDA acts as the primary national regulatory authority [17] and also manages the National Medicines Laboratory (NML). The NML is responsible for testing pharmaceutical products to ensure quality [KIN21]. It also evaluates drug-testing laboratories nationwide, sets reference standards, provides training on good laboratory practices, and conducts audits of laboratories in collaboration with national authorities [40].

Coordination

The findings show that DDA, QSRD, LMS, and NPC coordinate their activities through the Drug Advisory Council, which serves as a national platform for pharmaceutical policy development and implementation. One respondent described the council as follows:

The Drug Advisory Council provides policy and technical advice to the Government of Nepal on pharmaceutical matters, including regulatory reforms and medicine pricing decisions. It includes senior government officials such as the Health Minister (chair), the Health Secretary, the Director General of DDA, the head of the National Medicines Laboratory, and pharmaceutical experts. KIN21

In addition, QSRD collaborates with other NPSUs and external partners on antimicrobial resistance (AMR) initiatives. These include surveillance activities, awareness campaigns, and interventions to reduce the spread of resistant infections [KIN65].

Another respondent explained this coordinating role:

QSRD functions as the secretariat for antimicrobial resistance-related activities. In this capacity, it works jointly with development partners and non-governmental organizations to coordinate AMR-related programmes. KIN65

Strengths and weaknesses

A key constraint across the pharmaceutical sector is a shortage of human resources. Limited staffing and weak technical capacity contribute to heavy workloads, staff

exhaustion, and reduced decision-making quality [KIN58]. These shortages also undermine the effectiveness of regulatory oversight, quality assurance, and monitoring systems within NPSUs [KIN64, KIN65]. One respondent emphasized workforce limitations as follows:

The QSRD suffers from a shortage of personnel, and strengthening its operations requires dedicated staffing support and separate budget allocation. Improving human resources is essential for better performance and institutional effectiveness. KIN61

Another respondent highlighted structural workforce challenges:

Unclear role definitions, combined with inadequate staffing and insufficient technical training, significantly reduce the efficiency of NPSU operations. KIN32

There is also concern regarding professional recognition and employment opportunities. Despite producing qualified professionals, the system faces challenges with job placement and adjustments to the salary structure. One respondent noted:

Government authorities do not sufficiently recognize the profession. Although adequate human resources are trained, employment opportunities are limited, and salary structures need to be revised. KIN54

Furthermore, many staff within NPSUs lack sufficient contextual understanding of Nepal's pharmaceutical system, including market conditions and regulatory frameworks [KIN21, KIN52]. This knowledge gap limits policy effectiveness and can negatively affect the availability, affordability, and quality of medicine [KIN52].

Coordination between leadership units is also weak, with limited collaboration and poor use of data for decision-making [KIN21, KIN59, KIN28, KIN29]. This results in duplication of efforts and inefficiencies such as stockouts and poor planning. One respondent illustrated this issue:

Although the DDA has shared information with the Ministry of Health and Population, follow-up on supply chain activities has been weak. Similarly, coordination between LMS and other regulatory bodies has been insufficient. Requests for inspection support from QSRD have not been adequately addressed. KIN63

At a broader level, political interference poses risks to transparency and accountability in pharmaceutical governance, potentially leading to inefficient resource use [KIN54, KIN59]. Additionally, rigid administrative procedures can delay drug approval and registration, restricting access to essential and innovative medicines [KIN32, KIN41, KIN52, KIN55, KIN59].

Conflicts of interest among decision-makers may also compromise neutrality in regulatory processes, leading to biased decisions [KIN52, KIN59]. Finally, weak pharmacovigilance systems limit the country's ability to rapidly detect and respond to unsafe or substandard medicines [KIN61].

The study identifies three essential conditions for establishing effective National Pharmaceutical Service Units (NPSUs): (i) a clearly defined hierarchical position within the Ministry of Health, (ii) a formal legal or administrative mandate, and (iii) coherent national pharmaceutical policies guiding sector operations.

The structural placement of NPSUs within the ministry hierarchy—whether at a high level with direct ministerial reporting (typology I), an intermediate level reporting through another department (typology II), or as semi-autonomous/autonomous bodies (typology III)—significantly influences their authority, resources, and decision-making capacity. Typology I units tend to have stronger influence on national policy and budget allocation, while semi-autonomous structures allow greater operational flexibility. However, appropriate alignment with existing administrative systems is necessary to avoid duplication and ensure coherence across government structures.

A strong legal and institutional framework is equally important for clearly defining mandates and ensuring functional legitimacy. Such frameworks should clearly allocate responsibilities between NPSUs and other supporting institutions.

Based on the review of literature and case studies, a minimum set of core NPSU functions can be identified: pharmaceutical regulation, procurement and supply chain management, pharmacy practice regulation, and pharmaceutical policy and governance.

Medicine regulation refers to the lifecycle oversight of pharmaceutical products to ensure safety, quality, and effectiveness. This function is typically assigned to an autonomous regulatory authority that performs standard regulatory roles, such as product registration, surveillance, inspection, laboratory testing, clinical trial oversight, and enforcement actions, consistent with WHO global benchmarking tools [41, 42].

Procurement and supply chain management involve centralized or coordinated systems responsible for forecasting, purchasing, distribution, storage, pricing, and monitoring the availability of medicines. This

function is increasingly shifting toward stewardship roles, with operational tasks often outsourced to specialized logistics providers. Despite this shift, supply chain management remains a critical function because weaknesses in this area directly affect access to essential medicines [43, 44].

Pharmacy practice regulation focuses on controlling professional standards, education, licensing, and service delivery within pharmacy practice. This is typically managed by an independent regulatory or professional body overseeing pharmacists, pharmacy premises, and training institutions.

Finally, the study identifies a gap in pharmaceutical governance, which appears fragmented across multiple institutions. Therefore, a dedicated NPSU responsible for pharmaceutical policy and governance is recommended. This unit should provide leadership in policy development, regulatory coordination, legislation, monitoring and evaluation, and ensuring accountability and ethical standards within the pharmaceutical system. This role resembles functions performed by DHPT in Kenya, DAP in Côte d'Ivoire, and DDA/QSRD in Nepal (**Table 7**).

Table 7. Key proposed components of pharmaceutical policy and governance function

Policy or governance function	elements
Pharmaceutical policies	Involves the systematic collection, interpretation, and application of health and medicines data to design a national pharmaceutical policy and related strategies. It also includes formulating and executing evidence-informed strategic plans to achieve priority objectives in the health and pharmaceutical sectors.
Pharmaceutical laws and regulations	Encompasses the development, implementation, and enforcement of comprehensive legal frameworks governing pharmaceutical activities. This includes regulation of controlled substances, import and export processes, storage systems, prescribing and dispensing practices, reporting obligations, and oversight of the pharmaceutical workforce.
Coordination and leadership	Refers to mechanisms that provide strategic direction and ensure alignment among government and non-government actors. It involves coordinating stakeholders, harmonizing interests and activities across institutions, and ensuring efficient use of available resources within the pharmaceutical system.
Monitoring and evaluation	Covers the establishment and oversight of performance monitoring systems for the pharmaceutical sector. This includes tracking key indicators related to the implementation of the national medicines policy and promoting the use of data across functional areas to guide priority setting and inform decision-making.
Ethics, transparency, and accountability	Includes defining and promoting ethical standards governing professional conduct, integrity, and competence within the pharmaceutical sector. It also involves structured mechanisms for stakeholder engagement, public communication of major decisions, and accountability processes to ensure that institutions and decision-makers act responsibly and transparently.

Monitoring and evaluation

Monitoring and evaluation play a critical role in assessing how effectively the national medicines policy is being implemented and in measuring overall pharmaceutical system performance. For this reason, the responsible unit should be formally mandated to lead and harmonize data collection processes across all relevant system components and functional domains. It should also have the authority to analyze and apply this information to set policy directions and guide system improvement initiatives.

In addition, the NPSU should ensure that all relevant stakeholders clearly understand their roles within the pharmaceutical system and how their contributions affect overall system performance. This shared understanding is essential for achieving desired outcomes, particularly ensuring fair and timely access to safe, effective, quality-assured medicines, as well as their rational and cost-efficient use.

Conclusion

Drawing on evidence from three country case studies, this research highlights the diverse roles performed by National Pharmaceutical Service Units (NPSUs) and their varying positions within ministerial organizational hierarchies. A key observation is that higher placement

within the hierarchy is generally associated with greater institutional priority and improved access to resources.

Although the identified functions may be assigned to a single NPSU or distributed across multiple units, the extent to which these responsibilities are fragmented has important implications. It affects not only the effectiveness of monitoring and evaluation systems but also clarity around institutional mandates and the ability of different units to coordinate effectively in pursuit of national pharmaceutical system goals.

A central contribution of this study is the identification of the need for a dedicated pharmaceutical policy and governance entity. Such a unit would act as a steward of the national pharmaceutical system, responsible for strengthening system performance, ensuring coordination across stakeholders, and overseeing monitoring and evaluation functions to support continuous system improvement.

Acknowledgments: None

Conflict of Interest: None

Financial Support: None

Ethics Statement: None

References

1. World Health Organization. WHO guideline on country pharmaceutical pricing policies. 2nd ed. Geneva: World Health Organization; 2020.
2. Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. Defining pharmaceutical systems strengthening: concepts to enable measurement. Health Policy Plan. 2017;32(4):572-84. doi:10.1093/heapol/czw153
3. Bragazzi NL, Mansour M, Bonsignore A, Ciliberti R. The role of hospital and community pharmacists in the management of COVID-19: towards an expanded definition of the roles, responsibilities, and duties of the pharmacist. Pharmacy (Basel). 2020;8(3):140. doi:10.3390/pharmacy8030140
4. Khan N, McGarry K, Naqvi AA, Iqbal MS, Haider Z. Pharmacists' viewpoint towards their professional role in healthcare system: a survey of hospital settings of Pakistan. BMC Health Serv Res. 2020;20(1):610. doi:10.1186/s12913-020-05459-0
5. Okai GA, Abekah-Nkrumah G, Asuming PO. Perceptions and trends in the use of community pharmacies in Ghana. J Pharm Policy Pract. 2019;12(1):25. doi:10.1186/s40545-019-0186-0
6. World Health Organization. How pharmaceutical systems are organized in Asia and the Pacific. Manila: WHO Regional Office for the Western Pacific; 2018.
7. Hoebert JM, van Dijk L, Mantel-Teeuwisse AK, Leufkens HG, Laing RO. National medicines policies – a review of the evolution and development processes. J Pharm Policy Pract. 2013;6(1):5. doi:10.1186/2052-3211-6-5
8. Morrow NC. Pharmaceutical policy part 1: the challenge to pharmacists to engage in policy development. J Pharm Policy Pract. 2015;8(1):4. doi:10.1186/2052-3211-8-4
9. Perehudoff SK, Alexandrov NV, Hogerzeil HV. The right to health as the basis for universal health coverage: a cross-national analysis of national medicines policies of 71 countries. PLoS One. 2019;14(6):e0215577. doi:10.1371/journal.pone.0215577
10. Barros RD, Costa EA, Santos DBD, Souza GS, Álvares J, Guerra Junior AA, et al. Access to medicines: relations with the institutionalization of pharmaceutical services. Rev Saude Publica. 2017;51(suppl 2):8s. doi:10.11606/S1518-8787.2017051007138
11. Costa KS, Tavares NUL, do Nascimento Júnior JM, Mengue SS, Álvares J, Guerra Junior AA, et al. Pharmaceutical services in the primary health care of the Brazilian Unified Health System: advances and challenges. Rev Saude Publica. 2017;51(suppl 2):3s. doi:10.11606/S1518-8787.2017051007069
12. Braun V, Clarke V. One size fits all? What counts as quality practice in (reflexive) thematic analysis? Qual Res Psychol. 2021;18(3):328-52. doi:10.1080/14780887.2020.1769238
13. Ministry of Health Brunei Darussalam. Brunei pharmacy board [Internet]. 2022 [cited 2022 Apr 4]. Available from: https://www.moh.gov.bn/SitePages/Brunei%20Pharmacy%20Board.aspx.
14. Ministry of Health Brunei Darussalam. Pharmacy, ministry of health [Internet]. 2022 [cited 2022 Apr 3]. Available from: https://www.moh.gov.bn/SitePages/Pharmacy.aspx.
15. Management Sciences for Health. Evaluation of the public sector supply chain for essential medicines in Ivory Coast. Arlington (VA): Management Sciences for Health; 2016.
16. Ministère de la Santé et de l'Hygiène Publique et de la Couverture Maladie Universelle – Côte d'Ivoire. Politique pharmaceutique nationale [Internet]. 2009 [cited 2022 Apr 5]. Available from: https://dap.ci/wp-content/uploads/2021/06/POLITIQUE-PHARMACEUTIQUE-NATIONAL.pdf. French.

17. Ministry of Health Republic of Congo. Pharmaceutical country profile. Brazzaville: Ministry of Health; 2011.
18. World Health Organization. Pharmaceutical policies in Finland: challenges and opportunities. Copenhagen: WHO Regional Office for Europe; 2008.
19. Finnish Medicines Agency. Finnish Medicines Agency (FIMEA) [Internet]. 2022 [cited 2022 Apr 10]. Available from: https://www.fimea.fi/web/en/about_us.
20. Food and Drugs Administration Philippines. Food and Drugs Administration (FDA) [Internet]. 2022 [cited 2022 Mar 30]. Available from: https://www.fda.gov.ph/about-fda/.
21. Koduah A, Sekyi-Brown R, Kretchy I. The evolution of pharmacy practice regulation in Ghana, 1892-2013. Pharm Hist. 2020;50(4):97-108.
22. Ministry of Health Ghana. Procurement & Supply [Internet]. 2022 [cited 2022 Apr 5]. Available from: https://www.moh.gov.gh/procurement-supply/.
23. Ministry of Health Ghana. Technical coordination directorate [Internet]. 2022 [cited 2022 Apr 4]. Available from: https://www.moh.gov.gh/technical-coordination/.
24. Government of Kenya. Pharmacy and Poisons Act, Chapter 244. Nairobi: National Council for Law Reporting with the Authority of the Attorney-General; 2012.
25. Government of Kenya. The Health Act. Nairobi: National Council for Law Reporting with the Authority of the Attorney-General; 2017.
26. Ministry of Health Malaysia. Pharmaceutical services programme [Internet]. 2022 [cited 2022 Apr 4]. Available from: https://www.pharmacy.gov.my/v2/en.
27. Nepal Pharmacy Council. Home [Internet]. 2022 [cited 2022 Apr 4]. Available from: http://www.nepalpharmacycouncil.org.np/.
28. New Zealand Government Pharmaceutical Management Agency. PHARMAC [Internet]. 2020 [cited 2022 Apr 4]. Available from: https://www.govt.nz/organisations/pharmaceutical-management-agency/.
29. Pharmaceutical Division Philippines. Goals of the pharmacy division [Internet]. 2020 [cited 2022 Mar 30]. Available from: https://pharma.doh.gov.ph/the-pharmaceutical-division/.
30. Ministry of Health Rwanda. Rwanda health sector policy [Internet]. 2015 [cited 2022 Apr 5]. Available from: https://www.moh.gov.rw/fileadmin/user_upload/Health_Sector_Policy___19th_January_2015.pdf.
31. Ministère de la Santé et de l'Action Sociale Sénégal. Département de la Pharmacie et des Médicaments [Internet]. 2022 [cited 2022 Mar 30]. Available from: https://sante.gouv.sn/. French.
32. Ministry of Health Republic of Uganda. The national pharmaceutical services strategic plan 2020/2021–2024/2025. Kampala: Department of Pharmaceuticals and Natural Medicine; 2020.
33. Government of Ghana. Public Health Act, 2012 (Act 851). Accra: Ghana Publishing Company Limited; 2012.
34. African Health Business Limited. Kenya's health sector 2021. Nairobi: African Health Business; 2021.
35. Ministry of Health Kenya. Kenya health workforce report: the status of healthcare professionals in Kenya. Nairobi: Ministry of Health; 2015.
36. Government of Kenya. Kenya Medical Supplies Authority Act No. 20 of 2013. Nairobi: National Council for Law Reporting with the Authority of the Attorney-General; 2013.
37. Government of Côte d'Ivoire. Autorité ivoirienne de régulation pharmaceutique: le gouvernement adopte le décret de fonctionnement [Internet]. 2022 [cited 2022 Jun 21]. Available from: https://www.gouv.ci/_actualite-article.php?recordID=9511&p=7. French.
38. Republic of Kenya Ministry of Health. Health products and technologies supply chain strategy 2020–2025. Nairobi: Republic of Kenya Ministry of Health; 2020.
39. Ministère de la Santé et de l'Hygiène Publique et de la Couverture Maladie Universelle – Côte d'Ivoire. Ministère de la Santé et de l'Hygiène Publique [Internet]. 2017 [cited 2022 Apr 5]. Available from: https://www.sante.gouv.ci/welcome. French.
40. Khanal D. History of pharmaceutical development in Nepal. J Manmohan Mem Inst Health Sci. 2017;3(1):86-93. doi:10.3126/jmmihs.v3i1.19172
41. Twesigye G, Hafner T, Guzman J. Making the investment case for national regulatory authorities. J Pharm Policy Pract. 2021;14(1):16. doi:10.1186/s40545-021-00354-3
42. World Health Organization. WHO global benchmarking tool (GBT) for evaluation of national regulatory systems [Internet]. Geneva: World Health Organization; 2024 [cited 2024 Jan 15]. Available from: https://www.who.int/tools/global-benchmarking-tools.
43. Bornbusch A, Dickens T, Hart C, Wright C. A stewardship approach to shaping the future of public health supply chain systems. Glob Health Sci Pract. 2014;2(4):403-9. doi:10.9745/GHSP-D-14-00112
44. Perri J, Walker GC, d'Herlincourt S. Managing health supply chain risk through strategic outsourcing in low- and middle-income countries. J Supply Chain Manag Logist Procure. 2023;6(1):79-90.