

Drug Manufacturing and Access to Medicine in Nepal - A Literature Review of Challenges and Proposed Remediation

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(Received: August 21, 2021; Accepted: February 28, 2022; Published (Web): May 25, 2022)

ABSTRACT: In recent years considerable attention has been paid to the issue of access to medicine. Access to medicine cannot depend on the decision of private industries only but also on government policies and strategies. According to National Health Policy 2019, it is the right of all citizens to have basic health care service including access to safe, efficacious and quality medicine. Nepal is a landlocked country in South Asia. Nepal is a diverse country with a varied culture, language, and biodiversity, but generally affected by the common disease (e.g. tuberculosis, COPD, diarrhoeal disease, diabetes and malaria). There are 65 plus private pharmaceutical industries in operation in Nepal and approximately 60% of drugs are imported from India and third-world countries. The only government owned pharmaceutical industry is 'Nepal Aushadhi Limited' which is not fully operational in manufacturing essential medicine. Private manufacturers focus mainly on brand competition for private consumption but not in essential medicines. Some essential medicines are totally imported from India and other countries (e.g. insulin). The Nepal government has Free Drug List (FDL) consisting 70 medicines that should be provided free to the all patients but these are not accessible to all citizen of rural areas due to poor logistic management, supply chain and transportation facilities. Quality and adequacy of health services and medicines are the main problem in rural areas. This article mainly focuses on challenges of drug manufacturing and access to safe, efficacious and quality medicines in Nepal. It also emphasizes on strategies and policies being implemented to solve these problems. It is obvious that solving the challenges to provide safe, efficacious and quality medicine is collective responsibility of government of Nepal, private manufacturing industries, regulatory bodies, health professional, the patient and NGO, INGOs working on healthcare system of Nepal.

Key words: Access to medicine, safe, efficacious, Nepal, manufacturing, essential medicine, pharmaceutical, challenges

INTRODUCTION

Federal Democratic Republic of Nepal is a landlocked country in South Asia surrounded by India and China.¹ Nepal has a diverse geography, including fertile plains, subalpine forested hills, and eight of the world's ten tallest mountains, including Mount Everest, the highest point on Earth. Nepal has a geographic area of 147 181 km², and its population of just over 29 million has an average life expectancy of 69.2 years.¹ The average north-south dimension of

Nepal is 193 km, and the average east-west dimension is 885 km. Nepal is a multiethnic and multicultural country: 123 languages are spoken, and there are 125 caste and ethnic groups. Nepal is one of the poorest and least developed countries in the world. The country is heavily dependent on remittances, which amount to as much as 29% of gross domestic product (GDP).¹

Nepal is currently divided into 7 provinces and 77 districts and the districts are further subdivided into municipalities, village development committees, and wards. At the district level, there is a chief district officer to maintain law and order, a local development officer to coordinate developmental activities, and a district health officer responsible for all of the district's health activities, including

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Dhaka Univ. J. Pharm. Sci. **20**(3): 373-379, 2022 (June) Centennial Special Issue

DOI: <https://doi.org/10.3329/dujps.v20i3.59802>

organization and management of the district hospital, primary health care centers, health posts, and sub-health posts.¹

Health care services in Nepal are provided by both the public and private sectors. The public health system is governed by various departments under the Ministry of Health and Population (MOHP), Government of Nepal. Public health centers provide

70 essential medicines free of cost.² There are 65 plus pharmaceutical industries involved in manufacturing modern medicines. However there are numbers of critical issue affecting manufacturing medicine and access to medicine in Nepal. This review focuses on the major issues hindering access to medicine in Nepal.



Figure 1. Map of Nepal.

DISCUSSION

Manufacturing and accessibility of evidence based quality medicine are issues of global concern. For low income countries like Nepal, it is crucial to have affordable, evidence based quality medicine. There is bunch of critical issue affecting medicine manufacturing and access to medicine in Nepal. Following are the major challenges.

National income and income distribution. According to general assembly of United Nation (UN) in 1971, Nepal is listed as less developed country (LDC). The only source of access to medicine for poor is public sector, where medicines are distributed free. But the public sector health expenditure in Nepal is very low. In Nepal the public health expenditure is less than 2% of total GDP.³ This is the reason why majority of people have no

regular access to essential medicines. The private health expenditure is more than that of public. Majority of people in Nepal have to pay out of pocket for their healthcare in private.^{2,4,5} So the poor who cannot afford have no access to medicine.

Requirement of international standard Good manufacturing practice (GMP). Local producer of essential medicine must comply with international pharmaceutical standards in order to be eligible to compete in donor tenders.⁶ Nepali producers states that implementation of Good Manufacturing Practice (GMP)-standard is difficult due to low regulatory capacity, insufficient training of staffs in the industry and lack of investment. Nepal has started WHO GMP certification since 2006 on the voluntary basis. Nepal has started GMP code as a mandatory requirement. The WHO GMP certification is based on practice and

takes time. It is difficult to maintain international standard so local manufacturer engage mainly in brand competition for private market, not essential medicines.⁶ Local manufacturers are affected to some extent due to the international harmonization of regulation.

Price of medicines. Price of medicine in Nepal is not affordable for many because of poverty level. Most of the medicines used in Nepal are imported from India or third-world country. Moreover, price of medicines are high because local manufacturer utilize active pharmaceutical ingredient imported from India and China.³ The government of Nepal has Free Drug List (FDL) consisting 70 medicines that should be provided free to the all patient but government of Nepal allocated few health facilities for procuring these medicines.² Most of the essential medicines are not included in FDL, for examples insulin and cardiovascular drugs. Since Nepal is a country with no local insulin production, it entirely depends on India. Insulin access is limited in Nepal due to low availability and highly unaffordable price. Higher price of cardiovascular drugs is one of the reasons for not having access to medicine. The price of essential drugs in private retail pharmacies is significantly higher than public hospital pharmacy.⁷ All the essential medicines are not available in public hospital pharmacies; thus medicines are not accessible and affordable to majority of the patients.

Lack of government interest. Although the government of Nepal is committed to provide 70 essential medicines free of cost to its entire people, when the free medicine in hospital and health post ran out, the only alternative was for the patients to purchase drug from private pharmacies. When patients could not afford the prices of medicines, they often remain untreated.⁴

Nepal's national health policy addresses health as a fundamental right, but in reality only 61.8% of the Nepalese households have access to health facilities within 30 min.⁴ In Nepal overall investment in health sector is very low by the government. Some of the reasons are mentioned below:

- Lack of clear government policies to promote local manufacturer.
- Inadequate implementation of existing health policies. Health policy in Nepal has been influenced by 1978 Alma Ata Declaration emphasizing the preventive, promotive and curative health service.⁴ However, the health system in Nepal faces challenges such as unequal distribution of health care service, poor infrastructure, and inadequate supply of essential medicines.
- Inadequate implementation of Drug Act, 1978 and regulation under leading to smuggling of counterfeit medicines.
- Non availability of essential medicine in public sector.

Low literacy level in people. In Nepal there is low literacy level of medicine consumers. Less than 40% of adult males and 12% of adult female are considered literate. Self-medication and non-doctor prescribing are common in Nepal.⁸ Drugs especially antibiotics are not taken for proper duration.^{8,9} The low literacy level of Nepalese affects the rational use of medicines, affecting the access to medication.

Challenges in medicine regulation. Following are the challenges in medicine regulation in Nepal;

- Lack of full implementation of federalization in the sector of medicine regulation.
- Regulatory framework does not cover the regulation of health technology products, cosmetics and nutraceuticals.
- Limited resources in terms of human, financial and infrastructure.
- Illegal imports of medicinal products due to open and perforated boarder.
- Lack of inter-departmental coordination.
- Lack of dynamic and responsive medicine information systems
- Lack of effective marketing surveillance
- No clarity on online pharmacy, advertisement and market management

Furthermore, in Southeast Asian countries like Nepal, government bodies fix the retail price of

essential medicines. The Department of Drug Administration (DDA), drug controlling authority of government of Nepal, has fixed the maximum retail price of few medicines.¹⁷ However, the timely and regular update of pricing policy and implementation has become a challenge. This has created the problem to the pharmaceutical companies to manufacture the products within the given price limit which has affected the accessibility and availability of the products in market.

Despite on those challenges the Department of Drug Administration is working on strengthening regulatory system with the support of external development partners. WHO also supporting to assess the regulatory system and update it to at least maturity level (ML). Government of Nepal has given the priorities to formulate a new medicine policy and amend the current drug act to harmonize the regulatory system to the global practice. After all there will be reorganization of the regulatory structure as per the regulatory framework approved.

Challenges in medicine manufacturing.

Following are the challenges of manufacturing international standard medicine in Nepal;

- Lack Of sufficient infrastructure like communication network, power supply (load shedding).
- The health care system highly depends on medicine, medical device and diagnostics externally developed and procured especially from India and China.^{2,6}
- Raw material and manufacturing equipment in Nepal are imported. There is no any manufacturer of active pharmaceutical ingredient.³
- Difficulty with GMP implementation and enforcement due to low regulatory capacity, insufficient training of staff in pharmaceutical industry as well as financial limitation.⁶

Challenges to access and distribution. Access is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within 1 hour walk from the homes of population. It is characterized by four main

features- rational selection, sustainable financing, affordable price and reliable health and supply system.¹¹

According to WHO, rational selection of medicines involves choosing medicine appropriate to the countries health situation on the basis of effectiveness, safety and cost.¹¹ Institutionalizing rational choice involves using Essential Medicines Lists (EMLs), based on the best available evidence on local disease burden, efficacy, safety and cost of treatment for those diseases.¹¹ The governments of each country form committee made up of physician and pharmacist to develop Essential Medicine List (EML) of that country.¹¹ In Nepal essential medicines are procured by central government and distributed throughout the country. In Nepal most of prescriptions are not based on EML and health care professional are not familiar with EMLs. Thus access of essential medicine is further impaired.

The health care facilities mainly depend on private sector. The health insurance scheme does not have wide coverage. For non-communicable disease like cardiovascular disease and cancer, people are solely responsible for their care. In most case income of patient is less than medication charges, so most of people do not have access to essential medicines. Price of medicines in Nepal is not affordable because of poverty level and importation cost. In addition to importation cost there are other factors which increase the cost of medicines such as wholesale and retail margins.

Public procurement and distribution is done by government of Nepal through ministry of health. Government may face challenges while procuring medicines such as inadequate quantification, corruption, inadequate supply chain, lack of storage facilities, and lack of transportation facilities in rural areas of Nepal. This has led to impaired access to medicines.

Politics and corruption. Nepal is one of the least-developed countries with corruption. Nepal is suffering a serious problem of corruption. Nepal is ranked 122 out of 175 nations in the Corruption Perceptions Index (CPI).¹² Nepal received a score of

29 out of 100 in the CPI. Scores range from 0 (highly corrupt) to 100 (very clean).¹² This rank and score show that public sector corruption is rampant in Nepal.

Corruption is systemic issue in health and broader systems of governance in many countries. Corruption negatively affects the health outcome. Corruption in the health sector leads to leakage and pilfering of public resource, which ultimately affects manufacturing and access of medicines.

When Badri Shrestha, a resident of Salyan, western Nepal, took his 13-year-old son with a fractured leg to the Institute of Medicine (IOM), Tribhuvan University-one of the Nepal's best treatment centres, he expected his son to receive excellent care. He was wrong. Protesters had shut all hospital services, including the emergency department and him and his injured son had to return home. He had never thought that the country's premier hospital could turn into a battleground and would not provide treatment to people who are ill.¹³ This is a growing concern in Nepal, where strikes and protests stemming from political clashes are more common. Due to the political clashes all the administrative activities are slow including health sector.¹²⁻¹⁴

Strategies to address these challenges: Access of safe, efficacious and quality medicines in Nepal is common responsibility of the government, regulatory system, pharmaceutical industries, health care system, health professionals, NGOs and INGOs working on health sector and patients. International development agencies should also play important role because disease easily cross border and put the whole world at risk. Government of Nepal formed a Social Health Security Development Committee as a legal framework to start implementing a social health security scheme (SHS) after the National Health Insurance Policy came out in 2013.⁴ The program has aimed to increase the access of health care services and essential medicines to the poor and the marginalized, and people in hard to reach areas of the country. Mechanisms should be built for monitoring unfair pricing and unaffordable copayments and an

overall benefit package should be crafted to include coverage of major health services including non-communicable diseases. Health system strengthening should move along with the roll-out of SHS. Improving the efficiency of hospital, motivating the health workers, and using appropriate technology can improve the quality of health services.

In Nepal there is poor availability and lack of affordability of essential medicines like insulin. To make essential medicine more affordable and accessible, government of Nepal should employ strategic price negotiation with domestic industries and develop collaboration with neighboring countries.² Tiered pricing (selling of essential medicines in low and middle income countries at lower price than those in industrialized countries) could be the widespread support from industry, policy makers, civil society and academics as a way to improve affordability and accessibility of essential medicines.¹⁵ There is need to improve the availability of essential medicines, particularly in public sector, and that medicines used in treatment regimen should be made more affordable.

Self-medication and non-doctor prescribing of drugs is common in developing countries like Nepal. Drugs, especially antimicrobials, are not taken for the proper duration. Patients require education and training that will help to decide on the appropriateness of self-medication.^{8,9} Improving access of medicines requires improving public's perception about quality and rational use of medicines and health service via collaborative contribution of all the stakeholders.

Accessibility and affordability of safe efficacious and quality medicines are issues of developing countries including Nepal. Availability of safe, efficacious and evidence based medicines depends on the medicine procurement procedure. More than half of the population of developing countries does not have regular access to essential medicines due to absence of regulatory authorities or limited capacity of medicine procurement and distribution.¹⁶ Majority of hospital pharmacies in Nepal are using expensive direct procurement method for purchasing medicines

and had no formulary, thus purchasing solely depends on doctors' prescription.¹⁶ There is scope for improvement in current procurement practice of hospital pharmacies in Nepal. Many hospital pharmacies and drug stores do not follow the guidelines during medicine procurement and distribution. Adoption to regulation and guidelines of national and international policies is recommended for accessibility of safe, efficacious and evidence based quality medicines. Another challenging issue in procurement is medicine selection. Majority of hospital in Nepal are operated without formulary, the selection process do not follow guidelines, possibly due to the absence of formal pharmacy and therapeutic selection committee.¹⁶ Procurement officers could utilize the model and guide of quality assurance system developed by WHO or United States Pharmacopoeia (USP). Hospital pharmacies in Nepal can also minimize the risk of purchasing poor quality medicines and increase accessibility of evidence based medicines by utilizing the list generated by the WHO prequalification of medicine program.

Domestic manufacturer can also help to improve access of quality medicines by incorporating technologies to avoid counterfeit medicines, e.g. tamper proof technologies, use of special overt and covert features on their packaging and use of special coding system.¹¹ Furthermore accessibility of safe, efficacious and quality medicine can be enhanced by proper training of health care workers involved in manufacturing and distribution of medicines.

The regulatory body must take initiative on giving genuine evidence-based information about generic and branded medicine to medical prescribers. In Nepal, the information on generic prescribing and promotion is essential as it substantially reduces medicine cost and can enhances the easy access of medicine to the patients as they are not compelled to look for specific medicine with a brand name. The regulatory body should make strategy to formulate and evaluate the hospital guideline implementation and policy to monitor and improve the promotion of use of drug rationally in a health care setting. Rather

than controlling the retail price of medicines, one of the important aspects could be promotion of the use of generic medicine to control the escalating medicine.¹⁸ The presence of more generic medicines in pharmaceutical market also makes the market competitive, which ultimately plays an important role in lowering the prices of other medicines including generic equivalents.¹⁷

CONCLUSION

In Nepal the manufacturing and access to essential medicine has been increasing day by day. Nepal has already taken steps to increase access of safe, efficacious and affordable essential medicine to all citizens. The steps should be progressive. The article highlighted numerous challenges – lack of government interest, poor procurement and distribution channel, challenges in medicine manufacturing, low literacy level of patient, regulatory challenges, and price of medicines. All the stakeholders-government, regulatory authority, pharmaceutical industries, health care professional, patients and other development partners (NGOs, INGOs) should work together to overcome these challenges.

The focus on access to medicine is limited. Policy maker should take broader view of access to treatment instead of access to medicine. Access of medicine solely cannot improve level of health in developing countries like Nepal so it is important to expand the concept to access to treatment for the benefit of patient.

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