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RESEARCH ARTICLE

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An exploratory study of the mandate and functions of national pharmaceutical services units: global trends and the cases of Côte d'Ivoire, Kenya, and Nepal

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ABSTRACT

Background: National pharmaceutical services units (NPSUs) – organisational units within the central government usually responsible for pharmaceutical services and management – have an increasingly narrow mandate. Anecdotal evidence points to an increasing focus, almost exclusively, on logistics management, while pharmaceutical care and policy oversight have become fragmented. This study examined NPSUs' current functions and mandates, and proposed what should be the critical functions and roles of these units going forward.

Methods: Using case studies of Côte d'Ivoire, Kenya and Nepal, the study relied on a literature review and in-depth interviews. We triangulated and synthesised the findings to identify NPSUs by level in the health ministry's hierarchy and reporting line, mandate, and function.

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Results: We identified medicine regulation, procurement and supply chain management, selection and rational use of medicines, and pharmacy practice regulation as four broad sets of functions that NPSUs commonly have as their mandate. A clear position in the Ministry of Health's hierarchical structure, the legal or administrative framework that mandates an NPSU's functions, and national pharmaceutical policies and regulations to guide the pharmaceutical sector are three critical factors for effective functioning. It is essential to have a legislative framework that at a minimum identifies one NPSU as responsible for pharmaceutical policy and governance, serving as the steward for the pharmaceutical system. This role encompasses pharmaceutical system coordination and administrative functions, formulating and implementing policies for organising, managing, financing, regulating, monitoring, and evaluating the pharmaceutical system. As such, we recommend that NPSUs should at a minimum have four broad sets of functions: pharmaceutical policy and governance, medicine regulation, pharmacy practice regulation and procurement and supply chain management. **Conclusion:** The study substantiates the need for a pharmaceutical policy and governance unit that stewards the pharmaceutical system and is empowered to monitor and evaluate system performance and coordinate efforts for system strengthening.

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KEYWORDS Pharmaceutical service; pharmaceutical policy; governance; medicine regulation; pharmacy practice; health supply chain management; pharmaceutical system

Introduction

Medical products, as a major and increasing source of health expenditure (World Health Organization, 2020), require careful management and coordination within the ministries of health to achieve universal health coverage (UHC) and other health-related Sustainable Development Goals. Departments or divisions at the national level can be designated to promote coordination and management within the pharmaceutical system to ensure access to medical products and contribute to achieving UHC. Departments or divisions within the central government usually responsible for medicine regulation, the health supply chain, and pharmaceutical services can be defined as national pharmaceutical services units (NPSUs). NPSUs are usually government agencies that manage various aspects of the pharmaceutical system, which 'consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality medical products and related services that promote their appropriate and cost-effective use to improve health outcomes' (Hafner et al., 2017). NPSUs therefore play a key role in achieving UHC by ensuring access to safe, effective, quality, and affordable medical products and services within a country.

Some attention has been given to the role of pharmacists and pharmaceutical care at the facility level in the literature (Bragazzi et al., 2020; Khan

et al., 2020; Okai et al., 2019; World Health Organization, 2018). However, there is an apparent gap regarding NPSUs. Several high-level discussions in the last decade, some focused on the responsible use of medical products, highlighted some of the medicine-related challenges facing health systems and alluded to some of the areas in which NPSUs have a role to play (Hoebert et al., 2013; Morrow, 2015; Perehudoff et al., 2019; World Health Organization, 2018). These areas include the design and implementation of national medicine policy (NMP), essential medicines lists, evidence-based standard treatment guidelines, and coordination of the human and financial resources for activities to support NMPs. There is generally a need for greater involvement of pharmacists in pharmacy and medicine policy development and implementation and not just health care provision (Hoebert et al., 2013). For example, a lack of political commitment and policy champions for NMPs and inadequate integration in broader health policies have impeded NMP implementation and successes (Perehudoff et al., 2019). Whether the necessary policymaking, administrative, implementation management, monitoring and evaluation, and technical skills reside in pharmaceutical services units or elsewhere in the Ministry of Health (MoH) or government and how they are distributed and interlinked are important considerations for national health systems moving forward.

NPSUs need to be able to support governments' ability to address emerging policy priorities and needs. In Brazil, for example, the lack of pharmaceutical services as an organisational element in municipality health services was one of the factors that impeded the implementation of decentralised pharmaceutical services in the country's primary health care system (Barros et al., 2017; Costa et al., 2017). The current push toward UHC requires technical expertise in areas such as health technology assessments and benefits payment schemes. Similarly, the creeping crisis of antimicrobial resistance (AMR) and pandemic preparation and response requires a dedicated focus on antimicrobial stewardship and appropriate use of medical products more broadly. Strong linkages between policymaking, clinical, pharmaceutical, and pharmacological expertise, and other areas of technical expertise (e.g. infection prevention and control) are essential for an effective response to these health crises. Other emerging trends, such as the shift from development assistance to domestic resources, increasing private-sector engagement, and the ongoing epidemiological transition from communicable to noncommunicable diseases as the major source of morbidity and mortality, also require strong linkages between the loci of pharmaceutical policymaking and technical expertise. Further, with an increasing understanding that countries need to focus on the quality of their health service delivery to ensure UHC, an increased focus on the quality and rational use of medicines and quality implementation of pharmaceutical services is essential.

We posit that NPSUs are the public-sector units primarily responsible for coordinating the actors, structures, resources, and processes aimed at ensuring equitable, timely, and affordable access to safe, effective, quality medical products and related services that promote their appropriate and cost-effective use. Further, we posit that their specific functions include medicine regulation, health supply chain management, pharmaceutical policy and implementation, and monitoring and evaluation. NPSUs can perform any or all of these functions, and a country may have multiple NPSUs depending on how responsibilities are divided and the health sector is structured. However, given the lack of attention to this topic in the literature and absence of a guiding framework, we sought to examine the current status of NPSUs with respect to their mandate, role, and function in the health system.

Methods

The study used an exploratory mixed-methods approach. We convened a technical working group (TWG) to guide the methodology and review the findings and recommendations. The TWG members include US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Programme technical staff and the country programme directors for Kenya, Côte d'Ivoire, and Nepal and representatives from WHO, Pharmaceutical Systems Africa, and the Commonwealth Pharmacists Association.

The study relies on two sources of data: a document review and three case studies. We conducted a document review between March and July 2022 to determine the primary roles, functions, and mandates of government units responsible for pharmaceutical product regulation, health supply chain management, pharmacy practice, and pharmaceutical service within the central government (Table 1). Unit in this case refers to department, division, directorate or related term. We synthesised the findings to identify the different types of NPSUs with respect to their position in the MoH hierarchy and their broad functions.

We purposively selected Côte d'Ivoire, Kenya, and Nepal for case studies based on MTaPS' presence in these countries, which facilitated access to key stakeholders. The three countries also represent Asia and anglophone and francophone Africa. Drawing on findings from the document review and inputs from the programme's in-country teams, we conducted a stakeholder analysis to identify potentially relevant key informants. The country teams then purposively selected informants based on guide the purposive selection of key informants. We conducted 44 total interviews: 16 in Kenya in English from September to October 2022, 10 in Côte d'Ivoire in French from November 2022 to January 2023, and 18 in Nepal in Nepali from May to June 2023. We used a semistructured interview guide, which we designed

Table 1. Document review guidelines.

Objective	To synthesise evidence relevant to the roles, functions, and mandates of departments or divisions or directorates responsible for national medicines policy, medical products regulation, health supply chain management, pharmacy practice, and pharmaceutical service within the central government	
Research questions	(i) What is the name/typology of the national pharmaceutical service units (NPSU) responsible for policy making and implementation, medicine regulation, health supply chain, pharmacy practice, and pharmaceutical service? (ii) What are the current mandates/functions of the NPSU?	
Search strategy	Inclusion	Legislative and policy documents, (MoH) organograms, strategic planning, standard operating procedures, and other government documents and published papers Search key words (in various combinations): national, ministry, health, pharmaceutical, pharmacy, medicines, service(s), practice, department, directorate, division, policy(ies), functions, mandate, structure, organogram, management, governance, regulation, procurement, supply chain, selection, access, use Language: English Timeframe: No publication time limit
	Exclusion	Peer review literature search excluded languages other than English. For government documents, francophone team members conducted search in French for relevant documents
Selected bibliographic and grey literature	Google Scholar, PubMed, websites of selected ministries of health, WHO, International Pharmaceutical Federation, and USAID.gov	

according to the study's objectives and included questions regarding the current status of NPSUs with respect to their structure, roles and responsibilities, changes over time, and suggested critical roles and responsibilities going forward (Supplementary Material 1). The country teams translated the interview guide to French for Côte d'Ivoire and Nepalese for Nepal. The case studies received ethical approval from le 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 Strathmore University Institutional Scientific and Ethical Review Committee in Kenya (reference number SU-ISERC1414/22), and the Nepal Health Research Council (reference number 986).

For Côte d'Ivoire and Kenya, we audio recorded and transcribed each interview and anonymized the transcripts. In Nepal, key informants did not want to be audio recorded, so the study team took notes directly in Nepali during the interviews. We translated all notes and transcripts to English for analysis and assigned an anonymous code to each such that each respondent was labelled by country and a random number (e.g. KIK13 denotes Kenyan respondent number 13). We also translated the French transcripts into English for analysis. We conducted a thematic analysis of the transcripts using the framework method to identify the various NPSUs in each country, their position in the respective government ministry or department, and their mandate and function. The analysis also sought to identify the political and policy-related factors that facilitate or constrain their operation. In addition to the transcription, the framework method involves six steps: transcription, familiarisation with the data, coding, developing a working analytical framework, applying the analytical framework, charting data into the framework matrix, and interpreting the data (Braun & Clarke, 2021). The lead researcher and each country team lead worked on transcription and the lead researchers led the remaining six steps of the analytical process with inputs from the rest of the team. The team presented the preliminary findings to the TWG for discussion and review (April 19, 2023) before finalising the findings.

Results

We first summarise the literature review findings with respect to the NPSUs' typology based on position in the health ministry's hierarchy and reporting line and the general categories of functions identified from the literature. We then present the three case studies, highlighting the number and typology of units, their mandate and functions, and their strengths and weaknesses.

NPSU position in the hierarchy

An NPSU's position in the government determines the chain of command and is its level of access to resources and participation in decision-making

processes within the health ministry or department. Based on the document review, which included government organograms and policy documents from 16 countries, we identified three types of NPSUs with respect to their position in the organisational hierarchy and level of autonomy (Figure 1). We classify as typology I NPSUs that exist at a high level in the health ministry with a direct reporting line to the minister. Typology II consists of NPSUs at the mid-level in the organisational hierarchy, reporting indirectly to the minister through another unit. Typology III consists of NPSUs that are 'standalone,' semiautonomous, or autonomous, existing as an agency of the ministry or department. Table 2 provides examples of each typology.

NPSU mandate and functions

We identified four broad categories of functions: medicine regulation, procurement and supply chain management, selection and rational use of medicines, and pharmacy practice regulation (Table 3).

A national medicines regulatory authority is the NPSU typically responsible for medical products regulation. These units typically fit typology I or III, indicating their prominence in the health system. They operate with various degrees of autonomy and may perform only medicine regulation, as in the case of Uganda's National Drug Authority and Zambia's Medicines Regulatory Authority, or may also regulate pharmacy practice or food. For example, Laos' Food and Drug Department, Ghana's Food and Drug Authority (FDA), and Rwanda's FDA regulate both food and medicines, while Kenya's Pharmacy and Poisons Board (PPB) also regulates pharmacy practice. The functions of the national medicines regulatory authorities are mandated through legislative instruments, laws, and parliamentary acts. For instance, the Ghana Public Health Act 2012 (Act 851), which sets up the FDA, mandates the Authority to 'provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances' (Government of Ghana, 2012).

Case I: Kenya

In Kenya's devolved system, health care governance occurs at two levels: national and county. At the national level, the MoH provides policy direction with the core mandate of health policymaking and regulation, overseeing national referral health facilities, and providing technical assistance to counties. The county governments are responsible for the management of county health facilities, ambulance services, promotion of primary health care, disease surveillance and response, public health and sanitation, disaster management, veterinary services, and waste disposal (African Health Business Limited, 2021; Ministry of Health, 2015). There are four primary NPSUs at

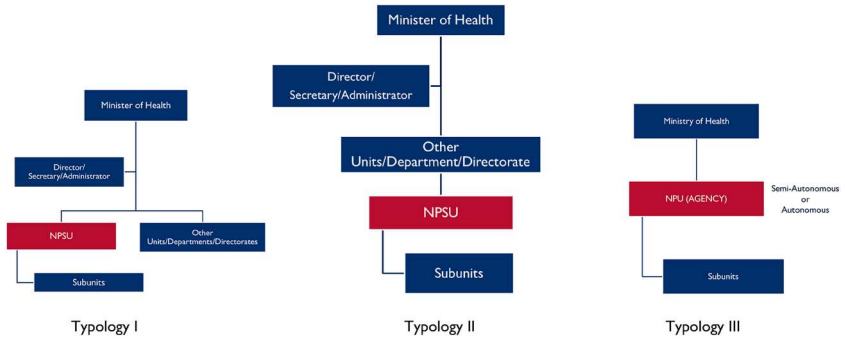

Figure 1. NPSU typology based on position in the health ministry's organisational hierarchy.

the central level: the Directorate of Health Products and Technologies (DHPT), the PPB, the Kenya Medical Supplies Authority (KEMSA), and the National Quality and Control Laboratory (NQCL) (Table 4). The DHPT aligns with typology I, and the PPB, KEMSA, and NQCL align with typology III because they are structured as semiautonomous or autonomous bodies in the MoH.

Function and mandate

The KEMSA – mandated by the Kenya Medical Supplies Authority Act No. 20 of 2013, which established it as a state corporation and autonomous agency – is responsible for the procurement, warehousing, and distribution of medical supplies and supporting county governments in establishing and maintaining appropriate drugs and medical supply chain systems (Government of Kenya, 2013). The PPB, a semiautonomous agency mandated by the Pharmacy and Poisons Act Chapter 244 (2012) Amendment, regulates and controls medicine manufacturing and trade and the pharmacy profession. The NQCL is also mandated by the Pharmacy and Poisons Act for quality assurance of medicinal substances and drugs (Government of Kenya, 2012). The NQCL ensures quality control of drugs and medicinal substances and is responsible for all pharmaceutical evaluations and testing. Table 5 summarises the functions of the four units.

Kenya's NPSUs' mandates depart from common practice in three ways. First, analogous to the case with NPSUs in other settings, the DHPT provides overall policy direction for the pharmaceutical sector with the core functions of health products and technologies (HPT) selection, security, and use. However, the DHPT and KEMSA share the mandate to oversee the distribution of medicines and commodities. While shared mandates between separate bodies can sometimes lead to lapses in oversight and planning, this does not seem to be the case with the DHPT and KEMSA in Kenya. As one respondent observed:

Table 2. Examples of NPSUs classified as typologies I, II, and III.

	Typology		
Country	I	II	III
Australia	Therapeutic Goods and Administration (World Health Organization, 2018)		
Brunei Darussalam	Pharmacy Office (Ministry of Health Brunei Darussalam, 2022a) Brunei Pharmacy Board (Ministry of Health Brunei Darussalam, 2022b)		
Côte d'Ivoire	National Public Health Laboratory (Management Sciences for Health, 2016)	Department of Pharmaceutical Activities (in Directorate General of Health and Public Hygiene) (Ministry of Health and Public Hygiene (MSHP) Cote D'Ivoire, 2009)	Pharmaceutical Regulatory Authority (Government of Côte D'ivoire, 2022) National Order of Pharmacists (Government of Côte D'ivoire, 1960) New Public Health Pharmacy (Management Sciences for Health, 2016)
Democratic Republic of Congo	Pharmaceutical Regulatory Authority (Ministry of Health Republic of Congo, 2011)		
Finland			Finnish Medicine Agency (Finnish Medicine Agency, 2022) Pharmaceutical Pricing Board (World Health Organization, 2008) National Agency for Medicines (World Health Organization, 2008)
Ghana	Procurement and Supply Chain Directorate(Ministry of Health Ghana, 2022a)	Pharmacy (in Directorate of Technical Coordination) (Ministry of Health Ghana, 2022b)	Food and Drug Authority (Food and Drugs Authority Ghana, 2022) Pharmacy Council(Koduah et al., 2020)
Kenya	Directorate of Health Products and Technologies (Government of Kenya, 2017)		Pharmacy and Poisons Board (Government of Kenya, 2012) Kenya Medical Supplies Agency (Government of Kenya, 2013) National Quality and Control Laboratory (Government of Kenya, 2012)

(*Continued*)

Table 2. Continued.

Country	Typology		
	I	II	III
Lao People's Democratic Republic	Food and Drug Department (World Health Organization, 2018)		
Malaysia	Pharmaceutical Service Division Ministry of Health Malaysia, 2022)		
Nepal	Department of Drug Administration (Khanal, 2017) Quality Standard and Regulation Division (Ministry of Health and Population in collaboration with the World Health Organization, 2011)	Logistics Management Section (in Department of Health Services) (Ministry of Health and Population in collaboration with the World Health Organization, 2011)	Nepal Pharmacy Council (Nepal Pharmacy Council, 2022)
New Zealand	Medicine Control Medicine and Medical Devices Safety Authority (New Zealand Government Pharmaceutical Management Agency, 2020)		Pharmaceutical Management Agency (New Zealand Government Pharmaceutical Management Agency, 2020)
Nigeria	Food and Drug Service Department (Ministry of Health Nigeria, 2022) Procurement Department (Ministry of Health Nigeria, 2022)		National Agency for Food and Drug Administration and Control (Ministry of Health Nigeria, 2022)
Philippines	Pharmaceutical Division (Pharmaceutical Division Philippines, 2020)		Food and Drug Administration (Food and Drugs Administration Philippines, 2022)
Rwanda	Pharmacy Desk (Ministry of Health Rwanda, 2015) Medical Production (Ministry of Health Rwanda, 2015) Procurement Division (Ministry of Health Rwanda, 2015)		Food and Drug Authority (Ministry of Health Rwanda, 2015)
Senegal	Directorate of Pharmacy and Medicines (Ministry of Health and Social Welfare Senegal, 2022) Public Procurement Unit (Ministry of Health and Social Welfare Senegal, 2022)		

(*Continued*)

Table 2. Continued.

	Typology		
Country	I	II	III
Uganda	Department of Pharmaceutical and Natural Medicines (Ministry of Health Republic of Uganda, 2020) National Medicines Stores (Ministry of Health Republic of Uganda, 2015)		National Drug Authority (Ministry of Health Republic of Uganda, 2020)

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

Medicine regulation	Procurement and supply chain management	Selection and rational use of medicines	Pharmacy practice regulation
Registration and marketing authorisation	Supply and distribution	Selection	Regulation of pharmacists and other pharmaceutical support staff
Vigilance	Distribution	Medicine policy and administration	Regulation of wholesale and retail medicine sale
Market surveillance and control	Supply chain strategic planning and logistics management	Access programmes design and implementation	Control the location of licensed pharmacies
Licensing establishments	Logistic data collection and analysis	Essential medicines list and standard treatment guideline updates	Regulation of education and training
Regulatory inspection	National procurement and supply chain policies and frameworks	Pharmaceutical policy implementation	
Laboratory testing	Central procurement coordination and central medical stores management	Strategic monitoring of the availability and accessibility of medicines	
Clinical trial oversight	Quantification, procurement, formulation of national medicines policies, and control of medicines prices	Regulation of compulsory stockpiling and medicine reimbursement	
National regulatory authority lot release		Pharmaceutical services Pharmaceutical care Emergency preparedness for medicines and medical technologies	

> The DHPT works with KEMSA to ensure harmony and information sharing within the sector. For example, DHPT and KEMSA bring all key stakeholders onto one platform i.e. the commodity security committees so that everyone is on the same page when it comes to planning. KIK6

Second, quality control of medicines is typically a core function of the national regulatory authority but in Kenya is performed by the NQCL, which is a separate entity. However, the PPB and NQCL work together as mandated by the Pharmacy and Poisons Act Cap 244 (Government of Kenya, 2012). One respondent noted;

> NQCL is the technical arm of the Pharmacy and Poisons Board. NQCL tests health products and technologies on behalf of the PPB. We are part of the committees, the technical working groups that are involved in the protocol development for post-market surveillance. KIK13

Third, unlike in other settings where medicines and pharmacy practice regulation functions are performed by separate entities, the PPB performs both

Table 4. NPSUs in Kenya: Name, typology, mandate and function, and legal framework.

NPSU name and typology	Functions	Mandate
Directorate of Health Products and Technologies (DHPT), typology I	• Establishes and sustains robust HPT product selection, quantification, procurement, distribution, and use system • Oversees the distribution of HPT across the country • Designs and coordinates the implementation of pharmaceutical policies, guidelines, and standards, e.g. Kenya Essential Medicines List, standard treatment guidelines, Essential Medical Supplies List, and Essential Medical Laboratory Commodities List • Provides technical assistance on HPT and related services • Designs guidelines for laboratory products, nutrition products, and medical technologies such as medical devices, e.g. Essential Medical Laboratory Commodities List • Ensures the security and delivery of HPT across all levels of the health care system in an equitable, reliable, and cost-effective manner • Technical and capacity building for counties: support HPT supply chain and service delivery and serve as a liaison between the national and county levels of government. The capacity building focuses on training national and county trainers of trainers • In collaboration with the MoH monitoring and evaluation department, monitors the availability and use of HPT • Advocates for increased capacity for research, local production, and full exploitation of TRIPS flexibilities for HPT • Harnesses collaboration and partnerships at all levels for effective resource mobilisation and implementation of HPT supply chain strategy	The DHPT operates in line with Kenya Health Policy, the Health Act, 2017, and the constitution of Kenya (Government of Kenya, 2017)
Pharmacy and Poisons Board (PPB), typology III	• Regulates pharmacy practice and training of pharmacists and other pharmacy staff • Regulates pharmacy premises – wholesalers and retail • Issues pharmacy certificate of analysis for tested health products • Market authorisation and licensing of health products • Provides license for manufacturing of medicinal substances	Pharmacy and Poisons Act Chapter 244 (2012) Amendment authorises the PPB to control and regulate the profession of pharmacy and the manufacture and trade of drugs and poisons (Government of Kenya, 2012)

(*Continued*)

Table 4. Continued.

NPSU name and typology	Functions	Mandate
	• Ensures compliance with good manufacturing practices and inspects manufacturing plants • Regulates quality of health products through postmarket surveillance and pharmacovigilance • Controls the trade-in and manufacture of medicines and poisons • Prepares the list of poisons for agricultural or horticultural purposes	
Kenya Medical Supplies Authority (KEMSA), typology III	• Procures, warehouses, and distributes drugs and medical supplies for public health programmes, the national strategic stock reserve, essential health packages, and national referral hospitals • Establishes a network of storage, packaging, and distribution facilities for the provision of drugs and medical supplies to health institutions • Partners with county governments for procurement, warehousing, and distribution of drugs and medical supplies • Monitors and evaluates the status and cost-effectiveness of procurement, distribution, and value of essential medical supplies delivered to health facilities and the supply chain system in general • Supports county governments to establish and maintain appropriate supply chain systems for drugs and medical supplies	Kenya Medical Supplies Authority Act No. 20 of 2013, an act of parliament that established KEMSA as a state corporation and autonomous agency of the MoH (Government of Kenya, 2013)
National Quality and Control Laboratory (NQCL), typology III	• Ensures quality of medicinal substances and drugs through testing • Undertakes chemical, biological, biochemical, physiological, and pharmacological analyses and other pharmaceutical evaluations • Tests locally manufactured and imported drugs to ensure safety and quality • Conducts postmarketing surveillance of health products, focusing on quality testing	Pharmacy and Poisons Act Chapter 244 (2012) section 35D authorises the NQCL as a legal entity of the MoH for quality assurance of medicinal substances and drugs (Government of Kenya, 2012)

functions. Generally, Kenya has been working to delink regulation from pharmaceutical policy and administration. A draft bill in 2019 to restructure the PPB into an FDA was resisted by stakeholders because it required the repeal of several acts, including the Pharmacy and Poisons Act Cap 244 and other institutional changes, which were deemed as weakening the regulatory environment (Kenya Ministry Health, 2020). However, the Kenya National Pharmaceutical Policy envisages a restructured regulatory environment, with the PPB and NQCL granted more autonomy and the PPB restructured as an FDA (Kenya Ministry Health, 2020).

Coordination

The findings indicate coordination between the four NPSUs. The PPB, NQCL, KEMSA, and DHPT provide intraorganizational support to each other and other MoH units. For example, the DHPT provides technical expertise in product registration, clinical trials, vaccine procurement, and logistics to the PPB. The DHPT also forecasts, quantifies, and procures family planning commodities in concert with the Division of Reproductive and Maternal Health and supports the drafting of family planning commodity requirements. Highlighting the importance of coordination, one respondent described their role this way:

> As a representative of the division of reproductive and maternal health, I am part of the post-market surveillance task force which brings together officers from DPHT, PPB, and other stakeholders. I also serve on the national medicines and therapeutic committee together with officers from PPB and other programs. KIK5

The four NPSUs also collaborate with donors, training institutions, and other external partners to build local capacity in various functions and to help advance other health system priorities. Improved relationships with the DHPT, donors, and the PPB, for example, aided the NQCL in attaining WHO prequalifications and ISO accreditation.

The NPSUs provide technical support at the county level. For example, the DHPT has coordinated the creation of HPT units in all 47 counties and supports their national pharmaceutical policy implementation and pharmaceutical service delivery coordination, including rational use of medicines, supply chain, and logistics management.

Five of the counties HPT units have Public Service Commission recognition, which grants the county HPT unit access to human resources from the Kenya Civil Service and local authorities. As part of their mandate to strengthen supply chain governance at the county level, the DHPT also provides capacity-building support to the county HPT units through staff continuous professional development and other interventions. One respondent described the mandate of the DHPT this way:

Table 5. NPSUs in Côte d'Ivoire: Name, typology, mandate and function, and legal framework.

NPSU name and typology	Functions	Mandate
Directorate of Pharmaceutical Activity (DAP), typology II	• Coordinates all pharmaceutical activities at the Ministry of Health and Public Hygiene • Serves as the technical service department for the ministry in terms of pharmaceutical services • Coordinates and monitors implementation of the National Pharmaceutical Policy • Ensures strategic planning on the drug supply chain • Develops a national list of essential medicines and establishes classifications by health level in the public sector • Prepares pharmaceutical technical documents for the attention of the Minister responsible for health • Ensures continuous strategic monitoring of the availability and accessibility of medicines and other strategic health products to populations living in Côte d'Ivoire • Strengthening of the supply chain of health products at the level of decentralised and national public establishments, distribution, electronic inventory management, and rehabilitation of pharmacy services • Ensures the follow-up of the regulatory texts proposed by the AIRP at the level of the MoH	The DAP is authorised by Law Order No. 0220/MSHP/CAB of November 15, 2020, to contribute to the health status of the population by leading the pharmaceutical activity described in the National Pharmaceutical Policy (Ministry of Health and Public Hygiene (MSHP) Cote D'Ivoire, 2009)
Ivorian Pharmaceutical Regulatory Authority (AIRP), typology III	• Regulates medications that are imported into and exported from the country • Regulates and oversees market authorisations, controls, and inspections • Contributes to the progress of the national pharmaceutical policy, controls the pharmaceutical sector, and ensures compliance with laws and regulations in areas within its competence • Regulates medicine and pharmaceutical product promotion in the pharmaceutical industry • Regulates pharmacies and medical analysis laboratories • Postmarket surveillance and pharmacovigilance • Inspection of pharmaceutical activities and medical analysis laboratories	The AIRP is established and authorised by Act No. 2017–541 of August 3, 2018, Decree No. 2018–926 of December 12, 2018, and the implementation decree of February 2019. (Government of Côte D'ivoire, 2022)
(New Public Health Pharmacy NPSP), typology III	• Responsible for health supply chain activities • Responsible for the distribution of health products from central-level to district pharmacies and hospitals across the country • Essential medicines purchasing/procuring centre, national public store, and distributor of medicines	The NPSP is authorised by Convention entre l'Etat et la Nouvelle PSP 2018–2023 as a semi-independent public-sector procurement agency (Management Sciences for Health, 2016)

(*Continued*)

Table 5. Continued.

NPSU name and typology	Functions	Mandate
	• Develops and implements a performance-based contract (agreement) with health facilities • Forecasting and supply planning for essential medicines and consumables in the public sector • Ensures accessibility of medicines in the pharmaceutical sector (public sector)	
National Public Health Laboratory (LNPS), typology I	• Ensures the conformity of products intended for consumption • Quality control of medical products, including medical devices, veterinary products and products derived from medicinal plants, dietetic products, para-pharmacy products, drinking water, foodstuffs, and beverages • Surveillance of the pharmaceutical market in collaboration with the AIRP • Expertise relating to fraud in the field of medical products, para-pharmacy products, drinking water, foodstuffs, and beverages, per the legal provisions in force regarding the repression of fraud • Industrial and medico-legal toxicological expertise • Development and technical organisation and external evaluation of the quality of medical biology analyses • Preparation, study, and proposal of analysis and hygiene standards in the area of public health • Any analysis and research relating to the protection of public health	The LNPS is authorised through Order No. 198/MSHP of 2009 to monitor the quality of medicines and other products (Management Sciences for Health, 2016)
National Order of Pharmacists, typology III	• Regulates pharmacy practice according to the standard code of ethics for the profession • Ensures compliance with professional duties • Ensures the defense of the honour and independence of the profession • Ensures continuous professional education and the evaluation of professional practices • Contributes to the promotion of public health	The National Order of Pharmacists is authorised by Act No. 60–272 of September 2, 1960, and a code of ethics, established through Act no. 62–249 of July 31, 1962, to regulate pharmacy practice (Government of Côte D'ivoire, 1960)

> We also offer technical and capacity building to counties. It is our constitutional mandate and so we do it around the HPT supplies chain and service delivery. We also deal with coordination especially when it comes to between the two levels of government, we bring in stakeholders within the HPT space to work together. KIK14

The counties use the national essential medicines list to procure medicines through the DHPT from the KEMSA. The PPB has trained county pharmacists to monitor the sector to enhance patient safety and product quality. As a result, county pharmacists have improved and sustained the provision of inpatient and outpatient pharmaceutical care and service [KIK2 and KIK6].

Strengths

Kenya is currently implementing the HPT Supply Chain Strategy 2020–2025 led by the DHPT, which has resulted in the development and dissemination of new pharmaceutical policy, a therapeutic committee, pharmaceutical-sector supervision, county HPT unit guidelines, essential health commodity lists, and other priority guidelines and policies. As one respondent observed:

> HPT Supply Chain Strategy 2020–2025 implementation has created a lot of interventions including policy documents and policy guidelines on quantification, medicines and therapeutic committee's guidelines, and aspect of the supervision guidelines and checklists and all that. KIK14

Additionally, the NPSUs promote multistakeholder engagement and buy-in in the design of these policies and guidelines. The DHPT coordinates with the PPB and other stakeholders to identify and orient committee (e.g. National Medicines and Therapeutics Committee) members for the design of pharmaceutical policies and guidelines, such as standard treatment guidelines. The Pharmaceutical Society of Kenya together with the PPB promote the pharmacy profession and the enforcement of laws that govern the profession. Efforts are also afoot to ensure that Kenya has a proper regulatory framework and to strengthen the regulatory system so the country can attain a stable, well-functioning, and integrated regulatory system.

Weaknesses

Despite financial support from the government and international donors, all four NPSUs have inadequate financial resources. Respondents attribute the budget shortfalls to economic issues and pandemic-related unexpected expenditures. The lack of financial resources has created several interrelated challenges for the NPSUs in fulfilling their mandates. For example, the DHPT has insufficient funds to ensure the constant availability of safe and quality medical products [KIK1]. Similarly, the NQCL had insufficient funds to purchase equipment and reagents for health product quality testing [KIK13].

The inadequate budget allocations have led to the deprioritization of pharmaceutical care and services. As one respondent observed:

> There is more weight on products and towards the supply chain. Even when you look at the mandate the pharmaceutical services part is silent or it is not coming out strongly compared to the regulation of the products, supply chain, inventory management, quantification, and all those other things. KIK14

The financial constraints also have human resource implications. Since devolution, NPSUs cannot simply transfer county-level pharmacists to replace those retiring at the national level. The lack of funding has caused the positions to go unfilled [KIK3 and KIK14]. As one respondent noted:

> The number of staff is very limited, especially after the post-devolution of healthcare services, employment at the national level is very limited. What has happened is that the county governments can employ new staff, but the national level is also not able to pick them because now they are independent. The process is not just the same as before, where you just do a transfer, so right now, you find our staff numbers are diminishing – some retire, and others find better opportunities elsewhere. KIK14

Respondents note that the remaining staff face competing priorities, especially with development partners, and this exacerbates delays in policy implementation and other mandates [KIK4 and KIK12].

Additionally, there is inadequate funding for continuous-development programmes for the staff to develop specific competence, e.g. in supply chain management, quality assurance, and clinical pharmacy. There are therefore inadequate human resources with respect to both numbers and skills. In the case of the PPB, this has caused some delays in the registration process and backlogs in inspections and pharmacovigilance [KIK8].

Case II: Côte d'Ivoire

Côte d'Ivoire has five main 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 NPSUs hold different organisational positions within the Ministry of Health and Public Hygiene (Ministère de la Santé et de l'Hygiène Publique et de la Couverture Maladie Universelle, MSHP CMU). The MoH is responsible for the implementation and monitoring of the government's policy on health and public hygiene (Ministère de la Santé et de l'Hygiène Publique et de la Couverture Sanitaire Universelle – Côte d'Ivoire, 2017). The DAP is a unit of the General Directorate of Health. The DAP and AIRP now perform functions of the former Department of Pharmacy, Medicines, and Laboratories, which was responsible for all regulations of medicines, including poisonous substances, and dietary,

cosmetic, and hygiene products. The LNSP and DAP align with typology I and typology II, respectively. The AIRP, NPSP, and the National Order of Pharmacists are typology III because they are independent/semi-independent units.

Functions and mandate

The DAP is mandated by Law Order No. 0220/MSHP/CAB of November 15, 2020, to contribute to the health status of the population by leading the pharmaceutical activity described in the National Pharmaceutical Policy (Ministry of Health and Public Hygiene (MSHP) Cote D'Ivoire., 2009). As two respondent observed, this essentially involves:

> […] the design and development of the national pharmaceutical policy with regulatory aspects that concern the pharmacy, medicines and some aspects of the supply of medicines. KICD1

> […] pharmaceutical policy and strategic planning. It ensures the security, and continuous strategic monitoring and supplies of health products, the strengthening of the supply chain of health products. KICD5

The AIRP is an independent and autonomous authority established and mandated by Act No. 2017–541 of August 3, 2018, Decree No. 2018–926 of December 12, 2018, and the implementation decree of February 2019. The AIRP's core mandate is to regulate the pharmaceutical sector, conduct surveillance, and inspect industries and pharmaceutical premises.

The NPSP is a mandated by Convention entre l'Etat et la Nouvelle PSP 2018–2023 as a semi-independent public-sector procurement agency. It operates as a not-for-profit organisation and reports to the Minister of Health and Public Hygiene. The NPSP started operation on June 21, 2013, to replace the former Pharmacie de la Santé Publique de Côte d'Ivoire, which had been in charge of public pharmaceutical service in the Ivory Coast since 1958 (Management Sciences for Health, 2016). Outlining the transition, two respondents noted:

> The supply chain used to be managed by the National Pharmaceutical Development Program (PNDAP), but now the NPSP a non-profit organization does the ordering, storage, and distribution for the public health establishments. KICD2 and KICD8

The LNSP is mandated through Order No. 198/MSHP of 2009 to monitor the quality of medicines and other products under the technical supervision of the Ministry of Health and Public Hygiene. The National Order of Pharmacists is an independent administrative authority established in 1960 and mandated by Act No. 60–272 of September 2, 1960, and a code of ethics, established through Act no. 62–249 of July 31, 1962, to regulate the practice of pharmacy.

The broad functions identified for the DAP (pharmaceutical policy directions and implementation), AIRP (medicine regulation), NPSP (medicine procurement and supply chain management), and National Order of

Pharmacists (pharmacy practice regulation) align with the functions identified from the literature review. However, similar to the NQCL in Kenya, the LNPS in Côte d'Ivoire is a 'standalone' unit for quality control, a function that is typically embedded in the national medicines regulatory authority. The LNSP works with the AIRP on medicine regulations and ensuring the availability of quality and safe medicines on the market. As one interviewee observed:

> LNSP has a good relationship with the AIRP concerning the quality of medicines certification, screening, and testing of medicines samples. LNSP shares report on medicines quality control and evaluation with the AIRP as it monitors the quality of medicines on the market. KICD2

Coordination

The findings indicate coordination between the five NPSUs. The DAP, AIRP, NPSP, LNSP, and National Order of Pharmacists collaborate to ensure effective supply chain management, quality control, and pharmaceutical policy development. For example, the DAP collaborates with the NPSP for effective medicine management through health product quantification and forecasting [KICD1]. The DAP shares a supply chain mandate with the NPSP [KICD6]. The DAP also collaborates with the regional directorates and districts for training programmes and with the National Institute of Public Health for personnel training in public health facilities [KICD9]. Donors also work with the DAP; for example, USAID MTaPS supports the DAP on AMR issues and has introduced AMR into the pharmaceutical policy. As one respondent explained:

> The DAP interacts with several structures within the Ministry of Health and Public Hygiene (MSHP), e.g. with the extended vaccination program and the National Institute of Hygiene Public (INHP). The DAP also works closely with the NPSP for effective drug management. KICD1

The NPSP works with the LNSP on medicine quality control during the procurement process. The NPSP together with DAP collaborates with the National Institute of Hygiene Public and the Expanded Programme on Immunisation for vaccine quantification and forecasting [KICD1]. The importance of these various collaborations was underscored by several informants who noted:

> If the DAP has not worked with the new NPSP and national health programs in the quantification, we cannot see the product or the quantities to order. One cannot distribute the products if the laboratory has not checked the products. KICD5

> Yes, there is a contract between the new NPSP and the national laboratory for testing of medicines and quality control. In this contract, even the terms and

> conditions for taking samples and deadlines for returning the results are stated. KICD3

The AIRP provides legal support to the NPSP in the importation of medicines [KICD2]. The AIRP also collaborates with other state institutions to monitor and check drug counterfeiting; these include the Ministry of Justice, the National Gendarmerie, the National Centre for the Fight against Counterfeiting, and the Narcotics and Drugs Police Directorate [KICD3]. One respondent further explained:

> The DAP and the AIRP work together on call offers for central purchasing of medicines, NPSP and the National Health Programs work together as part of the procurement committee of which the DAP coordinates. AIRP and the national laboratory work together to ensure quality control, the NPSP collaborates with the national laboratory for quality control. KICD8

The DAP and AIRP also work with the National Order of Pharmacists. The DAP has a representative on the Council, and the AIRP participates as an observer at the Council [KICD6].

Strengths

Four main facilitators were identified across the NPSUs in Côte d'Ivoire. The first is the units' autonomy and independent status. For example, the AIRP operates with little interference from the Minister of Health and Public Hygiene. However, the AIRP relies on state resources for its operation and so is not yet fully financially independent. This may be because the AIRP was instituted in February 2019 and so is relatively new in its operation.

The second facilitator is effective collaboration between the public and private health sectors, which has led to medicine pricing equalisation. Côte d'Ivoire has been successful in harmonising medicine prices across the country, and this is coordinated by the AIRP through the marketing authorisation system. As one informant noted:

> The pharmaceutical sector is very effective in terms of pricing. Our predecessors have adopted the system of equalization which ensures the price of the drug is the same throughout the country. KICD10

Third, the country has a functional supply chain system, especially with respect to the distribution of medicines from the manufacturer through the wholesalers and retailers to the consumer. One respondent noted that the country has no challenge with geographical access:

> We can bring the medicine to the last mile, and in less than 48 hours medication arrives at their destination. We need to improve on financial accessibility. KICD10

Financial accessibility has been addressed by government policies such as the generic and substitution policy mandated by Ministerial Decree No. 0082/mshp/cap of April 26, 2017; the repackaging policy mandated by Order No.

0083/mshp/cab/dpml of April 26, 2017; and the UHC policy instituted by Law No. 2014–131 of March 24, 2014. Explaining some of the effects of the policy changes, one respondent noted:

> There is improved financial accessibility to medicines because the country initiated three major policies. One is the generic policy which allows for the pharmacist to substitute a prescribed medicine with a generic one. Two, the repackaging policy authorizes the pharmacist to repackage medicines from their original medicines packs and dispense them to clients. Three, the Universal Health Coverage policy which provides health risk coverage and there is 100% enrolment. KICD10

As another respondent noted, the fourth facilitator is the high level of political support enjoyed by the NPSUs, which has helped to facilitate pharmaceutical policy implementation and some resource allocations:

> The first factor that impacts success is political will. Yes, if the government does not support the actors the activities won't go far, so the political will is a very important factor for the success of the pharmaceutical sector. KICD6

Weaknesses

The findings indicated institutional hurdles as a barrier. For example, the LNSP has yet to gain a WHO prequalification status, and as noted by a respondent, this may be due to the sometimes bureaucratic nature of the francophone systems in terms of operations and processes:

> LNSP is not yet WHO prequalified, our processes may have delayed this. Sometimes the francophone system is a bit heavy. KICD2

The pharmaceutical inspectorate division of the AIRP is under resourced and, as a result, has inadequate inspectors; this makes the fight against the illicit market a challenge. One respondent describes it this way:

> For failures, in terms of pharmacovigilance, we have made progress, but the pharmacovigilance center has not yet been able to show its full potential. The pharmaceutical inspectorate is another challenge, we do not have enough inspectors (some were sworn in 2021); The fight against the illicit market is also a problem, but with governance and the right means, the AIRP could make progress. KICD8

There is also a seemingly difficult relationship between the DAP and AIRP, and this may be due to potential overlapping roles, as these units emanated from the former Department of Pharmacy, Medicines, and Laboratories, which was leading and coordinating activities within the pharmaceutical sector. One respondent noted the attempts to address the issue:

> There is a difficult collaboration with AIRP and DAP. We have proposed quarterly meetings to discuss better collaboration processes so that we can see how to move forward, but that does not work. KICD10

Additionally, there are challenges with some decision-making processes. Sometimes the Ministry of Health and Public Hygiene does not consult the Council of the National Order of Pharmacists on pharmacy profession issues. As noted by a respondent, this approach is a major challenge because in the past the Council was consulted, and decisions were ratified at that level. Currently, Council decisions need ratification from the Minister, and this hinders the proper functioning of the profession.

Pharmacists are expected to constantly upgrade their knowledge through continuous professional development, yet there is inadequate continuous education opportunity in the country for the pharmacy profession. One respondent described efforts to provide more opportunities:

> Continuous education and professional development are mandatory. The National Order of Pharmacists is currently working on signing contracts with national organizations that can train pharmacists. Once the trainings are implemented, it will become a requirement for pharmacists to renew their registration at the Order. KICD4

Inadequate funding remains a challenge. For example, the DAP depends on the General Directorate of Health and is underfunded, so the unit also relies on donor financial support [KICD8]. But a respondent notes that the overdependency of the DAP on development partners is a challenge because it involves several reporting channels and procedures [KICD8]. The inadequate budgetary allocation from the government affects human resource numbers, as it is difficult to recruit and retain staff. One respondent noted:

> We are underfunded by government and partners. There is a reduced state budget and as a result, we have difficulty in retaining human resources because of the level of salaries in the civil service. KICD8

Case III: Nepal

In Nepal, we identified four different entities within the Ministry of Health and Population that encompass the responsibilities of NPSUs: the Department of Drug Administration (DDA), Quality Standard and Regulation Division (QSRD), Logistics Management Section (LMS), and Nepal Pharmacy Council (NPC) (Table 6). The DDA and QSRD align with typology I. The NPC and LMS align with typology III and typology II, respectively.

Functions and mandate

The DDA is authorised by the Drug Act 2025 of 1978 to prevent the misuse of and false information for medicines and related medical products and curtail the production, distribution, and utilisation of drugs that are not safe, effective, or of proper quality (Khanal, 2017). The DDA is additionally tasked with acting as the WHO pharmacovigilance focal point in-country, promoting rational use of

antibiotics, and developing a Nepalese drug formulary and essential medicines list on a periodic basis [KIN32]. One respondent described DDA's role:

> DDA registers the entities involved in the pharmaceutical business, issues licenses, and penalizes the entities working against the provisions mentioned in the Drugs Act, Regulations, codes, etc. It conducts routine and special inspections in the industries and pharmacies to assess compliance with prescribed standards. KIN3

The QSRD is responsible for all activities related to pharmaceutical regulation in Nepal. This function is mandated for the QSRD by the Drugs Act 2035 (1978) [KIN61]. These activities include coordination at the ministerial level, policy formulation and revision, and hospital monitoring and inspections [KIN21, KIN32, KIN52, KIN54, and KIN63 to KIN65]. One respondent noted some tension around the perceived role of the QSRD:

> It is not universally accepted that QSRD oversees all activities for pharmaceutical regulation, some pharmaceutical experts argue that the DDA is responsible for these activities and that QSRD only plays a supporting role. KIN32

The LMS is responsible for pharmaceutical supply chain management, medicine procurement, and management of health information systems [KIN65]. Two respondents described LMS' role as:

> [… supplying] medicines and other logistics to government health facilities. It also has central and regional stores, which provide health commodities to provinces, districts, and municipalities. KIN31

> […] main roles are procurement i.e. bidding and contracting and supply of the procured medicines and health related products. KIN63

The NPC's function is to work for quality assurance of pharmacy human resources, as per the needs of Nepal. The NPC was established in 2001 through the Nepal Pharmacy Council Act, 2057 (Humagain, 2073/74; Nepal Pharmacy Council., 2022).

The DDA and QSRD share the mandate to regulate the pharmaceutical sector. The DDA functions as the national medicines regulatory authority (Ministry of Health and Population in collaboration with the World Health Organization, 2011) and operates a national medicines laboratory (NML). The NML is responsible for testing the quality of pharmaceuticals [KIN21]. The NML also evaluates the standard of drug testing laboratories throughout the country, develops reference standards for pharmacies and laboratories, conducts training on good laboratory practices, and audits laboratories in national pharmacies (Khanal, 2017).

Coordination

Our findings indicate that the DDA, QSRD, LMS, and NPC work together through the Drug Advisory Council to ensure the development and implementation of medicine policies. One respondent noted:

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	• Responsible for testing the quality of pharmaceuticals in collaboration with National Medicine Laboratory • Evaluates the standard of drug testing laboratories throughout the country, develops reference standards for pharmacies and laboratories, conducts training on good laboratory practices, and audits laboratories in national pharmacies in collaboration with the NML • Registers foreign medicine manufacturers and their products for import and issues letters for medicine imports and exports • Recommends the establishment of pharmaceutical industries and issues and renews product manufacturing licenses • Oversees registering and renewing certificates for retail and wholesale pharmacy outlets. Provides authorisation certificates for individuals permitted to sell medicines • Grants permission for clinical trial and medicines advertisement • Conducts refresher training for medicine sellers and disseminates vital information about medicines, including adverse effects, contraindications, drug interactions, and storage conditions • Manages the publication and distribution of Nepal Drug Bulletin and works on recommendations for importing controlled substances • Manages national pharmacovigilance and adverse drug reaction monitoring and reporting • Conducts thorough inspections of pharmaceutical industries and takes appropriate measures in response to instances of noncompliance with the Drug Act of 2035 • Responsible for preparing necessary documents related to legal cases against pharmacies and industries that violate regulations set by DDA • Monitors the effective implementation of the Drug Act of 2035 and other regulations and ensures the integrity of drug imports and exports. WHO pharmacovigilance focal point in-country • Promotes rational use of medicines • Develops Nepalese drug formulary and essential medicines list periodically • Medicine price regulation • Establishes policies and quality standards for the pharmaceutical system	The DDA is authorised by the Drug Act 2035 (1978) (Khanal, 2017)

(*Continued*)

Table 6. Continued.

NPSU name and typology	Functions	Mandate
Quality Standard and Regulation Division (QSRD), typology I	• Develops policies and criteria related to the pharmaceutical department, Ayurvedic pharmacies, and medical measurements • Establishes criteria and guide the use of medical equipment in ministries, agencies, and health facilities • Establishes standards and procedures for service delivery in health facilities • Conducts periodic inspections of programmes managed by ministries, nongovernmental organisations, semigovernmental organisations, and committees • Defines and regulates standards for medical equipment and infrastructure • Executes tasks related to the WHO International Health Regulations	The QSRS is authorised by the Drugs Act 2035 (1978) (Ministry of Health and Population in collaboration with the World Health Organization, 2011)
Logistics Management Section (LMS), typology II	• Coordinates institutionalization of national-level supply chain management information systems • Develops national laws, policies, directories, quality criteria, and protocols regarding purchasing and supplies of pharmaceuticals • Prepares and updates national standards, health and equipment criteria, and specification repositories at the national level • Purchases essential health commodities, such as vaccinations, family planning equipment, and medical equipment, and maintains supply at the state level and local level	The LMS operates under the mandate of the Department of Health Services (Ministry of Health and Population in collaboration with the World Health Organization, 2011)
Nepal Pharmacy Council (NPC), typology III	• Prepares policies, plans, and programmes that ensure operationalisation and implementation in the pharmacy sector • Recognises and accredits schools of pharmacy and their degrees and enforces said accreditation • Prescribes details of the curricula, terms of admission, and examination systems for schools of pharmacy • Prescribes minimum standards for pharmacy education	The NPC is authorised to function through the Nepal Pharmacy Council Act, 2057 (2000) (Nepal Pharmacy Council, 2022)

> Drug Advisory Council advises Nepal Government on theoretical and administrative matters related to medicines, such as policy changes, and fixing the price of medicines. Health Minister (Chairman), Health Secretary, Director General of DDA, Chief of National Medicine Laboratory (NML), pharmaceutical experts, etc., are members of the council. KIN21

The QSRD coordinates with other NPSUs, and partners conduct activities related to AMR. These activities include awareness campaigns, surveillance, and interventions aimed at combating the emergence and spread of AMR in the country [KIN65]. Another respondent noted:

> QSRD is the secretariat for AMR related activities antimicrobial resistance. Thus, coordinate and collaborate with external development partners as well as non-profit organizations. KIN65

Strengths and weaknesses

The findings indicated inadequate human resources for the pharmaceutical sector as a major barrier. The shortage of human resources and the lack of capacity lead to increased workloads, burnout, and compromised decision making [KIN58]. They also hinder the NPSUs' ability to effectively manage medicine regulation, quality control, and monitoring and evaluation of the sector [KIN64 and KIN65]. Several respondents noted, for example:

> One significant factor is the inadequate manpower within the unit (QSRD), which requires attention and a separate budget allocation to operate effectively. Addressing this issue is crucial to enhance the unit's performance and overall operations. KIN61

> The absence of clearly defined roles and responsibilities and the lack of adequate human resources with appropriate skill sets and training can inhibit the performance of the National Pharmaceutical Service Unit. KIN32

> There is a recognition problem regarding our profession by the government. Additionally, despite producing an adequate number of human resources, there is a lack of sufficient job placement opportunities, and there is a need to revise the payroll system. KIN54

Knowledge of Nepal's pharmaceutical sector and its context is lacking among human resources within Nepal's NPSUs [KIN21, KIN52]. Without a comprehensive grasp of the local health care system, market dynamics, and regulatory framework, the NPSUs may struggle to develop effective strategies and policies. This can compromise the quality, availability, and affordability of essential drugs [KIN52]. In addition to inadequate human resources, leaders within Nepal's NPSUs are not coordinating with each other [KIN21 and KIN59] and are not using data to inform their decision-making processes [KIN28 and KIN29]. This can lead to duplication of efforts and stockouts, leading to inefficiencies and potential public health risks. As one respondent noted:

> DDA has shared information with the Ministry and Health and Population (MOHP), but the activities related to the supply chain have not been adequately followed up by either organization. The [LMS] activities and areas have also not been effectively addressed by MOHP and DDA. Although the [LMS] has requested follow-up and suggestions from the QSRD, inspections in the supply chain of medicines and related commodities have not been carried out by the QSRD. KIN63

At the macro level, political influence within NPSUs can compromise the integrity, transparency, and effectiveness of pharmaceutical management, potentially leading to the misuse of public resources [KIN54 and KIN59]. Inflexible regulations and bureaucratic red tape can delay the approval and registration of essential drugs, limiting access to innovative treatments and negatively impacting health care outcomes [KIN32, KIN41, KIN52, KIN55, and KIN59]. Conflicts of interest, be they conflicting personal or financial interests among decision makers at Nepal's NPSUs, can compromise the integrity and impartiality of their decisions, leading to biased policies and compromised pharmaceutical management [KIN52 and KIN59]. Additionally, the lack of pharmacovigilance systems challenges Nepal's health system in responding quickly to substandard/unsafe medicines [KIN61].

Discussion

The study points to three critical factors for the creation and proper function of an NPSU: a clear hierarchical structure in the health ministry, a legal or administrative framework that mandates the NPSU's functions, and national pharmaceutical policies to guide the pharmaceutical sector. How the NPSUs are structured within the ministry's hierarchy, whether typology I (high level, reporting directly to the Minister), typology II (mid-level, reporting to the Minister through another unit), or typology III (a semiautonomous or autonomous agency in the ministry), could influence how these NPSUs perform and their levels of resources. The NPSUs with typology I participate in high-level decision-making processes toward improving health outcomes and budgetary allocations for the health sector. Semiautonomous and autonomous NPSU structures promote flexibility in decision making and autonomy. In placing an NPSU within the ministry hierarchy, governments must consider other administrative structures and chains of command for existing departments or units to ensure consistency. Along with an elevated position in the organisational hierarchy, it is necessary to have a legislative or administrative framework granting the unit the necessary authority to exist and function with an articulated mandate. The framework should delineate roles and functional responsibilities such that the NPSU and any other entity supporting the NPSU has the authority or mandate to perform their functions.

Guided by the definition of the pharmaceutical system and the functions identified in the literature review and three cases, we can also identify a set of minimum functions for NPSUs: medicine regulation, procurement and supply chain management, and pharmacy practice regulation. We also propose that pharmaceutical policy and governance should be a requisite function.

Medicine regulation involves the regulation of medical products throughout the product life cycle for the entire country, with overall responsibility for ensuring the quality, safety, and efficacy of medical products. The study findings point to medicine regulation being performed by a separate (semi)autonomous unit as the national regulatory authority, whose eight functions are clearly outlined by the GBT for evaluation of national regulatory systems (Twesigye et al., 2021). The GBT – the globally accepted standard for regulatory systems – outlines eight key regulatory functions: registration and marketing authorisation, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trial oversight, and national regulatory authority lot release (World Health Organisation, 2024).

Procurement and supply chain management are historically performed by a single centralised NPSU or regional and subnational units mandated to procure and manage the supply chain system for health commodities. The unit within the MoH may report directly or through another unit to the health minister. Examples of specific minimal functions include (i) supply chain strategic planning and logistics management; (ii) quantification, procurement, and control of medicine prices; (iii) policy and governance; (iv) formulation and implementation of supply chain policy and related strategies; (v) distribution and storage; and (vi) monitoring and evaluation of performance (with system outcomes as access), information systems, data analysis, and information use. We recommend that the NPSU should serve as a steward of the health supply chain rather than operating it themselves. This would align with the trend of procurement and supply chain management function being increasingly outsourced to third – or fourth-party logistics providers from the private sector to perform the various elements of the procurement and supply chain management function (Bornbusch et al., 2014; Perri et al., 2023). Whether the NPSU conducts the various services directly or outsource them, this function must take primacy as one of the minimum functions because weak procurement and supply chain management systems interrupt the supply of safe, effective, quality-assured, and affordable medical products.

Pharmacy practice regulation is the regulation of pharmacy practice and the premises for providing pharmaceutical care and the overall responsibility for regulating the training and practice of pharmacy. Examples of specific minimal functions include (i) regulation of pharmacists and other pharmaceutical support staff, (ii) regulation of the provision of pharmaceutical care, (iii) regulation of pharmacy premises, and (iv) regulation of training of

pharmacists and other pharmaceutical staff. Pharmacy practice regulation is typically performed by an autonomous body.

The findings do not identify a locus for pharmaceutical system governance, a critical function that seems dispersed between two or more units. Therefore, we propose that there should be one NPSU specifically responsible for pharmaceutical policy and governance, serving as the steward for the national pharmaceutical system. The pharmaceutical policy and governance function should include policy; laws and regulations; coordination and leadership; monitoring and evaluation; and ethics, transparency, and accountability (Table 7). A unit dedicated to formulating and implementing legislation and policy is critical for providing the necessary framework for organising, financing, regulating, and monitoring the system. The coordination of resources and processes is also necessary to ensure access and appropriate use. This would be akin to the role of the DAP in Côte d'Ivoire, the DHPT in Kenya, and the DDA and QSRD in Nepal.

Monitoring and evaluation are essential to track the implementation of the national medicines policy and overall system performance. Therefore, the unit should be authorised to coordinate data collection and use across the various system components or functional areas and be empowered to use the data to inform policy priorities and system strengthening efforts. Importantly, the NPSU should be responsible for ensuring that disparate stakeholders understand their role in the system and its optimal performance to achieve the system outcomes of equitable and timely access to and appropriate and cost-effective use of safe, effective, and quality medical products.

Table 7. Proposed key elements of the pharmaceutical policy and governance function.

Policy or governance function	Elements
Pharmaceutical policies	Accessing, analyzing, and using data to formulate a national medicines policy and other pharmaceutical policies and strategies and developing and implementing evidence-based strategic plans to support the achievement of identified priorities and goals
Pharmaceutical laws and regulations	Formulating, implementing, and enforcing comprehensive legislation to regulate activities (including controlled-substance scheduling, importation, storage, prescribing, dispensing, and reporting) and pharmaceutical workforce management
Coordination and leadership	Systems for providing direction; engaging, coordinating and aligning expectations, interests, and activities among state and nonstate institutions and stakeholders; and maximising the use of resources
Monitoring and evaluation	Coordination of the development and monitoring of key system performance indicators, including those related to the implementation of the national medicines policy, and facilitating data use across the different functional areas to determine strategic priorities and inform policy
Ethics, transparency, and accountability	Stipulation of key principles to guide ethics and the integrity of professional behaviour, ethical practices, maintenance of professional competence, and compliance with regulations and accepted standards. Formal processes to consult with and inform key stakeholders, including civil society, about major decisions and actions in the pharmaceutical system and to hold entities and decision makers accountable for their decisions and actions

Conclusion

Built in part on three country case studies, this study provides evidence of the various functions of NPSUs and their various positions within the structure of the ministry's hierarchy. Importantly, we consider that an elevated status in the hierarchy conveys priority and access to resources. The broad functions outlined in the study could be performed by one or more NPSUs; however, the extent to which the broad roles are diffused across the NPSUs has implications not only for monitoring and evaluating performance but also for having a clear sense of what each NPSU is mandated to do and how NPSUs can relate and work with others to achieve national pharmaceutical system objectives. A major contribution of study is recognising the need for a specific unit for pharmaceutical system policy and governance that stewards and strengthens the pharmaceutical system and is empowered to monitor and evaluate system performance and coordinate efforts to improve system function and performance.

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