

Pills, Policy, and Prospect: A Credit Lens on Nepal's Pharma Sector

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Nepal's pharmaceutical industry is a critical component of its healthcare system, supplying essential medicines across allopathic (modern medicine), ayurvedic (traditional herbal), and veterinary segments. Allopathic medicines dominate in both production and consumption, reflecting global norms, while Ayurveda and other traditional systems play a complementary role^{[1][2]}. As of 2024, Nepal has 194 pharmaceutical industries registered in DAMS¹, out of which 129 produce human allopathic medicines, 53 produced ayurvedic medicines, and 12 produce veterinary medicines^[3].

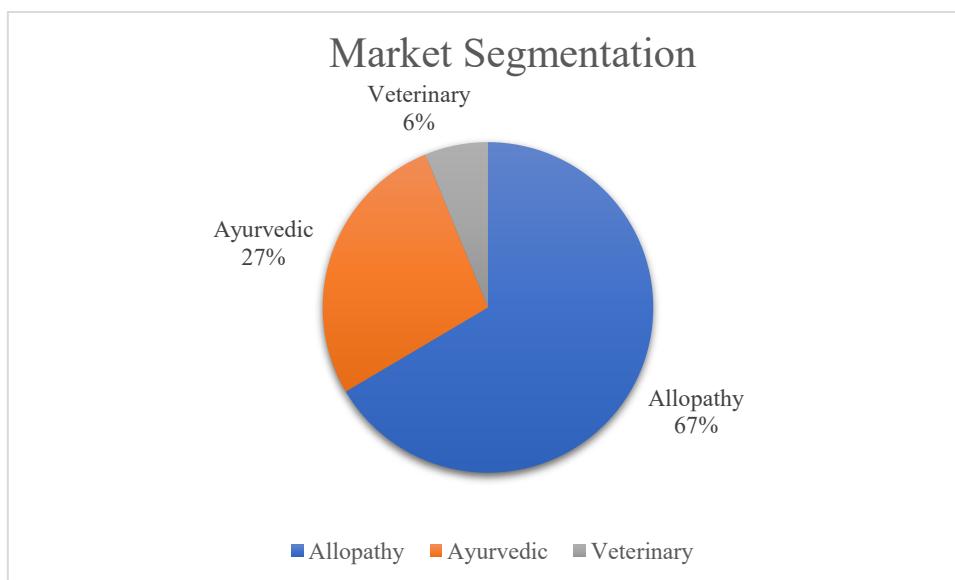


Figure 1: Nepal pharmaceutical market segmentation

The domestic producers focus almost entirely on generic drugs, off-patent formulations that are widely available in the public domain^[4]. Consequently, a large portion of the market demand, especially for more complex or patented drugs is met through imports. The national pharmaceutical market was estimated at NPR 45 billion (approximately USD 340 Million) which is more than the value five decades ago^[5]. Medicines constitute a substantial share of healthcare spending in Nepal, accounting for over half of out-of-pocket health expenditures by Nepali citizens^[6]. This underscores the sector's socio-economic importance and the need for reliable, affordable medicine supply.

¹ Drug and Medicine System

From a regulatory standpoint, Nepal's Department of Drug Administration (DDA) is the national authority overseeing drug quality, approvals, and market surveillance, under the auspices of the Drug Act 2035^[7]. Various rules and guidelines such as Drug Registration Rules 2038, Drug Standard Regulation 2043, and the National Drug Policy 2052 provide the legal framework for ensuring that pharmaceuticals marketed in Nepal are safe and effective. Notably, there are 398 medicines listed in Nepal's National List of Essential Medicines (NLEM) to prioritize access^[8]. Despite this framework, enforcement seems to be challenging due to resource constraints and market complexities which is discussed later.

In summary, Nepal's pharma sector comprises a mix of manufacturers producing mainly generics, alongside significant foreign suppliers providing medicines that local companies do not manufacture. The balance between these domestic and foreign sources, and the sector's overall trajectory in recent years, are shaped by growth trends, policy decisions, and market dynamics that have implications from a credit risk and industry sustainability perspective.

Growth and Trend

Nepal's pharmaceutical market experienced moderate growth from 2020 to 2025, albeit with some volatility due to external shocks. Annual demand for medicines was around 53.66 tons in 2020/21, and it has been projected to rise to 71.65 tons by 2024/25, reflecting an average growth rate of roughly 7% per year. This growth has been driven by increasing healthcare needs, greater awareness and diagnosis of chronic diseases, and expanded healthcare coverage. However, it was not a smooth upward trajectory as external factors like the COVID-19 pandemic temporarily disrupted both supply and demand.

For instance, during the first wave of COVID-19 (FY2020-21), local pharmaceutical production was hampered by supply chain issues and lockdowns. Many domestic factories could operate at only 20% of their production capacity due to difficulties in importing raw materials (Active Pharmaceutical Ingredients; APIs) from India and China during the pandemic^[9]. This led to intermittent medicine shortages in the market and a notable example is the shortage of paracetamol (a critical fever medicine) during a severe dengue outbreak, which occurred because domestic firms curtailed production and imports were disrupted^[10]. Consequently, some unauthorized or ad-hoc imports from India filled the gaps when Nepali pharmacies ran out of essential drugs^[11].

Despite these setbacks, the overall trend seems to be upward. *Figure 2* illustrates the recent most growth trajectory of Nepal's pharma market. The market value rose from about NPR 47-50 billion in 2016-2018 to over NPR 51 billion by 2020, with a dip in 2019 followed by a strong rebound^[12]. The dip around 2019 reflects a temporary contraction, possibly due to inventory adjustments or policy impacts, but growth resumed thereafter. Projected data (assuming supportive policies and normal conditions) showed that the market potentially reached over NPR 70 billion in 2025, although recent data are not available to validate this.

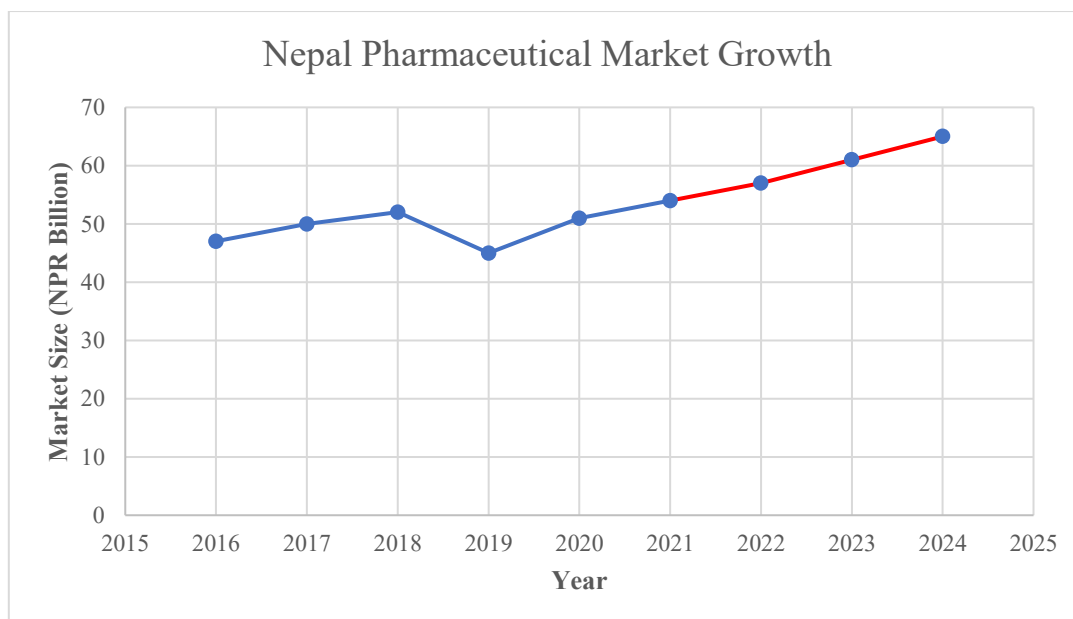


Figure 2: Nepal’s pharmaceutical market size (total sales) showing actual growth (2016–2020) and projected growth (2021–2025). Despite a temporary decline in FY2018/19, the overall market has expanded, with an expected annual growth rate of ~7%. Both domestic production and imports contribute to this trend, though recent years saw domestic output stagnate or decline slightly in absolute terms due to policy and competition factors. Data Source: Department of Industry (2021) and APPON projections^[9]

The composition of growth has been influenced by the balance between domestic manufacturers and imports. Notably, industry insiders reported that domestic pharmaceutical sales peaked around NPR 35 billion a few years ago but then declined to around NPR 29 billion by 2024^[13]. This suggests that while the overall market grew, local companies lost some ground to imports in the past 2-3 years. In fact, domestic firms that once supplied an estimated 55% of national demand at their height are now covering only about 45-50% of the market¹⁴. The erosion of domestic market share in the early 2020s can be attributed to challenges such as unchanged price controls, lack of government incentives, and aggressive competition from imported medicines, which are often cheaper. Meanwhile, imports (especially from India) have grown to fill the demand, particularly for categories that locals do not produce (like specialty drugs).

In summary, Nepal’s pharma sector has exhibited moderate growth in value, but there is an underlying disparity: the domestic industry’s growth has been essentially flat or negative in recent years when adjusted for inflation, while imports have expanded to meet increasing demand. This trend raises concerns from a credit perspective, as shrinking market share and underutilized capacity for domestic firms could impact their revenues and profitability. The growth potential remains significant (as the projections indicate rising demand), but realizing it for local manufacturers will depend on addressing structural issues and leveling the playing field vis-à-vis imports.

Domestic Players vs Foreign/Imported Goods

Market Share

A defining characteristic of Nepal’s pharmaceutical sector is the coexistence of domestic manufacturers and foreign (imported) medicines, with the latter holding a slight majority in market share by value. As of 2021–2022, roughly 46% of Nepal’s pharmaceutical market (by value) was supplied by domestic production, whereas about 54% was met through imports^[4]. The vast bulk of these imports originate from India, Nepal’s giant neighbour and one of the world’s leading generic drug producers. Indeed, Indian pharmaceutical imports alone account for ~52% of Nepal’s market, with imports from all other countries making up only around 2%^[15].

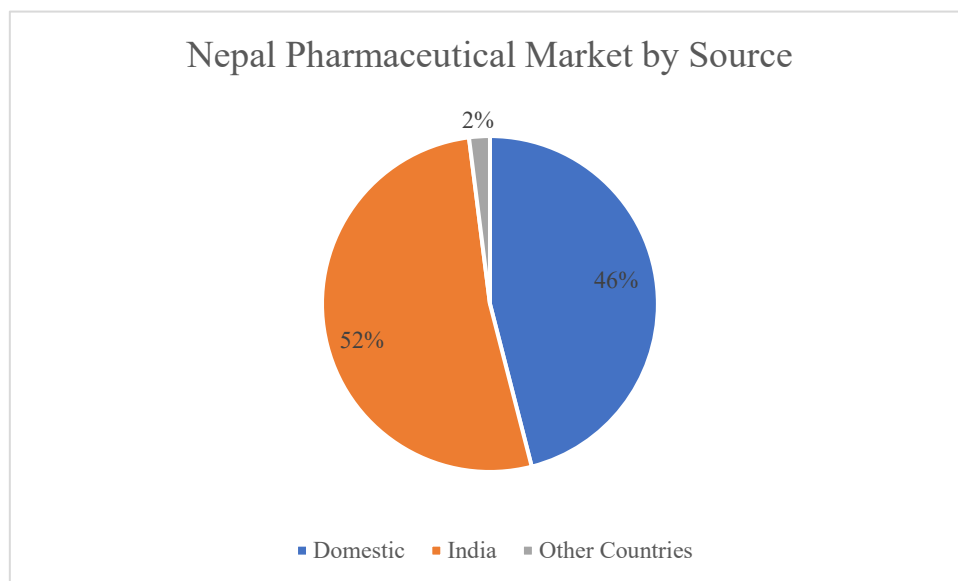


Figure 3: Breakdown of Nepal’s Pharmaceutical Market by Source (circa 2021). Data Source: Department of Industry Report^[15]

The market share distribution has important implications. Nepal’s domestic pharmaceutical companies primarily produce generic versions of essential medicines like, antibiotics, analgesics, vitamins, common chronic disease medications, etc. for which the know-how is readily available and no patent restrictions apply. Thanks to Nepal’s status as a Least Developed Country (LDC), it benefits from TRIPS (Trade-Related Intellectual Property Rights) exemptions until 2033–2034 for pharmaceuticals, meaning it can legally manufacture generic versions of patented drugs without royalty^[16]. However, despite this opportunity, Nepal’s industry has not significantly expanded into more advanced or patented drug manufacturing. Most local firms have stayed within the comfort zone of established generics, competing largely on price and distribution.

Meanwhile, foreign pharmaceutical companies (approximately 390 of them supply the Nepali market via local importers^{[17][18]}) fill in the gaps by providing medicines that Nepal does not make. These are often specialized or high-value drugs, for instance, vaccines, biotech products (like insulin analogs or monoclonal antibodies), oncology (anti-cancer) drugs, cardiovascular and neurological drugs, and other “critical care” medicines^[19]. Nepal’s domestic firms currently lack the technical capacity and scale to produce many of these items. As a result, even

for priority health needs such as heart disease, diabetes, or cancer, Nepal remains dependent on imports. It is noted that vaccines, anti-retroviral (ART) medications, and other biotech products are 100% imported^[20]. Similarly, complex biologicals and newer therapies are absent from local production lines. An analysis by Nepali experts highlighted that none of the ~100 local manufacturers produce key vaccines or life-saving biologics that the country needs (e.g. measles or DPT vaccines, rabies vaccines, snake antivenom)^[21]. This is attributed to the lack of investment in research and development (R&D) and technology in Nepal's pharma sector^[22]. Developing a new drug or vaccine requires significant innovation and trials, which Nepali companies have not engaged in; they instead prefer replicating established formulas.

The dominance of generic drugs in domestic production means that, for many categories where generics suffice (e.g. antibiotics, painkillers, basic antihypertensives), local companies can meet a good portion of demand. This is why the government of Nepal has occasionally taken protectionist measures to support them. For example, in 2017 the government banned the import of 37 generic medicines that were already produced domestically^[23]. The intent was to give local manufacturers a captive market for those products, improve capacity utilization (which was only 35–40% at the time^[23]), and reduce import reliance for basic drugs. Domestic industry associations like APPON (Association of Pharmaceutical Producers of Nepal) welcomed this move^[23], as cheaper Indian generics had been undercutting Nepali brands. Following the ban, those particular medicines (mostly common items like certain antibiotics, vitamins, etc.) had to be sourced from Nepali companies.

However, such measures have dual effects. On one hand, they can increase the domestic market share and utilization in the short term. On the other, they risk reducing competition, which can lead to higher prices or quality issues. Indeed, in the aftermath of restricting some imports, there were reports that medicine prices for consumers rose and substandard products proliferated in some cases^[24]. For example, one of the protected^[24] companies, the state-owned Nepal Drugs Limited, produced a batch of paracetamol that failed quality tests and had to be banned, yet patients had little alternative since imports were barred^[24]. This highlights a core tension in Nepal's pharma policy: balancing self-sufficiency with quality and affordability.

In the current market, Indian pharmaceutical companies hold a strong position not just because of cost, but also due to scale and trust. Indian firms often enjoy economies of scale that let them price drugs lower than Nepali companies (which have smaller production batches and higher unit costs)^[25]. Nepal's open border with India and similar pharmacopoeia mean Indian brands (or even unregistered Indian drugs) easily find their way to consumers. Some foreign firms (especially Indian generics giants) have local distributors and aggressive marketing, capturing prescribing preferences of Nepali doctors. A study noted that Nepal depends on imports for 60–70% of its medicine needs by volume, especially from India^[26]. This heavy dependence is a vulnerability: any disruption in India (such as export bans or production issues) can immediately affect Nepali supplies.

In summary, the market share battle between domestic and foreign pharmaceutical products in Nepal currently tilts in favor of imports for value and critical categories, while domestic players cover a substantial portion of routine generic needs. This fragmentation has implications for

investment and growth in the sector – which we examine next – as well as for the overall quality and resilience of medicine supply.

Investment in the Sector

Investment in Nepal's pharmaceutical sector comes from domestic private and public sources, with foreign direct investment (FDI) historically playing a minimal role. As of 2021, the total capital investment in Nepal's existing pharmaceutical factories exceeded NPR 35 billion (USD 300 million)^[27]. This includes investments in plant, machinery, and operations for the around 62 allopathic drug manufacturers and other producers. By 2025, industry leaders claim cumulative investments had reached NPR 80–90 billion, factoring in new factories and reinvestment over time^[28]. The sector's contribution to GDP is relatively small, but the assets involved (production facilities, quality control labs, distribution networks) are significant for a developing economy like Nepal.

Crucially, almost all major pharmaceutical companies in Nepal are locally owned. Many are family-run or privately held domestic enterprises that started in the 1970s–1990s period of import substitution. There is also one government-owned manufacturer, Nepal Drugs Limited (NDL) which was revived by the government in 2018 after years of closure, with the aim of producing essential drugs for the public system. NDL received government capital injection as a form of strategic investment in self-sufficiency; however, its performance has been underwhelming (it has struggled with quality compliance and financial losses)^[24]. Aside from NDL and a few older public ventures in traditional medicine (like the Singha Durbar Vaidyakhana for Ayurveda), the bulk of investment comes from private sector actors within Nepal.

On the other hand, foreign investment has been scant. Nepal for many years had restrictive policies that discouraged FDI in pharmaceuticals (partly to protect local SMEs). Only recently, with the Foreign Investment and Technology Transfer Act (FITTA) 2019, has Nepal opened up more fully to FDI in sectors like pharma^[29]. FITTA 2019 theoretically allows 100% foreign ownership in drug manufacturing and promises national treatment to foreign investors^[30]. Despite this, foreign interest has been limited, as of 2025, no major multinational pharmaceutical company has set up a manufacturing base in Nepal. The proportion of FDI in Nepal's GDP is only ~0.2%, one of the lowest in the world, and pharma has not attracted notable projects^[31]. This is in stark contrast to neighbors like India or Bangladesh, where collaborations with multinationals are common. Some exceptions exist in niche areas: for example, Dabur Nepal (an Indian-owned venture) produces herbal/Ayurvedic health products in Nepal, and Hester Biosciences Nepal (a joint venture with an Indian firm) produces veterinary vaccines in Nepal's Kavre district^[32]. These indicate the potential for cross-border investment if facilitated properly.

The lack of FDI means that technology transfer and advanced know-how are limited. Domestic companies invest primarily in generic production lines and basic formulation R&D. There's minimal investment in drug discovery or biotech. In fact, experts have pointed out that Nepal's pharmaceutical sector has yet to show innovation or significant R&D capacity – no new

molecules or advanced formulations have emerged locally^[33]. The cost and risk of such innovation are high, and local investors typically shy away due to uncertain returns.

From a credit perspective, the investment picture suggests that Nepal's pharma sector growth is constrained by capital availability and scale. Smaller firms may struggle to finance upgrades to meet international quality standards (like WHO-GMP certification) or to expand capacity. Banks in Nepal do lend to pharma companies, but the industry representatives have complained about short loan tenures and high interest rates. By comparison, in Bangladesh (a country Nepal often looks to for inspiration), pharmaceutical firms have benefited from long-term financing (e.g. 12-year loans) and tax breaks on R&D and equipment^[34]. In Nepal, loans for pharma are typically around 5-year terms only, which are less conducive to big capital projects^[35]. Additionally, Nepal imposes standard borrowing caps and collateral requirements that can limit large-scale expansion.

On the positive side, the Nepali government recognizes pharmaceuticals as a priority sector for self-reliance. It has included the sector in national investment summits and policy documents. The draft National Medicines Policy (2007) allows joint ventures between Nepali and foreign firms^[36], and subsequent plans have often mentioned upgrading production. The government has also started to offer some incentives, such as declaring intentions to make the country self-sufficient in essential medicines and possibly offering land or tax incentives for new pharma parks. However, many of these initiatives are in early stages or yet to be implemented fully^[37].

To summarize, investment in Nepal's pharma sector remains largely domestic and modest. There is significant untapped potential if foreign capital and expertise were to be leveraged, a move that could enhance production of more complex drugs and possibly make Nepal an exporter. Given the small scale of current players, consolidation or external partnerships might be needed for the industry to scale up. For credit analysts, the current scenario implies that companies may have limited financial buffers and rely on stable domestic cash flows, as they are not buoyed by large external investments.

Credit Lens: Industry Outlook

From a credit assessment perspective, Nepal's pharmaceutical industry outlook is a mixed bag of opportunities and risks. Key considerations include the degree of government support (policy and regulatory environment), the profitability and financial health of firms, and their market access (both domestic and potential export markets). Each of these factors influences the stability and creditworthiness of pharmaceutical enterprises operating in Nepal.

Government Support: Acts, Regulations, and Initiatives

Government policy plays a pivotal role in shaping the pharma sector's fortunes in Nepal. Historically, Nepal's policies have aimed at ensuring essential medicines are available and affordable, sometimes at the cost of producers' profitability. For instance, the government controls prices of certain essential drugs: 16 years ago (around 2007) it fixed the retail price of 96 essential medicines (including paracetamol) at a token NPR 1 per tablet, an extremely low

price^[38], and had not revised these prices as of 2025^[39]. While this price control was intended to keep medicines affordable for the public, it severely squeezed the margins for manufacturers on those products. Pharma companies report that the production cost of a paracetamol tablet far exceeds NPR 1 now, making it unviable to produce at the controlled price^[39]. As a result, many firms limit or stop production of such price-capped essential drugs, ironically leading to shortages (as seen with paracetamol during health crises)^[10]. This is a clear case where well-intentioned policy (price regulation) has credit implications: it erodes revenue streams for companies and can turn a would-be stable product line into a loss-maker, contributing to financial stress.

Another area of government intervention has been through import restrictions and trade policies. The decision in 2017 to ban import of 37 medicines that local companies make (discussed earlier) is one example of a “buy local” policy^[23]. More broadly, Nepal has enacted the Safeguard, Anti-Dumping and Countervailing Act, 2019 to protect domestic industries from unfair import competition^[40]. However, stakeholders note that these trade remedies have not been robustly implemented yet^[41]. APPON officials argue that despite policies stating domestic products should be preferred (even if up to 15% more expensive than imports), in practice government tenders and markets often still source cheaper imported drugs^[42]. The Drug Registration Rules also technically give regulators leeway to restrict foreign products if domestic equivalents exist, but enforcement has been inconsistent. DDA is often caught in a bind between ensuring medicine availability (via imports) and promoting local production. As a result, policy implementation gaps exist: for instance, even after the government announced a push for self-sufficiency in essential drugs, imports in those categories continued due to enforcement issues^[43].

On the positive side, the government provides some support through regulatory and capacity-building initiatives. The DDA, since its establishment in 1979, has been working to upgrade Nepal’s pharmaceutical standards. Many domestic companies have adopted WHO Good Manufacturing Practice (GMP) standards, in part due to DDA’s regulatory push and periodic plant inspections^[44]. The government has also facilitated training programs and fast-track approvals for companies that meet quality benchmarks. Additionally, recognizing the API dependency (Nepal currently imports 100% of its pharmaceutical raw materials, 70% from India and 30% from China^[45]), policymakers have discussed establishing an API manufacturing unit or industrial park. However, unlike Bangladesh which offered concrete VAT waivers and subsidies for local API production and set up infrastructure for it^[46], Nepal has yet to roll out comparable incentives.

Legal frameworks like the National Health Policy 2019 and periodic budget announcements have reiterated government commitment to the pharma sector, including establishing laboratories, research units, and encouraging Ayurvedic and herbal medicine development. For example, the government has considered leveraging Nepal’s rich biodiversity to support herbal and Ayurvedic drug production as a niche where Nepal could excel. Dozens of Ayurvedic manufacturers have been licensed, and traditional medicine is regulated under its own guidelines (with the Ministry of Health supporting Ayurveda hospitals and production units). Yet, the scale of support (grants or soft loans) to that sub-sector remains modest.

A critical area of government role is quality regulation. Ensuring drug quality protects the public and indirectly benefits reputable manufacturers by weeding out substandard competitors. Nepal's DDA has 38 drug inspectors nationwide^[47] which is a small number to oversee thousands of pharmacies and many border entry points. The National Medicines Laboratory under DDA tests samples of drugs on the market, but capacity constraints mean only about 500 samples are tested per year out of an estimated 25,000+ drug brands in circulation^[48]. The consequence is that substandard, counterfeit, or unregistered drugs can circulate for long periods before detection, undermining consumer confidence. The government, aware of this, has started increasing surveillance. It issues public drug recall notices when products fail quality tests. Over the past decade, the number of drug recalls has risen significantly, indicating either better surveillance or more quality problems (or both)^[49]. Government labs often take months to process samples, meaning problematic drugs might have been sold and consumed by the time a recall is issued^[50]. For the domestic industry's outlook, this is a double-edged sword: on one hand, stricter enforcement can eliminate bad actors and improve overall standards; on the other, it exposes several local companies to reputational risk if their products fail tests, which could affect their market access and credit profile.

In February 2025, for example, the DDA recalled multiple drugs from three Nepali companies after they failed quality tests, including a codeine phosphate painkiller that did not meet content standards and IV saline solutions found contaminated with microbes^[51]. The DDA ordered production halts and market recalls for those batches^[52]. Such actions, while essential for public safety, can impose sudden financial strain on the companies involved (lost sales, recall costs, potential liability). In the long run, companies with consistent quality compliance will likely outperform, and government policy seems to be moving towards tighter quality control in line with international norms. Strengthening the DDA (more manpower, better labs, stricter licensing) is a stated government goal; achieving it would improve the industry's credibility, possibly even enabling exports if WHO prequalification is attained by some plants.

In summary, government support for Nepal's pharma sector has been a mix of protective measures and regulatory oversight, but with some misalignment. Protectionist policies without complementary quality enforcement have led to market distortions. Moving forward, the outlook depends on whether policies can be recalibrated: e.g., updating price controls to sustainable levels, actually implementing anti-dumping rules against unfair imports, providing tax breaks or subsidies for local production (especially of essential and advanced drugs), and investing in regulatory capacity. For credit analysts, a more supportive and consistent policy environment would reduce risk, whereas continued policy uncertainty or adverse interventions (like prolonged price freezes) would raise risk for domestic pharma firms.

Profitability and Financials

The profitability of Nepali pharmaceutical companies has come under pressure in recent years, raising concerns about their financial health and creditworthiness. Margins are generally thin in this industry due to multiple factors: controlled prices on many common drugs, rising costs of imported raw materials, competition driving down prices, and underutilized capacity.

Industry data and statements from APPON reveal a worrying trend: domestic pharmaceutical sales fell from approximately NPR 35 billion to NPR 29 billion over a three-year period (around 2021–2024)^[14]. This decline in sales revenue directly impacts profit generation. Many companies have found themselves operating below break-even on key product lines. The fixed costs of running a pharmaceutical plant (quality control labs, regulatory compliance, skilled staff, etc.) remain high even if output drops. When capacity utilization fell (due to competition and COVID disruptions), those fixed costs were spread over fewer units, eroding profit margins.

Moreover, as noted, essential drugs price caps have made certain products loss-making. Manufacturers assert that they “are forced to limit production to avoid financial losses” on price-controlled medicines^[43]. Some have stopped producing them entirely, ceding that segment to either imports or black-market products. This is not a sustainable situation for companies or for medicine security.

The result is that the number of financially distressed pharma companies is rising. According to APPON, “*eight out of 80 pharmaceutical companies have shut down since COVID-19, 15 are on the verge of closure, and 40 are actively seeking buyers*”^[53]. In other words, out of about 80 operational firms, only roughly 60 remain in operation, and of those, only 10–11 are currently profitable^[13]. This is a startling statistic: it implies that up to 85% of operating companies are either running at a loss or barely breaking even. Such companies would have difficulty servicing debt or making new investments, thus representing higher credit risk. Indeed, credit rating agencies in Nepal have generally rated pharma companies in the mid-tier of credit quality, citing modest scale and policy risks. For example, ICRA Nepal’s rating rationales for companies like Quest Pharmaceuticals or Om Megashree Pharma often mention vulnerability to regulatory pricing and competition^{[54][55]}.

A deeper look at cost structure shows that raw material costs have surged in recent years. Nepal imports the majority of APIs from India, which itself imports many API precursors from China. During the pandemic and afterward, there were global supply disruptions that caused API prices to climb. The cost of raw materials reportedly went up 2-3 fold in some cases by 2021^[56]. Nepali manufacturers, unable to fully pass on these cost increases due to price-sensitive market and controls, saw gross margins shrink. Similarly, the Nepali rupee’s exchange rate (pegged to the Indian rupee) means any international cost inflation is directly felt. Packaging material imports (about NPR 2.5 billion worth in FY2019/20) also add to expenses^[27].

Operating expenses for compliance are also rising as companies have to invest in maintaining GMP standards, training staff, conducting product testing, etc. While the larger Nepali pharma firms have done so (many claim they meet WHO GMP and could “compete in quality with any other products in the world”^[57]), smaller firms struggle with the cost of compliance.

On the revenue side, competition from imports, especially subsidized Indian products, keeps domestic prices low. Indian state policies (like cheaper electricity, tax breaks) and sheer economies of scale allow Indian firms to export at prices Nepali firms find hard to match^[25]. One Nepali CEO gave an example: if an Indian company sells a tablet at NPR 10, Nepali manufacturers are expected to price lower to win tenders, but their production cost might be

higher due to smaller scale, squeezing their profit to near zero^[25]. There is also competition among the domestic players themselves as the top 5-10 Nepali pharma companies (such as National Healthcare, Deurali-Janta, Quest Pharmaceuticals, etc.) vie for market share, often engaging in aggressive discounting to pharmacies or bonuses to doctors to promote their brands. This further eats into margins.

As profitability declines, so does the ability of companies to service debt or invest. Several companies are reportedly up for sale or seeking mergers^[53], indicating distress. In a credit lens, this could presage consolidation in the industry: the stronger players might acquire weaker ones (if they have the financial muscle), or weak players will exit, which could eventually improve the survivors' market share. However, if too many exit too quickly, it could lead to supply gaps and over-reliance on imports, which is not ideal for national medicine security.

It's worth noting that a few Nepali pharma companies remain profitable and relatively stable. These are typically the ones who have a diversified product range, higher production volumes, and possibly export income (even if small). A handful of companies have started exporting in trace amounts to markets like Africa or Southeast Asia, although data is scant and exports are "very negligible" overall^[54]. Any export revenue, however small, can bolster a company's top line and expose it to hard currency earnings. But to export meaningfully, companies would need to achieve international certifications and scale, which most have not yet.

In conclusion, the financial outlook for the average Nepali pharmaceutical firm is challenging. Profitability has been hit by stagnant or falling revenues and rising costs, leading to closures and consolidation risk. From a credit standpoint, without policy changes (e.g. adjusting price controls, offering subsidies, or raising import tariffs where appropriate) or operational changes (cost-cutting or partnerships to improve scale), many firms could face continuing losses. Lenders would be cautious with the sector unless they see credible measures to restore profitability. The few firms that manage to maintain healthy financials will likely be those that innovate in their business model (niche products, maybe tapping into herbal/traditional medicine markets globally, or contract manufacturing for foreign companies) and maintain high quality, giving them an edge to possibly charge premium or access new markets.

Market Access

"Market access" for Nepal's pharmaceutical sector can be considered in two dimensions: access to the domestic market (i.e., the ability of companies to get their products to Nepali consumers and healthcare providers, in competition with others) and access to foreign markets (the ability to export and expand beyond Nepal). Both dimensions present notable challenges in the current context.

On the domestic front, access to market is generally straightforward in a physical sense as Nepal has an extensive network of pharmacies and drug distributors even in rural areas, and the regulatory environment allows any registered drug to be sold with a prescription (or over-the-counter for certain medicines). However, the proliferation of brands and competition in pharmacies is intense. Domestic companies need to invest in marketing and distribution to ensure their products are stocked and prescribed. Larger Nepali companies maintain their own

distribution channels and medical representative teams; smaller ones may partner with national distributors. The open-border nature with India means that unregistered Indian drugs sometimes enter the Nepali market and get sold illegally at lower prices^[58]. This undercuts legitimate companies' market share and can pose safety risks. The DDA has struggled to curb this influx of counterfeit or unregistered meds, especially along the 1,800 km open border where smuggling is easy^[47]. One report pointed out that India is a global hotspot for counterfeit drugs (estimated 35% of the market share of counterfeit medicines) and Nepal's proximity allows some of that to spill over^[59]. Such parallel markets reduce the effective market accessible to compliant companies, affecting their sales volumes.

Another aspect of domestic market access is government procurement. The government (through agencies like the Health Ministry and its Logistic Management Division) is a major buyer of medicines for public hospitals and health posts, including those needed for programs (TB, HIV, maternal health, etc.). Ideally, this could be a stable source of demand for domestic producers if they win tenders. The government has indeed stated policies to give preference to domestic products for procurement when possible^[43]. In reality, due to either pricing or donor-supplied imports, local companies have not fully capitalized on government procurement. For example, many essential program drugs (like anti-tuberculosis and anti-retroviral drugs) are supplied by international donors or imported using foreign aid^[12]. Hence, Nepali companies don't get to supply those even if they could produce them. Additionally, when local products have had quality issues, the government tends to be cautious in procurement. Therefore, improving quality and consistency is key for domestic firms to gain greater share of government orders which represent assured payment and volume (a credit positive if secured).

Turning to foreign market access (exports): currently, Nepal's pharmaceutical exports are minimal. As per the Department of Industry report, only a few companies export, and the volume is "very trace" with no consolidated data available^[54]. Barriers to export include: lack of international GMP certifications recognized by foreign regulators, small scale that makes pricing uncompetitive abroad, and lack of experience in regulatory filings overseas. Furthermore, many of Nepal's neighbors (India, Bangladesh, China) are themselves huge producers and exporters of generics, so finding a comparative advantage is difficult. One niche could be Ayurvedic or herbal products, where Nepal has rich resources. Indeed, some herbal products have found export markets (e.g., herbal supplements or essential oils). There was a case where a Nepali-French joint venture captured about 6% of Nepal's domestic herbal medicine market and aimed to export specialty herbal remedies^[60]. This indicates a potential path: leveraging unique Nepali herbal formulations under proper quality control to export as alternative medicine. But this requires investment and international marketing, which comes back to the need for foreign partnerships or significant capital.

The Nepali Times editorial argued that Nepal is "ideally placed to be a base for production and export of pharmaceutical drugs and vaccines" if the right policies and FDI come in^[61]. Geographically, Nepal is between two giant markets (India and China) and could hypothetically export to smaller countries in South Asia, Africa, or even developed markets by taking advantage of LDC exemptions (LDC-origin pharmaceuticals can sometimes enjoy duty-free access or lenient patent rules). However, to do so, Nepal must drastically improve its

regulatory standing. One concrete step would be achieving WHO prequalification for some products (especially in essential medicines like anti-malarials or vaccines). Bangladesh followed this route and now exports to many countries, including regulated markets, after upgrading quality and taking advantage of TRIPS flexibilities^[62]. Nepal so far has not leveraged its similar TRIPS exemption as not a single patented drug is being locally produced despite legal allowance, largely due to technical capability gaps^[63]. If Nepal could partner with a foreign firm, say, to produce a generic version of a high-demand patented drug (like a hepatitis C medicine or a new diabetes drug) for export to other LDCs, it could open a revenue stream.

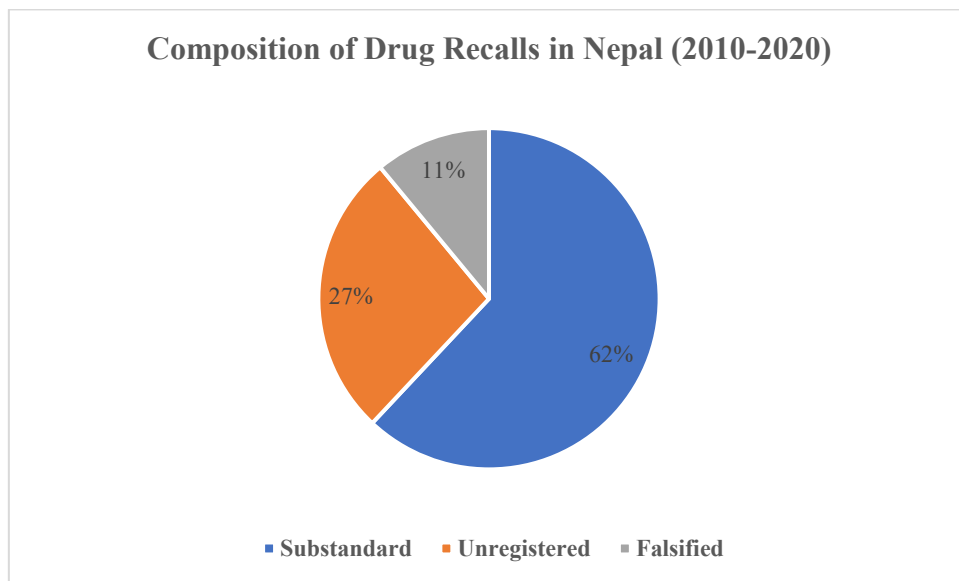
At present, no Nepali pharma company has a significant export footprint. This means their market access is almost entirely domestic, which, as we have seen, is strained. A lack of diversification markets makes the industry's fortunes highly correlated with Nepal's domestic economic conditions and policies. From a credit perspective, this is a concentration risk. The upside is that any improvements in export capability would provide a new avenue for growth. There have been some initial moves: Nepali firms have attended international pharma exhibitions, and a couple have registered a few products in countries like Myanmar or Cambodia. Also, with Nepal's impending graduation from LDC status (expected by 2026–2027), there is a sense of urgency: once it graduates, by 2033 it will lose the waiver to produce patented drugs without license^[16] and will also lose access to programs like GAVI (the global vaccine alliance that currently donates vaccines)^[64]. When GAVI support ends (because Nepal's income will be above the eligibility threshold), Nepal will need to procure or produce its own vaccines, which makes building local manufacturing capacity more pressing. This could be a catalyst for foreign collaboration, for example, establishing a vaccine manufacturing facility in Nepal through FDI or technology transfer.

In conclusion, market access for Nepali pharma is currently limited and competitive at home and almost non-existent abroad. Improving this will involve stronger regulatory enforcement internally (to clear out substandard competition and boost public trust), government procurement support, and strategic partnerships externally to enable exports. For creditors and investors, a company that manages to secure better market access say, exclusive supply contracts with the government, or entry into a foreign market would be viewed more favorably. Conversely, companies that remain confined to a shrinking domestic segment with many rivals may face stagnation.

Challenges and Way Forward

Nepal's pharmaceutical industry faces multifaceted challenges that inhibit its growth and threaten its sustainability. Key among these are quality assurance issues, import dependency (especially for advanced medicines and raw materials), inadequate economies of scale, policy constraints (like price controls and weak enforcement of supportive measures), and limited innovation. Addressing these challenges will be critical for strengthening the sector's credit profile and ensuring its long-term viability.

1. **Quality Control and Trust:** Ensuring drug quality is a foundational challenge. As discussed, substandard and falsified medicines have been a persistent problem in Nepal, undermining public health and confidence. From 2010 to 2020, Nepal recalled 346 pharmaceutical products due to quality issues, with a significant increase in recalls toward the latter part of the decade^[49]. The majority of these recalls (about 62%) were for substandard drugs (products that failed to meet pharmacopeial standards in potency, purity, etc.), around 27% were unregistered products illicitly sold, and about 11% were outright falsified drugs^[65]. The prevalence of substandard drugs (both domestic and imported) is attributed to inadequate regulatory surveillance, weak border controls, and sometimes negligence or corner-cutting by manufacturers.



*Figure 3: Composition of drug quality recalls in Nepal (2010–2020). Among recalled pharmaceuticals, 62% were substandard (failed quality tests), 27% were unregistered products circulating without approval, and 11% were falsified/counterfeit drugs. This highlights the need for stronger regulatory enforcement to ensure that only quality-assured medicines (domestic or imported) reach patients. Data Source: Neupane et al. (2022), *BMJ Open*^[65].*

Way Forward (Quality): Nepal must strengthen its regulatory infrastructure. This means investing in the DDA: increasing the number of drug inspectors significantly (from 38 to perhaps a few hundred, deployed across provinces), upgrading the National Medicines Laboratory to increase testing throughput (aim to test thousands of samples annually, not just 500^[50]), and leveraging technology for surveillance (e.g., track-and-trace systems for pharmaceuticals to detect counterfeit entries). The government could seek technical assistance from WHO or more experienced regulatory agencies in the region (like India’s CDSCO) to build capacity. Another strategy is to enforce stringent penalties for non-compliance: companies found producing substandard drugs should face heavy fines, license suspensions, or public blacklisting. Conversely, companies that consistently meet quality standards could be rewarded with fast-track approvals for new products or preference in government procurement. Over time, a reputation for

quality will also help Nepali firms if they pursue export markets. Essentially, quality assurance is non-negotiable – it will improve patient outcomes and also filter out disreputable players, indirectly strengthening the industry’s credibility and performance.

2. **Import Dependency and Self-Sufficiency:** Nepal’s reliance on imports is twofold, one is for finished pharmaceutical products (especially specialized medicines) and the other is for raw materials (APIs). This dependency poses supply risk (as seen when India’s export restrictions or global shortages struck during COVID) and perpetuates a trade imbalance. Despite being an LDC with the ability to produce generics, Nepal hasn’t made drugs like vaccines, oncology medicines, or biotech therapies. The challenge is that developing capacity for these requires significant technical know-how, capital, and scale. Similarly, producing raw materials (APIs) is a heavy chemical industry undertaking that Nepal currently lacks. Bangladesh’s experience is instructive: by abolishing patent protection early and heavily incentivizing local production of APIs with tax waivers until 2032, Bangladesh became almost self-sufficient in drugs (meeting 97% of domestic demand) and now exports to 150+ countries^[66]. Nepal, however, still imports 54-55% of its medicines by value and 100% of APIs^[67].

Way Forward (Reducing Dependency): Nepal should craft a strategic plan for pharmaceutical self-reliance for essential medicines. This could involve: identifying a list of critical drugs (for major public health burdens like cardiovascular disease, diabetes, cancer, antibiotics, maternal health, etc.) that are currently imported and formulating a roadmap to produce at least some of them domestically. The government can encourage technology transfer agreements, for example, inviting an Indian or international generic manufacturer to set up a production line in Nepal for insulin or cancer drugs, perhaps through joint ventures with Nepali firms. Given Nepal’s small market size, the government might need to provide assured purchase agreements (i.e., guarantee it will buy X volume per year for public hospitals) to make it worthwhile for such production to occur. For APIs, a full-fledged local bulk drug industry may be unrealistic in the short term, but regional collaboration could help as Nepal could partner with Indian API producers or explore production of a few select APIs (maybe herbal-derived ones or simple molecules) where it has some resource advantage. Additionally, Nepal might explore the concept of pooled procurement or regional stockpiles for vital drugs so that it isn’t left stranded during crises.

3. **Scale and Cost Competitiveness:** Most Nepali pharma companies are small-scale by global standards. This lack of scale leads to higher unit costs and inability to compete on price with imports. It also means they have limited budgets for research, quality assurance, and diversification. The challenge is to achieve greater scale in a market that is itself limited (Nepal’s population is ~30 million). The present scenario of around 60 operational companies splitting 45-50% of a NPR 65 billion market means each company on average has very small revenue (though in practice the top 10 companies take a lion’s share and many smaller ones have tiny slices). Market fragmentation thus hurts overall efficiency.

Way Forward (Scale and Collaboration): There may be a need for industry consolidation or cooperation. Encouraging mergers or acquisitions could create a few larger entities that benefit from economies of scale. While forcing consolidation is not straightforward, the government and industry associations could facilitate dialogues for partnerships, for example, sharing production facilities for costly processes, or forming consortia for API procurement to get bulk discounts. Another approach is to focus on specialization rather than everyone doing the same generics. If a few companies specialize in certain categories (say Company A focuses on antibiotics, Company B on cardio-metabolic drugs, Company C on injectables, etc.), they could achieve scale in that domain and even export, rather than each company making a bit of everything and not achieving critical volume in anything. Government policy can nudge this by creating centers of excellence or pharma industrial zones with shared facilities (common testing labs, waste treatment, etc.) to reduce overhead for individual firms.

4. **Policy and Regulatory Environment:** Nepal's policies need reform to align incentives correctly. The challenge here is overcoming bureaucratic inertia and interest group pressures. For example, price controls should be periodically updated, perhaps linked to an inflation index so that they remain fair to consumers but not ruinous to producers. A recommendation could be to revise the NLEM price list from NPR 1 per tablet set in mid-2000s to a more realistic price in 2025, or implement a subsidy where the government reimburses manufacturers for the gap if it insists on keeping consumer prices ultra-low. Additionally, import tariffs or taxes could be calibrated: currently, some imported drugs might be cheaply flooding the market; a slight tariff can both discourage low-quality imports and generate revenue that can be used to support local industry (for instance, via an innovation fund or quality upgradation fund). The Safeguard Act should be operationalized so that if Indian companies are found dumping products below cost, Nepal can legally impose countervailing duties^[41].

On the regulatory front, ease of doing business for pharma should improve. Obtaining approvals for new drugs or renewing licenses should be made quicker (perhaps by adopting digital applications and approvals at DDA). Corruption and red tape need to be curtailed, as these can otherwise discourage genuine investors. The government should also update and finalize the National Medicines Policy (the 2007 draft could be modernized) to clearly chart the course for integrating allopathic, Ayurvedic, and veterinary medicine development in Nepal's context. This policy should include plans for human resource development encouraging pharmacy and pharmacology education, retaining talent, and maybe inviting Non-Resident Nepali experts back home to lead research initiatives.

5. **Innovation and Diversification:** A fundamental long-term challenge is the lack of innovation – Nepal's pharma remains a generics-copying industry. Without innovation, it's hard to climb the value chain or create unique products. The traditional medicine segment (Ayurveda) could be an area of innovation by scientifically developing herbal drugs or nutraceuticals that could even be exported, but this requires investment in

research to validate efficacy and safety. As of now, R&D spending by Nepali pharma companies is minimal.

Way Forward (Innovation): Public-private partnerships could be key. The government might fund a Pharma R&D Institute in collaboration with universities and private firms, focusing on formulation development, herbal medicine standardization, and even biotech in the long run. Incentives like tax credits for R&D expenditure or grants for patent filing could spur companies to invest in research. While expecting breakthrough drug discovery in Nepal may be far-fetched at this stage, even incremental innovation like developing improved formulations (say, fixed-dose combinations tailored for local needs, or heat-stable vaccine forms suitable for remote areas) would add value. For Ayurvedic products, establishing standards and quality testing for herbal ingredients will allow those companies to market their products credibly (both domestically and abroad as alternative remedies). Nepal can also seek collaboration through cooperation: perhaps work with countries like India, China, or Thailand on joint vaccine development projects (especially because Nepal will need vaccine production post-GAVI support). Being part of regional clinical trials or manufacturing networks (for instance, producing certain vaccine components) could bring technology into Nepal.

Finally, drawing from the Bangladesh example that was cited in a 2024 column, Nepal can adopt several of Bangladesh's strategic initiatives: utilize the extended TRIPS waiver period effectively by producing some high-value drugs now (before patent obligations kick in), provide financial incentives such as low-interest long-term loans for pharma plant expansion (Bangladesh gave 12-year loans vs. Nepal's 5-year norm^[35]), allow firms more borrowing flexibility (Bangladesh removed single borrower limits for pharma to enable bigger investments^[68]), and consider export facilitation like allowing retention of foreign currency earnings for pharma exporters (so they can reinvest in quality and R&D). These measures helped Bangladesh become a pharma exporting powerhouse; Nepal could tailor similar measures to its scale.

In conclusion, the Nepalese pharmaceutical sector stands at a crossroads. The challenges are significant i.e. quality issues, policy bottlenecks, competition from imports and financial stress but none are insurmountable. With judicious reforms and strategic investments, Nepal can strengthen its domestic pharma base. The payoff would be multifaceted: improved public health security (less risk of drug shortages or substandard drugs), economic benefits (jobs, possibly export revenue), and better credit prospects for the companies involved (as profitability and stability improve). The next five years (2025–2030) will be crucial. If Nepal implements the suggested measures i.e. tightening quality regulation, adjusting pricing policies, attracting foreign partnerships, and building capacity, its pharmaceutical industry could regain growth momentum and increase its domestic market share from the current 45% towards the ambitious goal of 75% self-sufficiency envisioned by some policymakers^[37]. Such progress would echo the journey of peer countries and ensure that “Pills, Policy, and Prospects” align favorably in Nepal's pharma sector, benefiting both the industry's stakeholders and the public at large.

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