Preparedness of Nepal's Pharmaceutical Sector to Cope with the Challenges of the Country's LDC Graduation

South Asia Watch on Trade, Economics and Environment (SAWTEE)

TWN
Third World Network

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NOTE

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1 Introduction

NEPAL met two of the three criteria for graduation from its least-developed-country (LDC) status and was eligible for graduation in 2018. It did not meet the income criterion. Owing to this and the disastrous earthquake that struck the country in April 2015, Nepal felt vulnerable to falling back should it graduate based on the other two criteria. Hence, Nepal requested the United Nations Committee for Development Policy (CDP), which reviews LDCs' graduation, for a deferral. The CDP accepted Nepal's request and agreed to undertake the review again in 2021. In February 2021, the CDP reviewed a few LDCs, including Nepal, for their eligibility for graduation. As in 2018, Nepal again met two criteria for graduation, but not the income criterion. Following due process, the CDP has recommended the United Nations Economic and Social Council (ECOSOC) to graduate Nepal from the LDC category. However, instead of the usual three-year transition period, it has recommended providing a five-year transition period owing to the impacts of the COVID-19 pandemic. Thus, Nepal is set to leave the LDC group and become a developing country in November 2026.

As an LDC member of the World Trade Organization (WTO), Nepal receives special and differential treatment in several areas related to trade. One of these relates to the application of the WTO's requirements on intellectual property in its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to the pharmaceutical sector. As an LDC, Nepal enjoys a general transition period until 1 July 2034 for implementation of the TRIPS Agreement. While the WTO has granted this general transition period to LDCs, it has also specifically recognized that Nepal and other LDCs need not provide patent protection to pharmaceutical products until 1 January 2033. To complement this decision, the

WTO General Council also decided to waive certain obligations regarding mailbox applications and exclusive marketing rights that may otherwise apply pursuant to Articles 70.8 and 70.9 of the TRIPS Agreement (UN-DESA 2024).

In the absence of patent protection, generic manufacturers in Nepal have full freedom to produce any pharmaceutical product through reverse engineering (i.e., as generic versions of pharmaceutical products). As Bangladesh's case has shown, this is an important factor for the growth of domestic pharmaceutical manufacturing capacity in LDCs and in ensuring people's access to medicine (UNCTAD 2011; Gay and Gallagher 2020).

The idea that credible domestic production capabilities in pharmaceuticals are critical in addressing health concerns has been buttressed at forums such as the 61st World Health Assembly. Nepal's National Drug Policy 1995 envisages self-sufficiency in medicines, considering it as a key to access to safe, effective and affordable medicines. It aimed at producing 80 percent of the medicines listed in Nepal's Essential Drugs List (EDL) by 2005. The country's National Health Policy 2014 has also reiterated the self-sufficiency aspiration. However, Nepal is still far from achieving the self-sufficiency goal. According to the Department of Drug Administration (DDA), which is the regulatory agency related to pharmaceuticals in Nepal, of the drugs listed in the EDL, Nepal produces 52 percent of the solid and liquid forms of drugs, 86 percent of external preparations such as ointments, and 24 percent of sterile preparations such as injections. Biologicals, such as vaccines (for human use), are not produced in Nepal.

It has been an agenda of the World Health Organization (WHO) since the 1970s that the domestic pharmaceutical sector needs to expand for improvements in public health outcomes (Brhlikova et al. 2015). Moreover, the expansion of domestic pharmaceutical production capabilities is critical not only from the viewpoint of reliable access to affordable medicines but also for the overall economic development agenda in developing countries in which industrialization is a major driver (Brhlikova et al. 2015; UNCTAD 2011). Due to the critical need for a strong pharmaceutical

production base, many developing countries have made efforts to achieve self-sufficiency in pharmaceuticals. In South Asia, countries such as India and Bangladesh have built their capacities to not only cater to their domestic needs but also export, the latter being the only LDC to do so in significant amounts and in a sustained manner (UNCTAD 2011; Gay and Gallagher 2020).

Development of the domestic production base for pharmaceuticals depends on a number of factors. In relation to the production of pharmaceutical items in LDCs, the aforementioned exemption provided by the WTO TRIPS Agreement and related decisions thereafter is significant. As stated above, generic manufacturers in Nepal have full freedom to operate and produce any generic pharmaceutical product. Nepal can also export such medicines to jurisdictions where patent protection does not exist for the specific medicine or to a country that has adopted policy options such as compulsory licensing to overcome the patent barrier.

Upon exiting the LDC group, however, Nepal will need to fully implement the TRIPS Agreement, including by providing patent protection to pharmaceutical products. This will significantly limit the freedom of Nepal's pharmaceutical industry to produce generic pharmaceutical products, as it will only be able to produce off-patent medicines. Where patents are granted in Nepal, generic versions can only be produced by invoking public health flexibilities in the TRIPS Agreement such as a compulsory licence or if there is a successful opposition to the patent application, for example, in the case of patent applications for only minor modifications to known substances (Dhar and Joseph 2019). The use of TRIPS flexibilities depends in turn on various factors such as the domestic patent law, regulations and directives, institutional and policy support, etc.

In this context, the objectives of this study are to:

- Analyze the strengths and weaknesses of Nepal's pharmaceutical industry to face pharmaceutical product patent protection
- Identify the major legal, policy and institutional challenges for the optimal use of TRIPS flexibilities

- Identify the preparedness of the pharmaceutical industry to make use of TRIPS flexibilities
- Develop a set of recommendations/strategies to optimize the use of TRIPS flexibilities and effect a smooth transition to the TRIPS pharmaceutical product patent regime.

Regarding data collection for this study, while some information was collected through secondary sources, primary data collection was the major means given the lack of adequately published information and data required for the study. We conducted virtual interviews through telephone and the use of social media and meeting platforms such as Zoom and Skype with 11 pharmaceutical manufacturers and importers (owners, executives and managers), office bearers of the pharmaceutical industry association, pharmacists and regulators (specifically officials of the DDA). Each in-depth interview spanned 60 to 90 minutes. Follow-up interviews were conducted in most cases for clarification and further information.

Despite our best possible efforts, this research has some limitations. Soon after we commenced the study, the COVID-19 pandemic changed the usual course of things. The Government of Nepal called for a nationwide lockdown. This badly hampered our access to an adequate number of relevant stakeholders. Moreover, almost all the stakeholders' attention was diverted to tackling the pandemic and there was inadequate response to our request for information for the study. Since the study was to be based mainly on primary data, this was a serious limitation. Nevertheless, we believe that the findings we present based on the limited amount of data and information we could gather are not off the mark.

The second major limitation is the unavailability of disaggregated data on the domestic production of generic versions of patented and off-patent medicines. This is a crucial aspect in analyzing the impact of LDC graduation since it is the production of generic versions of patented medicines that could suffer from graduation. In the absence of such data, we have relied on information provided by a few manufacturers regarding the composition of their production to perform our analysis.

The paper is structured as follows: We begin with a brief history of Nepal's pharmaceutical sector. This is followed by a discussion of the present characteristics of the sector, and Nepal's institutional and policy structures, challenges and opportunities in the sector, especially in the context of the country's WTO membership and hence the TRIPS provisions. We then briefly discuss issues related to the use of TRIPS flexibilities by Nepal's pharmaceutical sector. Finally, we provide recommendations regarding Nepal's preparedness to address the challenges that it could face in the pharmaceutical sector upon its graduation from LDC status and conclude the paper.

2 Brief History of Nepal's Pharmaceutical Sector and Intellectual Property System

WITH the formulation of development plans starting in the mid-1950s, Nepal's health sector saw a gradual expansion. The first dedicated health policy, named the 15-year Health Policy, was rolled out in the early 1970s (Khanal 2017). The Royal Drugs Research Laboratory (RDRL) was set up in 1964 (Khanal 2017), which followed the establishment of the Royal Drugs Ltd. as a public sector undertaking. It started manufacturing allopathic medicines in 1972 (Brhlikova et al. 2015).

The Institute of Medicine (IoM), under Tribhuvan University, introduced a pharmacy diploma course in 1972. In the same year, the Nepal Pharmaceutical Association, which included professionals such as pharmacists, chemists and biochemists, was set up (Brhlikova et al. 2015). By 1979, there were over 400 pharmacies throughout the country, especially in urban areas. This increased to roughly 7,000, including retail and wholesale pharmacies, by 1992 (Khanal 2017).

The first private sector pharmaceutical unit, Chemidrug, was established in 1971. By 1979, two more pharmaceutical companies were established, but Nepal was still very much an extended market for Indian companies and multinationals as there was little domestic capacity (SAWTEE and Matrix 2005). Domestic production capacity of medicines started growing by the late 1980s. Pharmaceutical producers established the Association of Pharmaceutical Producers of Nepal (APPON) in 1990.

The Drug Act 1978, which was Nepal's first dedicated regulatory code for pharmaceuticals, led to the formation of the pharmaceutical

sector regulator, the DDA, in 1979. The DDA was given the mandate to monitor the import, distribution, storage and production of medicines as well as prohibit the abuse and misuse of drugs and misleading information on medicines to ensure safe, effective and affordable medicines. Today, the DDA engages in important functions such as drug registration, licensing and monitoring of drug production and sale, granting of Good Manufacturing Practices (GMP) certificates, and assessment of quality and availability of medicines mainly via information exchange from pharmacies, producers and importers. The DDA operates through its offices in Kathmandu, Biratnagar, Nepalgunj and Birgunj.

Similarly, as per the Drug Act 1978, RDRL was to be the key national research laboratory to assess drug quality and efficacy. Today, the National Medicine Laboratory (as RDRL is now known) is the country's national drug testing, research and control body. However, it remains without WHO prequalification, bioequivalence testing capacity or ISO 17025 certification although the National Health Policy 2014 aims at attaining such standards (WHO 2018).

During the past two decades, Nepal saw a significant rise in the establishment of pharmaceutical manufacturing units. Domestic production of different kinds of medicines has increased over the years.

Regarding the country's intellectual property (IP) system, Nepal is a signatory to two World Intellectual Property Organization (WIPO) treaties, namely the Paris Convention on the Protection of Industrial Property and the Berne Convention on the Protection of Artistic and Literary Works. At the national level, the first Patent, Design and Trade Mark Act was enacted around 85 years ago by Prime Minister Juddha Shumsher Jung Bahadur Rana when industrial and commercial activities began expanding in the country (Sharma and Pande 2018). However, due to the lack of data, it is not clear how many and what kinds of IP were registered under this Act. In 1965, a new Patent, Design and Trade Mark Act replaced the old Act and a Copyright Act was also enacted. While the Patent, Design and Trade Mark Act of 1965, with a few amendments, survives to this day, a new Copyright Act enacted in 2002 replaced

the old Copyright Act of 1965. In 2017 the government prepared the first Intellectual Property Policy. It has also prepared a draft of a new integrated Bill covering all different types of intellectual property, which, upon enactment, will replace the existing Patent, Design and Trade Mark Act and Copyright Act.

In the pharmaceutical sector, the most relevant form of IP is patents. Despite the 85-year history of a legal regime to protect patents in Nepal, the country has not seen the registration of many patents related to any sector (Sharma and Pande 2018). In the case of pharmaceuticals, it seems there has been no patent registration in Nepal. This could be because, among other factors, holders of pharmaceutical patents did not feel threatened by Nepal, a poor country with a low technological base and level of innovation, and hence were not interested in seeking patents in Nepal. In fact, as an LDC member of the WTO, Nepal need not provide patent protection to pharmaceuticals. However, after it graduates from LDC status, it will be obligated to do so in accordance with TRIPS Agreement rules. As such, it should amend/introduce relevant domestic IP legislation fully incorporating all exemptions and flexibilities available to those implementing the Agreement.

While Nepal has made good progress in the pharmaceutical sector compared with the past, it appears that it might also not be making full use of the policy options available as it prepares for graduation and implementation of the TRIPS Agreement, as we analyze in later sections. First, however, we discuss the characteristics of Nepal's pharmaceutical sector.

3 Characteristics of Nepal's Pharmaceutical Sector

3.1 Overview

THE right to basic healthcare, in which medicines are a critical component, is enshrined as a fundamental right in Nepal's Constitution. The National Drug Policy 1995 and National Health Policy 2014 stipulate access to safe, efficacious and affordable medicines as a critical goal. However, pharmaceutical consumption in Nepal, financed predominantly by household expenditure, or what is termed out-of-pocket expenditure, is problematic owing to the lack of accessibility as well as affordability.

Nepal's latest available National Health Accounts, covering the period 2012/13 to 2015/16, show that its total health expenditure in fiscal year (FY) 2015/16 was NPR 151 billion, which was 6.7 percent of the country's gross domestic product (GDP).[1] This included NPR 9.7 billion worth of capital expenditure, primarily on physical infrastructure such as residential and non-residential buildings. Of the remaining NPR 141.3 billion in current health expenditure, slightly over 55 percent was out-of-pocket expenditure while health expenditures by the government, non-governmental organizations (NGOs) and rest-of-the-world financing schemes[2]

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1 The National Health Accounts track consumption of health-related goods and services, looking at expenditures made by the government, households, donors, non-governmental organizations and health insurance providers.

2 Rest-of-the-world financing schemes mainly include two sub-categories: compulsory schemes and voluntary schemes. These comprise financial arrangements involving institutional units or managed by institutional units that are resident abroad, but who collect, pool, resource and purchase healthcare goods and services on behalf of residents, without transiting their funds through a resident scheme.

were about 22 percent, 12 percent and 9 percent, respectively (GoN 2018). Less than 2 percent of the current health expenditure came from enterprise financing schemes.[3]

The National Health Accounts Assessment published in 2018 terms the out-of-pocket health expenditure as catastrophic because health-related expenditures for about 2.4 percent of households are about 25 percent of their total annual household expenditure (GoN 2018). According to the assessment, 1.9 percent of households were pushed below the poverty line owing to high out-of-pocket health expenses.

In terms of expenses by disease type, signifying the rising incidence of non-communicable diseases (NCDs), over 27 percent of the total health expenditure in Nepal is spent on NCDs, and only a third of this comes from public sources (GoN 2018). Over 60 percent of the out-of-pocket health expenditure goes into NCDs.

Out of the total health expenditure in Nepal in 2015/16, slightly over a third was spent at pharmacies and medical goods providers. This is corroborated by the *Nepal Medical Products Profile 2019*, which states that 29 percent of the annual per capita spending on health in Nepal goes into medicines (WHO 2019). As of July 2019, there were 20,232 retail pharmacies in Nepal, of which 70 percent sold allopathic medicines. The number of wholesale pharmacies was 3,351 (DDA 2019). Both wholesalers and retailers are critical components in the pharmaceutical distribution chain.

According to APPON, Nepal's pharmaceutical market – or the monetary value of total annual consumption of medicines in Nepal – is valued at around NPR 45 billion, which is more than five times the value two decades ago. WHO estimates that nearly 90 percent of the annual spending on medicines in Nepal is out-of-pocket expenditure (WHO 2019). In fact, nearly two-thirds of all health-related out-of-pocket expenditures are spent on purchasing

[3] Enterprise financing schemes include arrangements where enterprises/companies directly provide or finance health services for their employees.

medicines (nearly all of it on purchasing allopathic medicines) and medical goods (GoN 2018).

The shifting burden of diseases towards NCDs undermines affordability and hence access. According to a 2013 Nepal Health Research Council (NHRC) survey, access to medicines remains highly problematic when it comes to NCDs (Aryal et al. 2014). The survey found that only under 5 percent of the sampled respondents diagnosed with diabetes were taking the required medicines. Even more problematic is that over three-quarters of those living with diabetes go undiagnosed and hence untreated, meaning that many people continue to live with morbidities and experience premature mortality.

Public procurement of medicines in Nepal is carried out to distribute medicines free of cost to vulnerable groups as well as to address major health issues such as maternal and infant mortality (KC et al. 2013). Public procurement is centralized in that the Logistic Management Division under the Department of Health Services handles the majority of the public procurement of medicines. Industry sources suggest that annual public procurement of medicines in Nepal amounts to around NPR 3 billion, which is about 7 percent of the size of the Nepali pharmaceutical market. The share of the domestic pharmaceutical industry in annual public procurement, according to a senior executive of a domestic pharmaceutical company, is more than 60 percent. However, only about a dozen domestic firms dominate the arena of public procurement of medicines in Nepal.

It is important to highlight that in public procurement of medicines, domestically manufactured medicines are given a preference margin of 15 percent. This could be why, as informed by APPON representatives and senior executives of some pharmaceutical firms, the share of imports in annual public procurement has been declining gradually.

3.2 Major medicines consumed in Nepal

Major factors that shape the consumption of medicines are the population-wide burden of disease, demographic changes such as ageing and population growth, and public health policies (Bumpas, Kostermans, and Nair 2007). According to the Nepal Burden of Disease 2017 report, nearly two-thirds of deaths in Nepal at present can be attributed to NCDs (NHRC, MoHP, and MEOR 2019). The National Health Policy 2014 suggests that while CDs like tuberculosis and measles are under control, NCDs such as heart-related diseases, cancer, diabetes and respiratory diseases are the new drivers of mortality and morbidity in Nepal (GoN 2014). Among non-NCD diseases, diarrheal diseases, lower respiratory infections, drug-susceptible tuberculosis, neonatal encephalopathy, tetanus and measles are ranked among the top causes of mortality.

There has been a significant shift in the burden of diseases since 1990 (Table 1). While deaths caused by communicable, neonatal, maternal and nutritional diseases such as diarrheal diseases and lower respiratory infection declined by over 70 percent between 1990 and 2017, those caused by NCDs such as ischemic heart disease, ischemic stroke and Alzheimer's disease registered between 20 percent and 100+ percent growth.

Table 1: Top 10 causes of deaths in 1990 and in 2017

1990		2017		
Disease	**Rank**	**Disease**	**Rank**	**Percentage change in death rate per 100,000 population since 1990**
Lower respiratory infections (Communicable, neonatal, maternal and nutritional diseases or CNMN group)	1	Ischemic heart diseases (NCD)	1	60
Diarrheal diseases (CNMN)	2	Chronic obstructive pulmonary disease (COPD) (NCD)	2	15
Ischemic heart diseases (NCD)	3	Diarrheal diseases (CNMN)	3	-74
Neonatal encephalopathy (CNMN)	4	Lower respiratory infections (CNMN)	4	-78
Chronic obstructive pulmonary disease (COPD) (NCD)	5	Intracerebral hemorrhage (NCD)	5	-4
Drug-susceptible tuberculosis (CNMN)	6	Ischemic stroke (NCD)	6	20
Tetanus (CNMN)	7	Asthma (NCD)	7	-47
Measles (CNMN)	8	Drug-susceptible tuberculosis (CNMN)	8	-73
Other neonatal disorders (CNMN)	9	Alzheimer's disease (NCD)	9	>100
Asthma (NCD)	10	Neonatal encephalopathy (CNMN)	10	-79
Intracerebral hemorrhage (NCD)	12	Other neonatal disorders (CNMN)	17	-74
Ischemic stroke (NCD)	15	Tetanus (CNMN)	81	-98
Alzheimer's disease (NCD)	29	Measles (CNMN)	119	-99

Source: NHRC, MoHP, and MEOR (2019)

Insights into consumption of as well as access to medicines are further provided by the Years of Life Lost (YLL) assessment, which captures causes of premature mortality, or death earlier than the prevalent life expectancy average.[4] Table 2 outlines the major drivers of YLL in Nepal.

The conditions/diseases causing premature mortality are rather mixed, with both communicable and non-communicable diseases causing such deaths. There are also significant changes in YLL due to different diseases in 2017 compared with 1990. It is important to note that the "HIV/AIDS and other diseases" category accounted for less than 0.01 percent of total YLLs (with a rank of 208) in 1990, but increased significantly to 2.15 percent of total YLLs (with a rank of 10) in 2017. In the case of tuberculosis, according to the *National Tuberculosis Prevalence Survey 2018–2019*, there was an average annual reduction of 3 percent in new TB cases in the past decade, which was better than the global reduction of 1.5–2 percent.[5] However, in 2018, 69,000 people developed TB in Nepal and there were 117,000 people living with TB in the country, with TB incidence higher than expected. Additional effort is needed to meet the WHO's "End TB Strategy", for which access to medicine is an essential requirement.

Similarly, another disease that needs attention is hepatitis C. The total burden of infection with the hepatitis C virus (HCV) in Nepal is estimated to be 130,000 (Shrestha 2016). HCV is one of the most important causes of morbidity and mortality, particularly for people living with HIV (Naveira et al. 2018). Although the cost of treatment for HCV has declined over the years, accessibility to drugs and their affordability is still an issue for many people living with HCV infection in Nepal (Shrestha 2016).

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4 YLL gives greater weight to deaths at a younger age and lesser weight to deaths at an older age. The basic formula to calculate YLL is: YLL(c,s,a,t) = N(c,s,a,t) x L(s,a), where N(c,s,a,t) is the number of deaths at age a of sex s due to cause c in a given year t and L(s,a) is the years of life lost for a death at age a for sex s (see https://www.who.int/data/gho/indicator-metadata-registry/imr-details/4427).

5 https://www.who.int/nepal/news/detail/24-03-2020-nepal-completes-first-national-tuberculosis-prevalence-survey-another-step-towards-endtb

Table 2: Top 10 causes of YLL (1990 and 2017)

1990		2017	
Disease	**Percentage of total YLL**	**Disease**	**Percentage of total YLL**
Lower respiratory infections (Communicable, neonatal, maternal and nutritional diseases or CNMN group)	17	Ischemic heart diseases (NCD)	11
Diarrheal diseases (CNMN)	13	Lower respiratory infections (CNMN)	8
Neonatal encephalopathy (CNMN)	8	Neonatal encephalopathy (CNMN)	6
Measles (CNMN)	6	Chronic obstructive pulmonary disease (COPD) (NCD)	5
Tetanus (CNMN)	6	Diarrheal diseases (CNMN)	3
Other neonatal disorders (CNMN)	4	Other neonatal disorders (CNMN)	3
Drug-susceptible tuberculosis (CNMN)	3	Drug-susceptible tuberculosis (CNMN)	3
Protein energy malnutrition (CNMN)	3	Pedestrian road injury	2
Neonatal preterm births (CNMN)	3	Intracerebral hemorrhage (NCD)	2
Ischemic heart diseases (NCD)	2	HIV/AIDS and other diseases (CNMN)	2
Chronic obstructive pulmonary disease (COPD) (NCD)	2	Neonatal preterm births (CNMN)	2
Intracerebral hemorrhage (NCD)	1	Protein energy malnutrition (CNMN)	1
Pedestrian road injury	1	Tetanus (CNMN)	<1
HIV/AIDS and other diseases (CNMN)	<1	Measles (CNMN)	<1

Source: NHRC, MoHP, and MEOR (2019)

While drivers of premature deaths comprise both communicable and non-communicable diseases, conditions that reduce the quality of life and result in morbidity – measured as Years Lived with Disability (YLD)[6] – are predominantly non-communicable conditions such as chronic obstructive pulmonary disease (COPD), back pain, migraine, nutritional challenges, age-related hearing impairment, depression and anxiety, type-II diabetes and vitamin A deficiency.

When it comes to risk factors that cause premature deaths, the major ones are high blood pressure, smoking and high fasting plasma glucose, among others (Table 3).

Accordingly, in recent years the most consumed medicines in terms of therapeutic categories in Nepal are related to NCDs (Table 4). According to APPON, this accounts for over 60 percent of the annual sale of medicines in Nepal.

Table 3: Top 10 risk factors for premature death (all ages, both sexes) in 2017

Risk factor	Percentage of deaths attributable
High blood pressure	12
Smoking	11
High fasting plasma glucose	9
Ambient particulate matter	7
High bad cholesterol (LDL)	7
Household air pollution	6
Impaired kidney function	6
Unsafe water	5
High BMI	5
Low whole grains	4

Source: NHRC, MoHP, and MEOR (2019)

[6] YLD is a measurement of the burden of disease. It is calculated by multiplying the prevalence of a disorder by the short- or long-term loss of health associated with that disability (see https://www.nimh.nih.gov/health/statistics/disability/what-are-ylds.shtml).

Table 4: Top 15 therapeutic categories, 2019

Group	Rank
Anti-infectives	1
Gastrointestinal	2
Respiratory	3
Cardiac	4
Dermatology-related	5
Pain management/Analgesics	6
Nutrition-related (such as vitamins and minerals)	6
Antidiabetic	8
Neuro-related	9
Gynaecology	10
Ophthalmology	11
Urology	12
Hormones	13
Anti-parasitic	14
Hepatoprotectives	15

Source: APPON

Anti-infectives, which have continued to be the top therapeutic group for over two decades, accounted for over a fifth of the total medicines consumed in Nepal in 2019. These are followed by gastrointestinal, respiratory, cardiac, dermatological and pain management groups, with each group accounting for 8–10 percent of annual medicine consumption. The top 10 therapeutic categories account for more than 85 percent of the annual drug consumption in Nepal.

According to APPON, Nepal's pharmaceutical consumption in 2019 was more than 14 percent higher than that in 2018. The highest growth in consumption, at over 30 percent, was for drugs in the antidiabetic group. Consumption of drugs in the neurological, gastrointestinal, respiratory, ophthalmological, urological and hormonal groups grew by more than 15 percent each. Consumption growth of anti-infectives, gynaecological and nutrition-related medicines was over 10 percent.

As discussed above, issues related to drug consumption should also take into account challenges in terms of accessibility and affordability of medicines necessary to treat diseases such as HIV/AIDS and hepatitis C.

3.3 Domestic production

As of July 2019, there were 73 domestic pharmaceutical manufacturers in Nepal producing allopathic/modern medicines (DDA 2019). Of these manufacturers, only 62 are fully operational, according to APPON. Many of these 62 domestic pharmaceutical producers are large firms as per the classification of Nepal's Industrial Enterprises Act 2020.[7]

Based on the annual sales figures in 2019, 13 of the 20 dominant pharmaceutical companies in Nepal are Nepali firms (Table 5). The remaining seven are foreign firms, mostly Indian, that supply medicines to Nepal through exports (Table 6). Nepal Aushadhi Limited is the only public sector undertaking that produces allopathic medicines in Nepal but does not feature in the list of top companies. It used to be a major producer but was then shut for over seven years for various reasons. It resumed production in early 2018.

Among the top foreign firms (Table 6), Alkem Laboratories, Micro Labs and Sun Pharmaceuticals are the top three and ranked 4th, 7th and 10th in terms of their share in the overall Nepali pharmaceutical market in 2019.

[7] According to the Industrial Enterprises Act 2020, firms with fixed capital above NPR 500 million are classified as large enterprises.

Table 5: Top domestic firms in the Nepali pharmaceutical market

Firm	Rank among domestic firms	Rank overall in the Nepali pharmaceutical market
National Healthcare	1	1
Deurali-Janta Pharmaceuticals	2	2
Nepal Pharmaceuticals	3	3
Aristo Pharmaceuticals	4	5
Quest Pharmaceuticals	5	6
Lomus Pharmaceuticals	6	8
Asian Pharmaceuticals	7	9
Time Pharmaceuticals	8	12
Arya PharmaLab	9	14
Intas Pharmaceuticals	10	15
Amtech Med	11	16
Magnus Pharma	12	19
Curex Pharmaceuticals	13	20

Source: APPON

Table 6: Top foreign firms in share of Nepali pharmaceutical market

Firm	Rank among foreign companies	Rank overall in the Nepali pharmaceutical market
Alkem Laboratories	1	4
Micro Labs	2	7
Sun Pharmaceutical Industries	3	10
Cipla	4	11
Glenmark Pharmaceuticals	5	13
Abbott	6	17
Blue Cross Laboratories	7	18

Source: APPON

The above top 20 firms, according to APPON, accounted for around 60 percent of the Nepali pharmaceutical market in 2019.

Nepal's pharmaceutical sector directly employs around 15,000 people (excluding temporary daily wage workers). The need for advanced production-related knowledge means several firms, especially the major ones, employ foreign consultants. However, except for the extremely small number of foreigners working in these highly skilled areas, the rest employed are Nepali citizens.

A senior executive of one of the major pharmaceutical manufacturing companies observes that no pharmaceutical company in Nepal has a research and development (R&D) division in the real sense of the term. He sees this as natural given the small scale of production, associated risks linked to non-recovery of investment, lack of policy incentives and absence of public funding. As he claimed, firms, on their own, will not be able to raise R&D infrastructure.

Domestic pharmaceutical manufacturers cater to about 50 percent of the Nepali market in volume terms. In monetary terms, according to industry insiders, the share of domestic pharmaceutical manufacturers is about 45 percent due to the comparatively lower-priced Nepali pharmaceuticals against higher-priced and technologically complex products such as inhalers, injectables, critical care products, anti-cancer medicines, vaccines and new molecules produced abroad (DoHS 2018; Dhakal et al. 2016; Brhlikova et al. 2015; Poudel and Ishii 2016). There has been an expansion of domestic pharmaceutical production in recent years as the share of imports in the Nepali pharmaceutical market has declined from about 70 percent in the early 2000s (SAWTEE and Matrix 2005).

According to APPON, seven of the top 20 brands of medicines sold in Nepal in 2018 were produced by domestic pharmaceutical manufacturers. Until July 2019, a total of 19,106 brands of pharmaceutical products had obtained marketing authorization (DDA 2019). Of these, 9,940 were foreign brands and the remaining 9,166 were domestic brands. Brhlikova et al. (2015) found that of the 15 highest-selling medicines produced by

domestic pharmaceutical manufacturers in Nepal, nearly half were on the Essential Drugs List. The Essential Drugs List 2016 has 390 medicines under generic formulation names, of which nearly 80 percent are being produced in Nepal, as informed by APPON.

Nepali pharmaceutical manufacturers produce medicines belonging to various therapeutic groups. In the cardiac therapeutic group (which includes hypertension), Nepali producers have a market share of roughly 50 percent. For orally administered anti-diabetes drugs – since insulin is not manufactured domestically – the share of domestic producers is 30–40 percent. According to industry sources, two dozen or so firms produce hypertension drugs but three to four dominant players command two-thirds of the domestic producers' share. In the COPD group, which falls in the respiratory therapeutic category, domestic firms' share is minimal given that this condition requires inhalers which are not currently produced domestically. According to APPON, a few firms have been attempting to manufacture injectables as well as metered-dose inhalers.

Backward linkages, which are considered a key element for growth and development via industrialization, remain mostly underdeveloped in the sector. Much like two decades ago, Nepal's pharmaceutical industry imports virtually all inputs from active pharmaceutical ingredients (APIs) to excipients, suspending agents, preservatives, packaging materials and other agents and colours. Two major factors have been highlighted for the lack of backward linkages: i) absence of policy support for the development of ancillarization, and ii) issue of scale and sophistication (especially in producing APIs). Regarding the first, there are areas wherein there is scope to develop ancillary units and clusters, such as establishing special zones for ancillary activities, but this would require active industrial policy support that incentivizes and guides such activities. In terms of the second factor, according to some respondents, producers from China and India supply inputs at unit prices that will be difficult for domestic producers to achieve unless the government institutes relevant policy measures and provides incentives. Nepali producers, therefore, are currently producing mainly final products.

Despite minimal backward linkages, the industry association estimates that there is value addition of around 50 percent in pharmaceutical manufacturing in Nepal. For instance, according to APPON, in 2015, NPR 16.5 billion worth of pharmaceuticals were produced by the Nepali pharmaceutical industry and this required input imports worth NPR 8.3 billion (NPR 6.1 billion of APIs and NPR 2.2 billion of packaging materials).

Regarding the quality of medicines produced in Nepal, a study conducted by the Nepal Health Research Council in 2017 sheds some light (Karki et al. 2017). The research, covering 90 health facilities in 15 districts in Terai, Hills and Mountains, assessed 10 different kinds of medicines, with five different brands of each. Some of these medicines belonged to the list of essential drugs that are distributed for free by the government. It found that labelling requirements such as expiry date, storage requirements and usage directions were mostly met by the medicines while cautions were labelled in only 80 percent of the medicines. Paracetamol supplied by the government was found to be substandard while eight medicines, including two essential ones supplied by the government and six non-essential medicines supplied by the private sector, failed to meet the required standard. There were almost 400 percent variations in price among different brands of at least four similar medicines.

The issue regarding quality of medicines brings the WHO Good Manufacturing Practices into the picture. The WHO GMP, aimed at producing drugs of good and consistent quality, has been guiding national GMP codes and is a key component in the quality assurance mechanism to produce medicines that are safe, effective and appropriate for their intended use. Currently 30 pharmaceutical manufacturing units in Nepal are either GMP-certified or in the process of being certified, according to the DDA. It is important to highlight that the critical components of the GMP code are binding on all firms and need to be complied with to engage in production. A GMP certificate is provided to a firm for a specific product if it meets standards on the base material (kind and quality of inputs that go into manufacturing the product), production and storage premises, equipment, processes, documentation, training

of personnel and staff hygiene, among other things (Bumpas, Kostermans, and Nair 2007). As can be predicted, country-specific regulatory capacity determines the quality of GMP enforcement since the WHO GMP only guides the national GMP codes.

Most public procurement contracts require GMP compliance. The only public sector undertaking and one of the oldest units in the country, Nepal Aushadhi, has not been participating in public procurement contracts due to the lack of GMP compliance.

3.4 Consumption and production of patented medicines in Nepal

According to industry sources, imports of originator medicines account for less than 10 percent of the annual medicine consumption in Nepal. In terms of domestic production of generic versions of originator medicines (that are patented in other countries), there is a lack of organized data. Our communication with domestic pharmaceutical manufacturers in relation to this study revealed that dominant domestic firms have been producing generic versions of some originator medicines. These are produced by a dozen or so dominant firms that currently capture about 60 percent of the domestic producers' share of the pharmaceutical market in Nepal.

Four of these top firms, which were interviewed for this study, suggested that generic versions of originator medicines account for between 10–30 percent of their annual sales. Drugs such as those in the gliptins category (a new class of oral medicines for diabetes) and sofosbuvir (a new drug for hepatitis C), both of which are patented in other countries, are being produced in Nepal. One Nepali firm, Deurali-Janta Pharmaceuticals, started producing favipiravir, which was used for treating COVID-19 infection. The same treatment continues to have patents in several jurisdictions.[8]

[8] Leibniz Institute for Information Infrastructure (http://www.stn-international.de/sites/default/files/STN/Generell%20pdfs/Report-Favipiravir-20200529_STN.pdf) and https://www.medspal.org/?cHJvZHVjdD1GYXZpcGlyYXZpciUyMDIwMCUyMG1n

Senior executives of major firms claim that the manufacture of generic versions of new originator products which are often under patent protection abroad, has been the driver of their firms' growth in recent years amid the competitive pressures exerted by extremely large Indian corporations. As one executive put it, "these new drugs have kept us growing … although a small proportion in volume terms, these new … drugs have quickly come to account for between 15 to 20 percent of my unit's annual sales".

Another executive of one of the largest Nepali pharmaceutical firms remarked that the production of generic versions of medicines under patent in foreign jurisdictions is not very different from that of off-patent medicines although for the former, the manuals come at a premium and the APIs are relatively difficult to source.

In the box below, we provide a brief case study of one of the dominant pharmaceutical manufacturing firms in Nepal so as to give a sense of the state of domestic pharmaceutical manufacturing in the country.

Brief case study of Quest Pharmaceuticals

Quest Pharmaceuticals was founded in 1999 as a private limited company. It started formal operations in 2001. Within five years of beginning production, the firm received GMP certification, and it continues to be a GMP-certified unit. It set up its formulation and development (F&D) wing in 2005, which was tasked with coming up with new and more effective formulations.

The current staff strength at Quest Pharmaceuticals is more than 500 across divisions such as production, quality assurance, sales and F&D. At present value, the firm's investment is close to NPR 2 billion, which is around the general level of capital expenditure among the top five to seven pharmaceutical manufacturing companies. One of Quest's senior executives is a foreign national who brings critical expertise in the marketing of pharmaceuticals and has an equity stake in the company.

Since the mid-2000s, annual sales at Quest have registered a growth rate of nearly 15 percent. Between August 2019 and August 2020, its revenue grew by 34 percent and reached NPR 2.2 billion, putting it among the top five domestic firms.

Quest Pharmaceuticals currently produces medicines belonging to six of the top 20 therapeutic groups in Nepal and plans to produce medicines in at least 10 of these groups in the coming 10 years.

The firm, along with the other 10 to 12 dominant firms, has routinely manufactured generic versions of originator medicines. It received about 30 percent of its revenue from producing generic versions of originator medicines in the past five years. The top-selling therapeutic categories for these kinds of medicines for Quest are cardiac (including hypertension and drugs that treat cholesterol) and antidiabetic.

The firm is confident that with its existing production capabilities and the ability to tap external expertise, it can produce generic versions of patented medicines at highly competitive prices. For instance, Quest and the other dominant firms have been able to

produce and market their generic versions at less than half the price of select originator products in the cardiac and antidiabetic groups that get imported into Nepal. Originator medicines are 100–150 percent costlier even when their producers apply differential pricing.

Quest Pharmaceuticals' growing portfolio of generic versions of originator medicines has been its core driver of growth for over a decade now, the annual growth rate across therapeutic groups ranging between 30 percent and 100 percent. Such high growth rates are suggestive of burgeoning demand in the cardiac and antidiabetic segments. In these two therapeutic groups, where demand is growing at 20–30 percent annually, Quest commands a market share of 15 percent and 20 percent, respectively, making it among the market leaders.

While these are impressive developments, there are also challenges in the production of generic versions of originator medicines in Nepal. Production of such drugs is essentially a trial-and-error process where different permutations and combinations are experimented with. Such experiments, requiring formidable capabilities and resources, often take several years and frequently result in costly failures. Another challenge in the production of generic drugs is related to the sourcing of APIs, which can be complicated. Moreover, being able to source the API does not guarantee that the generic version of the originator medicines can be produced. The principal reason for this is that most APIs do not come with technical instructions. Detailed and more crucially useful instructions come with only a small proportion of APIs. Subsequent production of generics essentially depends on experimentation that often has to be undertaken under the supervision of external specialists brought in from abroad.

Source: Based on an interview with Mr Umesh Lal Shrestha of Quest Pharmaceuticals

3.5 Import and export

As discussed above, although domestic pharmaceutical manufacturing capacity in Nepal has expanded over the years, it is nowhere close to fully meeting the country's pharmaceutical needs. Nepal relies on imports for several therapeutic categories of drugs and almost all the APIs. There are currently more than 100 registered importers that import allopathic medicines from 373 foreign companies. As observed by one of the largest importers of medicines in Nepal, about a dozen importers command a market share of nearly 60 percent in the total imported medicines market.

In the last three years, on average, Nepal imported medicines worth around US$215 million per year.[9] Nepal imports medicines from various countries, both developed and developing, but more than three-fourths of its medicine imports are from India. According to APPON, in terms of the size of the Nepali pharmaceutical market, Indian firms' share is 50–52 percent. The share of non-Indian foreign firms is about 2 percent (Dhakal et al. 2016).

The top therapeutic categories that are imported into Nepal are anti-infectives, cardiac (including hypertension), respiratory (including COPD), gastrointestinal and dermatological products. Vaccines, anti-cancer medicines, HIV drugs (antiretrovirals or ARVs), injectables, insulin and metered-dose inhalers are not produced in Nepal and are therefore sourced completely through imports. A major Indian multinational is the dominant player in the metered-dose inhaler segment of the respiratory therapeutic group and supplies about 70 percent of the inhalers consumed in Nepal.

Virtually all inputs required to produce medicines – APIs, excipients, suspending agents, preservatives, packaging material and other agents and colours – are imported. In this sense, backward linkages have not been exploited (Bumpas, Kostermans, and Nair 2007).

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[9] This includes products in the 4-digit HS code groups 3003 and 3004 but excludes items such as ayurvedic and homeopathic medicines within them to cover only modern/allopathic medicines, which are the focus of this study.

Unlike with most other inputs, production of APIs entails a sophisticated biochemical process and owing to the scale economies and complex learning processes involved, even advanced developing countries such as India which have significant pharmaceutical production capabilities do not produce much APIs. Nepal's pharmaceutical industry overall, and almost every domestic pharmaceutical production unit, imports over three-quarters of the APIs from India. China is the second most significant source of APIs for the industry. However, for some firms specializing in specific drugs such as for the cardiac category, it appears that only around 60 percent of the APIs are sourced from India. The rest come from places such as China, Hong Kong and Europe. Industry executives remark that much of the APIs sourced from India are in fact from China and that Nepali firms are having to source from India because of low-volume sourcing.

Regarding exports of modern medicines from Nepal, a few Nepali pharmaceutical companies have been exporting some medicines. Nepal's export of such medicines in FY 2018/19 was about US$200,000, which was an increase from previous years. However, in FY 2019/20, Nepal's exports of modern medicines rose significantly to US$5.5 million, of which almost 98 percent were exported to a single country, Uganda.

In terms of the types of drugs exported, Nepali firms mostly export basic drugs such as paracetamol. Lately, according to one of the exporting firms, cardiac and anesthesia drugs were also being exported, such as to Uganda.

To export to developed-country markets or to take part in global procurement of medicines by major donors, pharmaceutical manufacturing firms need to meet at least one of these three certification criteria: i) have WHO prequalification; ii) obtain recognition from a stringent regulatory body in a developed country; and iii) obtain certifications from relevant international bodies such as the UN Children's Fund (UNICEF). Since, among other things, existing Nepali pharmaceutical manufacturing firms are unable to meet any of these criteria, which are considered

significantly more stringent standards compared with national GMP codes in developing countries, they have not been able to export their products to developed countries.

3.6 Price controls

Nepal's Drug Act 1978 confers the power to fix drug prices to the DDA. The Act states, "The [DDA] may, if it deems necessary, fix the price of any drug, by obtaining approval of the Government of Nepal. If the Department so fixes the price of any drug, a notice thereof shall be published in the Nepal Gazette." Except for this broad mandate, there are no fixed mechanisms for the DDA to employ in fixing drug prices. As UNCTAD (2016) notes, there is no effective medicine price regulation in Nepal.

In practice, according to the DDA, it compares prices of similar drugs and fixes the price during the time of drug registration. However, it does not fix the price of all drugs. According to an order issued in the Nepal Gazette in August 2015, there is price control on 96 different kinds of medicines. These have been divided into two groups. Group A lists medicines that are widely sold over the counter such as anti-infectives and pain management drugs. Group B, which has 78 types of medicines, lists drugs for chronic illnesses such as cancer and diabetes. The government provides a limited number of pharmaceuticals free of charge, such as those related to the treatment of malaria, kala-azar, tuberculosis, HIV/AIDS, sexually transmitted diseases, and vaccines for children (UNCTAD 2016).

Issues related to price control appear to be one of the most contentious between the DDA and pharmaceutical companies. While the DDA does not agree with all the claims made by the companies in relation to price control, such as the claim that prices are so low that the firms barely meet their production costs, it does accept that there is a lack of a scientific price control mechanism and says that efforts are being made to address it.

The most problematic aspect of the price regulation regime is the weak periodic review mechanism. Consequently, prices do not get reviewed and updated as required. This is unlike elsewhere, such as in India, where the regulated price regime is inflation-indexed.

4 Institutional and Policy Structures

AS discussed above, the institution that governs all aspects of the pharmaceutical sector – production, import, export, quality, price, etc. – is the DDA. The DDA operates mainly as per the mandate of the Drug Act 1978, National Drug Policy 1995 and several related rules and regulations. The major objective of these items of legislation has been to make Nepal self-sufficient in pharmaceutical products. They had been put in place before Nepal became a WTO member in 2004.

Becoming a WTO member entails making several changes in national laws, regulations and practices but when it comes to intellectual property laws, LDCs are exempted from having to apply most of the standards set by the TRIPS Agreement, including for the pharmaceutical sector. However, as Nepal is set to leave the LDC group in 2026, it will have to comply with the full TRIPS Agreement norms thereafter – including the obligation to provide patent protection for pharmaceutical products – unless graduating LDCs are provided additional transition periods.[10]

Current national legislation governing intellectual property in Nepal consists of the Patent, Design and Trade Mark Act, 1965 and the Copyright Act, 2002. The Department of Industry within the Ministry of Industry, Commerce and Supplies is the agency responsible for patents, designs and trademarks. Within the department is the Industrial Property Section that provides services

[10] A case has been made for extending the transition period for pharmaceuticals for LDCs in the COVID-19 era (see Gay and Gallagher 2020).

for registration and renewal of patents, designs and trademarks and related complaints, among others. The Nepal Copyright Registrar's Office within the Ministry of Culture, Tourism and Civil Aviation is the agency responsible for copyrights.

Provisions on patents in the Patent, Design and Trade Mark Act, 1965 are general in nature; there are no provisions specific to pharmaceuticals. Thus, pharmaceuticals are covered by the general provisions. The Act provides patent protection for seven years, with the possibility to renew twice, with each renewal period also lasting seven years. Hence, the maximum duration of patent protection is 21 years.

Nepal prepared an Intellectual Property Policy in 2017 and the Ministry of Industry has prepared a draft of a new Intellectual Property Act, which is yet to be tabled in the parliament. The IP Policy 2017 takes into consideration Nepal's international commitments on IP issues, including the TRIPS Agreement. It states that during the course of preparing national IP legislation, Nepal will take into consideration the flexibilities and special provisions granted to LDCs in the TRIPS Agreement. One of the objectives of the Policy is to ensure balance between the rights of the creators of intellectual property and society's interests and benefits. Accordingly, it stipulates that the state can take control of patents during periods of national crisis such as threats to national security and pandemics. One of the working policies also relates to the use of compulsory licensing. The IP Policy states that compulsory licences can be issued, among other things, to domestically produce or import life-saving drugs for non-commercial use if the patent holder of a medicine refuses to either produce the drug or provide generic companies permission to produce it or if there are anti-competitive practices. The Policy also provides for parallel importation of medicines to protect consumer rights and interests.

The draft of the new IP Act looks comprehensive compared with the existing Acts on patents, designs and trademarks, and copyright. It has been developed as an umbrella Bill covering all areas of intellectual property. The section on patents deals with aspects related to product and process patents, including provisions on

compulsory licensing in line with the IP Policy 2017, but appears to have significant gaps. The draft published for public comments shows that it has not incorporated to the fullest extent flexibilities available to countries implementing the TRIPS Agreement. For example, it does not have provisions to effectively avoid or at the very least limit the granting of secondary patents and thus the practice of patent evergreening in the pharmaceutical sector. Similarly, there is no provision allowing parallel imports. The draft also has provisions granting the right to secrecy to a patent applicant, which could create barriers to capacity development of the domestic pharmaceutical industry. Similarly, critical exceptions to patents for enabling timely and affordable access to pharmaceuticals, such as the Bolar exception, are not included in the draft Bill. The Bill also does not have provisions requiring sufficiency of disclosure or the best mode of working of an invention. The provided pre-grant opposition procedure makes it unworkable while provisions regarding compulsory licensing are inadequate. Overall, there are elements in the Bill as well as major gaps that would undermine the development of local capacity, generic production and the ability of the government to take action in support of Nepal's national interest.

We have learnt that the Department of Industry has released another draft version of the IP law based on comments received in 2019. However, the new draft is not available in the public domain. It is important for the government to hold domestic stakeholder consultations on the new draft and to ensure that it optimally incorporates all flexibilities provided by the TRIPS Agreement before sending it to the parliament for adoption.

Until FY 2008/09, only 70 patents were registered in Nepal, of which 31 were granted to nationals and 39 to foreigners (GoN 2019). In the 10 years after that, not a single patent was registered by a foreigner. As for local patent holders, only nine were registered in the 10-year period from 2008/09 to 2018/19. Of these overall patent registrations, it is not clear how many relate to pharmaceuticals. According to stakeholders interviewed, there are no patents granted for pharmaceuticals in Nepal.

One of the ways through which the Government of Nepal has been providing policy support to the domestic pharmaceutical industry is tax concessions. Industry sources say that nearly 90 percent of APIs are subject to only 1 percent customs duty and exempt from 13 percent value-added tax (VAT). Similarly, equipment directly related to production, which usually makes up under a fifth of the initial project cost, is charged 4 percent customs duty and is VAT-exempt. However, several important types of equipment such as those concerning quality assurance are subject to both VAT and 15 percent customs duty. Also, according to a key APPON official, items such as construction materials (e.g., metals to construct clean rooms), cooling units and air-conditioning equipment, which make up nearly two-thirds of the initial project costs, are subject to up to 20 percent tariff plus VAT. Likewise, excipients, which often make up 30-50 percent of the input costs, are subject to 1 percent tariff plus VAT. Production of paracetamol, for instance, requires more than 10 excipients. Several respondents stated that while the government provides them assurances that excipients will be made VAT-exempt, it has not been implemented. One possible reason regarding such issues with customs duty and VAT exemption could be the possibility of dual use of the imported item in question. This is a contentious issue that needs to be resolved through communication between stakeholders.

5 The Use of TRIPS Flexibilities

AS discussed above, LDCs are exempted from implementing most of the rules under the TRIPS Agreement, including the obligation to provide patent protection for pharmaceuticals. In the absence of patent protection, an LDC has full freedom to produce generic versions of any medicines for domestic consumption and to import from and/or export to any other country where patents are not a barrier. Upon its graduation from the LDC group in 2026, however, Nepal will have to grant patent protection for pharmaceutical products, and the freedom to produce, import and export will be curtailed. Significant adverse consequences for the local generics industry can be anticipated given the importance of the exemption of pharmaceutical patents for the development of the industry. Nepal's graduation from LDC status could strike a severe blow to this nascent development. Similarly, affordable access to medicines will be affected, given the prevailing dependency on low-cost generics. This is especially concerning in Nepal's context where a significant portion of the expenditure on medicines is out-of-pocket. In a country where 27 percent of the total health expenditure and 60 percent of the out-of-pocket health expenditure go into treating NCDs, the inability to access cheaper generic versions of originator medicines needed to treat these diseases will severely jeopardize the nation's public health.

Following graduation, Nepal's ability to produce, import and export affordable generics will very much depend on the implementation and utilization of the flexibilities provided by the TRIPS Agreement.

The starting point for this would be to incorporate all the available TRIPS flexibilities into the new IP law being developed. Musungu and Oh (2006) and UNCTAD (2016) offer important recommendations in this regard.

Musungu and Oh (2006) state that the use of TRIPS flexibilities can promote access to medicines in developing countries. They suggest, however, that there are gaps in the incorporation and usage of the flexibilities in developing countries, which need to be addressed to make effective use of the flexibilities. Some of the important flexibilities include those related to the transition period; compulsory licensing; public, non-commercial use of patents; parallel importation; exceptions from patentability; and limits on data protection (Musungu and Oh 2006). Moreover, these flexibilities must be not only included but also clarified adequately. For example, possible grounds for the issuance of compulsory licences should be specified clearly in the Act. These and additional selected flexibilities are elaborated in Table 7 below, drawing from UNCTAD (2016).

These are highly useful recommendations for Nepal as it seeks to enact a new IP law ahead of its graduation from LDC status.

Table 7: Some key public health flexibilities in the implementation of the TRIPS Agreement

TRIPS flexibility	Remarks
Patentable subject matter and subject matter exclusion	Allows patent law to exclude from patentability naturally occurring substances, new uses or forms of known substances, and diagnostic, therapeutic and surgical methods of treatment.
Patentability criteria	Strict application of patentability criteria – novelty, inventive step and capable of industrial application – improves the quality of patents granted and the scope for generic production of pharmaceuticals.
Patent examination and opposition procedures	Patent examination, administrative pre- and post-grant opposition procedures can influence the overall quality of patents, and prevent erroneous grant of patents.
Research exception	Allows researchers to undertake research on or with the patented technology to improve the technology or use the technology as a research tool.
Regulatory exception (Bolar exception)	Allows generics manufacturers to research on patented pharmaceutical products and submit their application for marketing authorization before the expiration of the patent.
Parallel importation	Allows generic manufacturers to source APIs and other inputs, or health authorities to authorize importation of pharmaceuticals, from wherever the products are legitimately placed in the market.
Government/public use	Enables the government to use a patented technology for non-commercial purposes, without the consent of the patent holder.
Compulsory licence	When negotiation for a voluntary licence fails, third parties can be authorized to exploit the patent without the consent of the patent holder. Such compulsory licences may also be granted to remedy anti-competitive practices, even in the absence of a prior negotiation.
Compulsory licences for export/import	A special regime that permits the export of all pharmaceuticals produced under compulsory licence for the benefit of a developing-country or LDC member with no or limited manufacturing capacity.
Control of anti-competitive licensing practices	Allows countries to address anti-competitive licensing practices and abuses of patent rights that may unduly affect licensees and consumers.
Fair and equitable procedures for the enforcement of IP rights	Procedures and remedies for IP enforcement need to be fair, equitable and proportional. No obligation to provide criminal procedures and special border measures to enforce patents, as well as to issue injunctions in cases of government use and compulsory licensing, or even in other cases.

Source: UNCTAD (2016)

6 Conclusion and Recommendations

NEPAL'S domestic pharmaceutical production capacity has grown over the years. While this has been mostly in the production of off-patent generic medicines, a few dominant firms have in recent years strengthened their capacities to produce generic versions of originator medicines, which is encouraging. However, Nepal's impending graduation from the LDC group might reverse this trend if these and other newer medicines are subsequently patented within the country. Domestic production of generic versions of originator medicines will then not be possible unless TRIPS flexibilities are utilized to address the patent barrier.

Since Nepal's current production of generic versions of originator medicines is small, the inability to produce such medicines after the country's graduation from LDC status might not have too big an effect in financial terms. However, given that many of these generics produced by domestic manufacturers in Nepal are for treating NCDs such as hypertension and diabetes, which have been major causes of deaths in recent years, the impact will be felt in terms of access to these medicines. The need to pay higher prices for patented medicines thereafter will seriously undermine public health outcomes. The COVID-19 pandemic has also reinforced the need for countries to have pharmaceutical manufacturing capacities.

Stakeholders in Nepal, including the government and the private sector, appear to be insufficiently prepared to face the patent regime in the pharmaceutical sector after Nepal's LDC graduation. There is a lack of adequate deliberations on this aspect. There is also a lack of dedicated policy to strengthen the domestic pharmaceutical sector, mainly in relation to preparing the sector to face the post-

graduation patent regime by understanding, implementing and utilizing the TRIPS flexibilities.

To address the challenges that Nepal's domestic pharmaceutical sector could face after the country's LDC graduation, we offer the following recommendations:

For the government:

- There is a lack of organized data on domestic production, import and export of generic versions. This hinders understanding of the full impact for Nepal when it implements the TRIPS patent regime upon its graduation. Hence, there is a need to make improvements in collecting and maintaining data on production, import and export involving the pharmaceutical sector.
- The Industrial Property Section (within the Department of Industry), which oversees patent-related matters, needs to build its technical and human resource capacity in examining patent applications, maintaining the patent database and avoiding the grant of frivolous patents, among others. Transparency and accountability mechanisms also need to be put in place.
- As long as Nepal remains an LDC, maximize the use of LDC-specific flexibilities granted by the TRIPS Agreement, including exemption from providing patent protection to pharmaceutical products.
- The IP legislation should fully and optimally incorporate all public-health-related flexibilities to facilitate the production and supply of affordable generic versions and access to quality and efficacious new medicines. In doing so, Nepal should also learn from the experiences of other developing countries in implementing and using TRIPS flexibilities.
- The government needs to hold consultations with domestic stakeholders on the new draft of the IP law before sending it to the parliament for adoption. Meaningful consultations with local generic pharmaceutical manufacturers, civil society organizations, academicians, practitioners and relevant government agencies should be undertaken to ensure that the

IP Bill incorporates all the necessary safeguards and TRIPS flexibilities.

- A dedicated policy regarding support to be provided to the domestic pharmaceutical sector, especially in terms of strengthening it to face the patent regime, needs to be prepared immediately. The government has been providing support through, for example, tax concessions in the import of inputs necessary for pharmaceutical production and a 15 percent margin to domestic pharmaceutical manufacturers in public procurement of medicines. However, domestic manufacturers still do not find the support enough. There also appears to be a lack of clarity between the government and domestic pharmaceutical manufacturers in understanding each other's positions regarding the support measures. This needs to be rectified through regular dialogues.
- Nepal should advocate at the multilateral level for LDCs to be allowed transition periods for a certain duration post-graduation to facilitate a smooth transition from LDC to developing-country status.

For domestic generic pharmaceutical manufacturers:

- Convey concerns on the 2019 draft IP law and seek consultations on the new draft.
- Manufacturers need to continue to strengthen their capacities in the production of generic versions of originator medicines.
- Manufacturers should maximize and fully use Nepal's current exemption, as an LDC, from implementing most rules of the TRIPS Agreement.
- Manufacturers also need to build their capacity to utilize other flexibilities allowed by the TRIPS Agreement such as opposition systems and compulsory licences.

For civil society organizations:

- Civil society organizations working on issues of international trade, intellectual property and other relevant areas should build their capacity to understand the TRIPS flexibilities and advocate for effective implementation and use of those flexibilities.

- Civil society also needs to play an active part in the legislative process of the IP law and ensure the patent regime is designed and implemented in a public-health-friendly manner. After the legislation comes into force, they need to monitor the impact of patents on access to medicines and encourage the full use of TRIPS flexibilities.

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As a least-developed-country (LDC) member of the World Trade Organization, Nepal is not required, under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to provide patent protection for pharmaceutical products. With no patent restrictions in force, Nepal's domestic pharmaceutical industry has expanded over the years to meet an increasing share of the country's medicine needs. This growth is now under threat, however, as Nepal is set to lose its LDC status – and, with it, the TRIPS exemption – in 2026.

This paper assesses how the Nepali pharmaceutical sector can face the challenges posed by implementation of the WTO intellectual property rules after the country's graduation from the LDC category. It calls for full utilization of policy flexibilities allowed by the TRIPS Agreement and strengthened government support to boost the local pharmaceutical industry and enhance access to affordable medicines.

South Asia Watch on Trade, Economics and Environment (SAWTEE) is a non-government organization registered in Nepal with a vision of ensuring fair, equitable, inclusive and sustainable growth and development in South Asia. Established in 1999, SAWTEE has been actively engaged in research, advocacy, capacity building, sensitization and alliance building on issues of trade, economics and environment. The SAWTEE team is comprised of highly skilled and experienced professionals who are passionate about contributing to informed and inclusive policymaking. Researchers at SAWTEE have provided inputs to regional and global organizations, besides the Government of Nepal and the Nepali private sector.