



# Strengthening Domestic Pharmaceutical Manufacturing in Nepal

Presented on behalf of the Association of Pharmaceutical Producers of Nepal (APPON) at the 12th National Summit of Health and Population Scientists | Parallel Session | 12 April 2026 | The Soaltee, Kathmandu

SESSION THEME: RESEARCH GOVERNANCE FOR EVIDENCE-INFORMED DECISION MAKING

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## Presentation Roadmap

# What We Will Cover Today

This 10-minute scientific talk traverses the landscape of Nepal's pharmaceutical sector — from ground realities to governance, from collaboration gaps to research frontiers. Our goal is to catalyze evidence-informed dialogue that bridges industry, policy, and science.

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### Current Status

Pharmaceutical industry landscape in Nepal

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### Policy Frameworks

Drug-related regulatory and legal architecture

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### Implementation

On-ground status of policy execution

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### Collaboration

Cross-sector partnership approaches

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### Research Priorities

Agenda for pharmaceutical research in Nepal

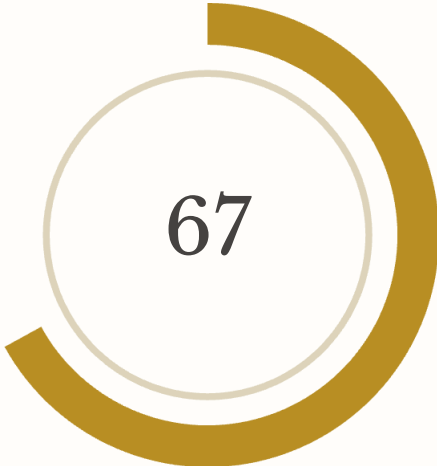
Chapter 1 — Industry Overview

# Current Status of Pharmaceutical Industries in Nepal

Nepal's pharmaceutical sector has grown substantially over the past two decades yet continues to face structural constraints that limit its full potential in ensuring domestic medicine security.



# Industry at a Glance



**Domestic  
Manufacturers (80)**  
WHO GMP-certified  
pharmaceuticals operating  
across Nepal



**Domestic Market Share**  
Local manufacturers supply  
roughly 50% of national medicine  
demand



**Import Dependency**  
Over 50% of medicines  
consumed in Nepal are imported,  
primarily from India



**Pharmaceutical Market**  
Estimated annual value of  
Domestic pharma market Share

## Key Industry Challenges

# Structural Barriers Limiting Growth

Nepal's pharmaceutical manufacturers face a convergence of infrastructure, financial, and regulatory constraints that impede competitiveness and restrict the range of medicines that can be produced domestically.

### Raw Material Dependency

Almost 100% of APIs and excipients are imported, making manufacturers vulnerable to supply disruptions and price volatility.

### Limited Technology Investment

High capital costs for upgrading to WHO-GMP standards remain a barrier for many small and medium enterprises.

### Skilled Workforce Gaps

Shortage of trained pharmaceutical scientists, quality assurance professionals, and regulatory affairs specialists.

### Market Access Constraints

Public procurement mechanisms often favor lowest-cost imports, undercutting domestically produced quality medicines.

Chapter 2 — Governance Architecture

# Drug-Related Policy Frameworks

Nepal has progressively built a regulatory and policy architecture for pharmaceuticals. However, alignment between existing frameworks and the evolving needs of the industry remains a work in progress.



# The Policy Landscape

Nepal's pharmaceutical sector is governed by a layered set of policies, acts, and regulations. The following frameworks form the core of the drug governance ecosystem.

## Drug Act, 1978 (Revised)

The foundational legal instrument governing drug registration, manufacturing, import/export, distribution, and quality standards in Nepal. Periodic revisions have attempted to align with international norms.

## National Drug Policy Revision, 2007

The 2007 revision strengthened rational use of medicines, updated the essential medicines list, improved drug procurement systems, and aligned pharmaceutical governance more closely with WHO standards.

## WHO-GMP Certification Framework

Department of Drug Administration (DDA) mandates progressive adoption of WHO Good Manufacturing Practice standards for all licensed manufacturers to ensure product quality and export readiness.

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## National Drug Policy, 1995

Initially established principles of drug procurement, rational use, and affordability, with a revision in 2007 that reaffirmed its focus on essential medicines and generic prescribing — a landmark in Nepal's pharmaceutical governance.

## Industrial Policy & Export Promotion

Government incentives including tax holidays, customs duty waivers on machinery, and priority sector lending for pharmaceutical manufacturers under the Industrial Enterprises Act.

Chapter 3 — On-Ground Reality

# Implementation Status: The Gap Between Policy and Practice

While policy frameworks are increasingly sophisticated, implementation gaps persist across regulatory enforcement, healthcare delivery, and manufacturing quality assurance.

 Progress Made

DDA has strengthened post-market surveillance. E-registration systems for drugs are partially operational. GMP compliance rates among larger manufacturers have improved significantly since 2015.

 Ongoing Challenges

Counterfeit and substandard medicines persist in the supply chain. Pharmacovigilance reporting remains weak at facility level. Regulatory human resource capacity at DDA is overstretched relative to the volume of registrations.

 Systemic Gaps

Federal restructuring has created ambiguity in provincial versus central jurisdiction over drug regulation. Essential medicine lists are not consistently procured or distributed to health posts across all provinces.

## Regulatory Infrastructure

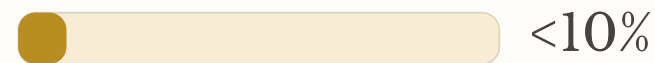
# DDA Capacity & Coverage

The Department of Drug Administration (DDA) remains the apex regulatory body, but faces significant resource and capacity constraints in keeping pace with sector growth.



### WHO-GMP Compliance Rate

Among In-operation Domestic manufacturers (estimated)



### Pharmacovigilance Reporting

Healthcare facilities actively reporting adverse drug reactions

### Post-Market Surveillance Coverage

Proportion of districts with active drug quality monitoring

## Essential Medicines Access

# Last-Mile Delivery

Access to essential medicines at primary care level remains uneven. Supply chain resilience, cold chain infrastructure, and procurement efficiency are critical intervention areas.

### → Urban vs. Rural Divide

Availability of essential medicines drops significantly in remote hill and mountain districts compared to urban centers and Terai belt.

### → Logistical Bottlenecks

Road infrastructure limitations, particularly in post-earthquake zones, hamper timely distribution to health facilities.

### → Procurement Delays

Government procurement cycles through DoHS and provincial health directorates frequently experience delays, creating stock-outs at point-of-care.

## Chapter 4 — Working Together

# Collaboration Approaches in the Pharmaceutical Sector

Sustainable pharmaceutical development in Nepal requires deliberate, structured collaboration across government, industry, academia, and international partners — moving from ad hoc engagement to institutionalized partnerships.



# A Multi-Stakeholder Collaboration Framework

The Association of Pharmaceutical Producers of Nepal (APPON) advocates for a cross-sector partnership model that leverages the distinct strengths of each stakeholder to build a resilient, self-reliant pharmaceutical ecosystem.



## Government & Regulators

MoHP, DDA, and DoHS must create enabling policy environments — streamlining registration, enforcing quality, and ensuring fair public procurement that rewards domestic quality manufacturers.



## Academia & Research Institutions

NHRC, universities, and research institutes should co-design research agendas with industry to generate locally relevant evidence — from bioequivalence studies to post-market surveillance data.



## Development Partners

WHO, USAID, PTB, and bilateral donors can provide technical assistance for GMP upgrades, regulatory system strengthening, and financing for pharmaceutical technology transfer.



## Industry (APPON)

Producers must invest in quality systems, engage transparently with regulators, share real-world data with researchers, and champion ethical marketing and rational medicine use.

## Regional & International Linkages

# Leveraging SAARC and Global Partnerships

Nepal has a unique opportunity to position itself as a pharmaceutical hub for the SAARC region — provided strategic investments in quality infrastructure and trade diplomacy are made.



### SAARC Pharma Network

Harmonizing drug registration and pharmacovigilance standards across South Asia to reduce duplication and facilitate legitimate cross-border medicine trade.



### Technology Transfer

Partnerships with Indian and Chinese generic manufacturers with technology licensing and joint production agreements to expand Nepal's domestic product range.



### WHO PQ | EU GMP

Supporting select Nepali manufacturers in achieving WHO prequalification or EU GMP— a gateway to international procurement markets and global quality recognition.



## Chapter 5 — The Research Agenda

# Research Priorities in Pharmaceutical Products in Nepal

Generating robust, locally relevant evidence is central to the Summit's theme of *Research Governance for Evidence-Informed Decision Making*. APPON proposes a focused research agenda aligned with Nepal's disease burden and pharmaceutical realities.

# Priority Research Areas for Nepal's Pharmaceutical Sector

These five research domains represent the most critical knowledge gaps where evidence generation will directly translate into better policy, stronger regulation, and improved patient outcomes across Nepal.



## Drug Quality & Bioequivalence Studies

Systematic post-market surveillance studies on commonly used generics manufactured in Nepal. Bioequivalence data is urgently needed to establish therapeutic equivalence and build prescriber confidence in domestically produced medicines.



## Pharmacovigilance & Adverse Drug Reactions

Strengthening ADR reporting systems and conducting population-level pharmacoepidemiology studies — particularly for antimicrobials, anticoagulants, and immunosuppressants — to inform rational prescribing guidelines.



## Traditional & Herbal Medicine Formulations

Rigorous scientific validation of traditional Ayurvedic and herbal formulations prevalent in Nepal, with standardization of active ingredients and clinical efficacy studies to integrate evidence-based traditional medicine into the health system.



## Medicine Access & Affordability Research

Health economics research on out-of-pocket medicine expenditure, catastrophic health spending, and the impact of generic substitution policies on household financial protection — particularly for chronic disease management.

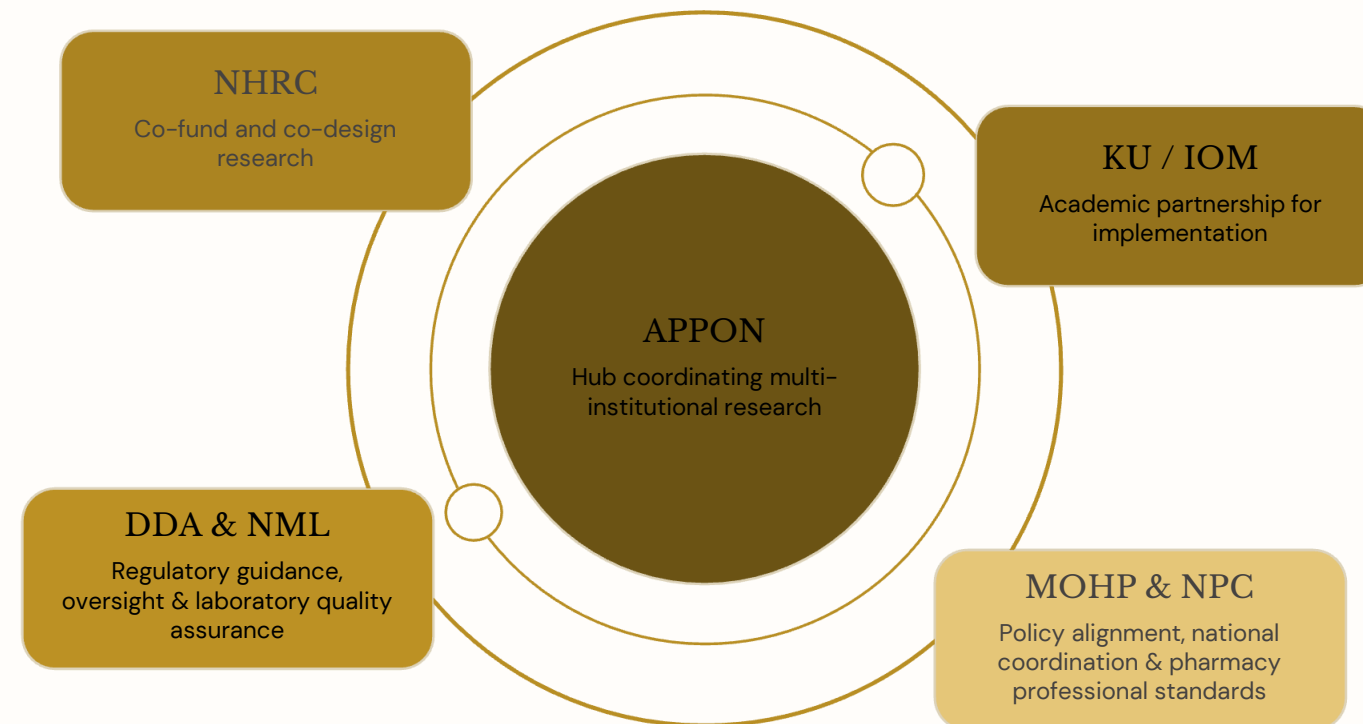


## Antimicrobial Resistance (AMR) Surveillance

Nepal-specific AMR surveillance integrated with pharmaceutical consumption data to identify high-risk prescribing patterns, inform antibiotic stewardship programs, and guide local formulary decisions.

# APPON's Proposed Research Collaboration Model

APPON proposes a structured, institutionalized research partnership with NHRC, Regulatory Bodies, Ministry, council and academic institutions to co-fund, co-design, and co-implement pharmaceutical research that bridges industry insight with scientific rigor.



This hub-and-spoke model positions APPON as the central coordinating body, ensuring research governance integrity while enabling multi-stakeholder contribution. APPON commits to data collection and ethical engagement with all research partners.

## Closing Remarks

# The Path Forward: Key Recommendations

### **Strengthen Domestic Manufacturing**

Invest in GMP upgrading, API & PM production, and technology transfer to reduce import dependency from 50% to below 20% within a decade | Restrict Imports : medicines that domestic industries are already capable of producing in sufficient quantities to meet national demand | Mandatory Public Procurement | Zero tolerance on Quality; Prefer Quality over cost (competitive)

### **Regulatory Strengthening and Capacity Building**

Reform the DDA and the NML | Fast-Track Services | Regulatory Expansion: Immediately establish legal frameworks for the production and regulation of surgicals, nutraceuticals, and cosmeceuticals

### **Institutionalize Research Collaboration**

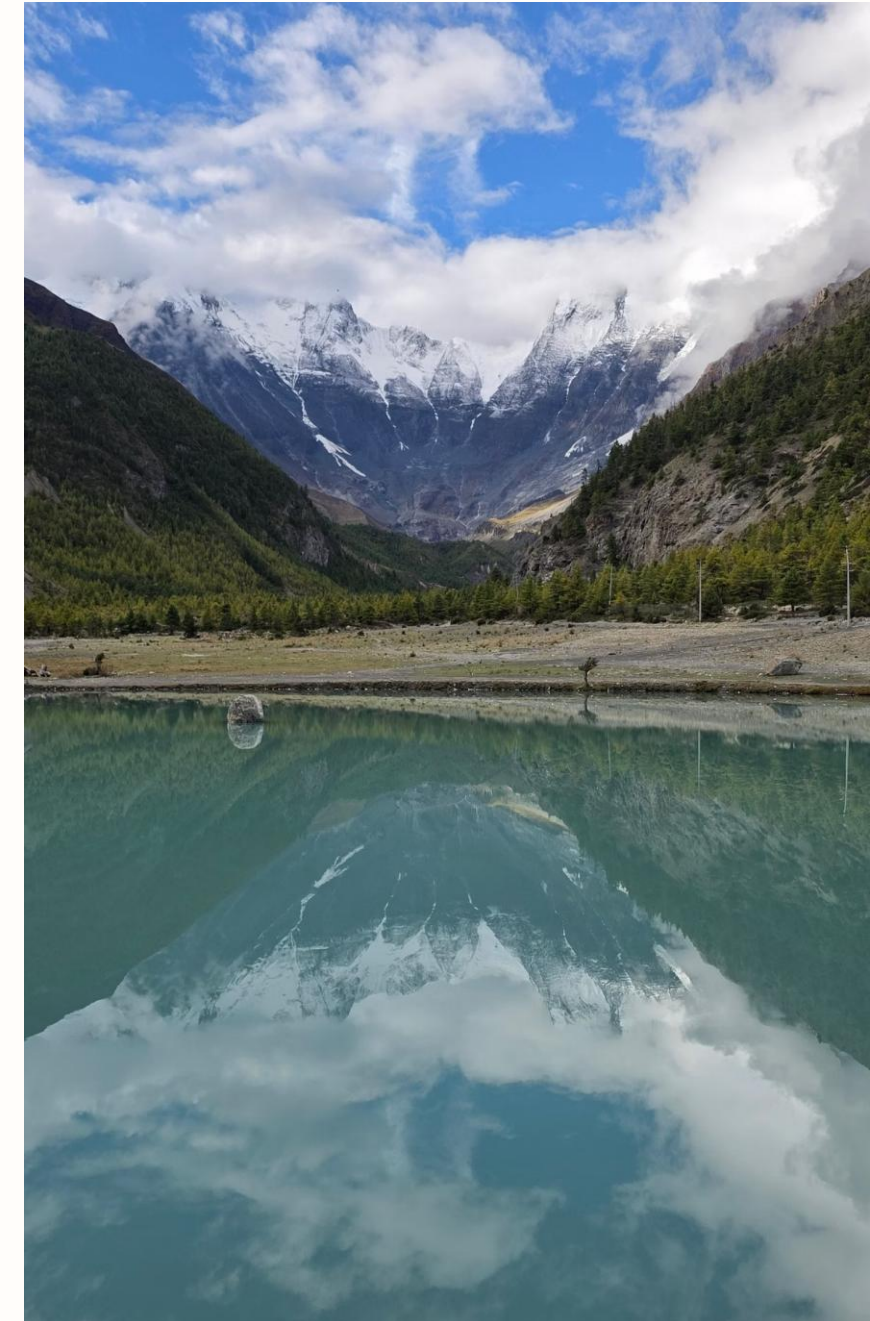
Establish a formal Pharmaceutical Research and Innovation collaboration with NHRC, DDA/NML, Academia, MoHP, NPC and APPON as a permanent multi-stakeholder platform.

### **Fund Priority Research**

Allocate dedicated research funding for bioequivalence, AMR surveillance, herbal medicine validation, and medicine access studies – aligned with NHRC's research governance agenda.

### **Export Promotion and Institutional Support**

Explore Export opportunities & Promotion | Establishment of a Medicine Export Promotion Council



"Nepal's pharmaceutical future cannot be imported — it must be manufactured, regulated, and researched at home. Every tablet made in Nepal is a step toward sovereignty; every study conducted here is a step toward safety."

— Association of Pharmaceutical Producers of Nepal (APPON) | 12th National Summit of Health and Population Scientists, April 2026

APPON stands ready to partner with NHRC, the Government of Nepal, academic institutions, and development partners to build a pharmaceutical sector that is self-reliant, quality-assured, and grounded in evidence — serving the health of every Nepali citizen.



## Connect with APPON

Association of Pharmaceutical Producers of Nepal | [www.appon.org.np](http://www.appon.org.np)



## Summit Details

12th National Summit of Health and Population Scientists | 10–12 April 2026 | The Soaltee, Kathmandu



## Session

Parallel Session: Pharmaceuticals and Access to Medicine | Sunday, 12 April 2026 | 12:10–13:10