

PRESS RELEASE

Preparedness of Nepal's Pharmaceutical Sector in the Face of LDC Graduation

Kathmandu, 2 October 2024.

As Nepal approaches its graduation from the least developed country (LDC) category in 2026, its pharmaceutical sector faces significant challenges due to the loss of flexibilities under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Currently, as an LDC, Nepal is not required to provide patent protection for pharmaceutical products, allowing local companies to produce patented medicines without paying royalties and/or seeking the consent of the patent holder. This advantage will cease with the country's LDC graduation, posing critical concerns to the future of the industry and access to affordable medicines.

A [study](#) by South Asia Watch on Trade, Economics and Environment (SAWTEE), in collaboration with the Third World Network, finds that although the growth of Nepal's pharmaceutical production capacity has been driven by 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. It cautions that graduation from LDC status might reverse this trend if these and other newer medicines are subsequently patented within the country.

The findings of the study were presented at a workshop organized by SAWTEE and Third World Network in Kathmandu.

The study emphasizes that as many of these generics produced by domestic manufacturers in Nepal are for treating non-communicable diseases (NCDs), such as hypertension and diabetes—major causes of death in recent years—the impact will be felt in terms of access to these medicines. In addition to maximizing the use of LDC-specific flexibilities granted by the TRIPS Agreement as long as Nepal remains an LDC, the study recommends that, in the post-graduation context, the Intellectual Property Section (within the Department of Industry), which oversees patent-related matters, build its technical and human resource capacity in examining patent applications, maintaining the patent database and avoiding the grant of frivolous patents, among others. It also suggests that the intellectual property bill 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, adding that the government needs to hold consultations with domestic stakeholders on the new draft of the intellectual property law before sending it to the parliament for adoption. In doing so, Nepal should also learn from the experiences of other developing countries in implementing and using TRIPS flexibilities.

In the workshop titled **“Preparedness of Nepal's Pharmaceutical Sector in the Face of LDC Graduation”**, participants deliberated on the findings of the study and discussed the risks posed by the loss of TRIPS-related flexibilities and stressed the need for Nepal's pharmaceutical industry to adapt to the resulting challenges.

Dr. Paras Kharel, Executive Director, SAWTEE, said that despite the importance of the issue, there is an acute dearth of research in the context of Nepal on the implications of LDC graduation for intellectual property rights-related policy space, and SAWTEE's study is an attempt to fill part of this void with a focus on the pharmaceutical sector.

Dr. Posh Raj Pandey, Chair Emeritus, SAWTEE, highlighted that flexibilities allowed by the TRIPS Agreement should be incorporated into Nepal's Intellectual Property (IP) Bill to protect the domestic pharmaceutical industry as well as Nepalis' affordable access to medicines. He noted that production of medicines in Nepal is heavily dependent on imported inputs. He also mentioned that exports are minimal, with only paracetamol and cardiac and anesthesia products being exported to Uganda. He flagged the absence of organized data on Nepal's pharmaceutical sector, noting that much of the information is based on industry discussions. Therefore, relevant stakeholders should prioritize making the data more readily accessible and systematically organized. Dr. Pandey also identified the communication gap between the pharmaceutical industry and the government, stressing the need for better cooperation and collaboration to address industry concerns. He encouraged the private sector to take an active role in the legislative process of IP law and advocate for the effective implementation of TRIPS flexibilities.

Prof. Shiva Raj Adhikari, Vice-Chairman, National Planning Commission, Government of Nepal, in his special remarks, stated that the pharmaceutical industry is often neglected and urged further research and greater engagement with the private sector in government discussions to ensure the sector receives the attention it deserves.

Mr. Narayan Prasad Dhakal, Director General, Department of Drug Administration, Ministry of Health and Population, Government of Nepal, emphasized that Nepal should intensify its lobbying efforts for extending TRIPS flexibilities, both in its domestic policy framework and on the international stage. He noted that the lack of comprehensive data on medicine production, importation, and consumption across different categories is hindering effective policy formulation and implementation. Furthermore, he stressed the importance of including any remaining TRIPS flexibilities in the new draft bill that is currently in the process of being finalized.

Mr. Mahesh Prasad Pradhan, President, Association of Pharmaceutical Producers of Nepal, emphasized the significance of Nepal's pharmaceutical industry, which, according to him, employs around forty thousand people. He pointed out that Nepal's pharmaceutical industry is grappling with high taxes on imported raw materials and inadequate government support, with drug prices set 16 years ago still in place.

Dr. Anil Bikram Karki, President, Nepal Medical Association, remarked that health is recognized as a fundamental right in the constitution. However, the loss of patent rights could impact the affordability of medicines, with individuals currently paying for one-third of their medical expenses out of pocket. To address this, government health delivery policies, along with efforts from civil society, must go beyond merely being stated in the constitution and ensure practical implementation to make healthcare

accessible and affordable for all. Further, he added that scrutiny concerning drug quality should be applied to imported and domestically manufactured drugs in equal measure; the narrative that drugs sold by multinational companies are always beyond reproach must be strongly challenged.

Mr. Krishna Gyawali, Former Industry Secretary of the Government of Nepal, stated that the intellectual property office provided for in the draft intellectual property bill needs to be granted autonomy, and backed by adequate human and financial resources for it to deliver. He further added that, within Nepal's Industry Department, there is an IPR section; however, its roles, responsibilities, and functions need further clarity and empowerment. With support from organizations like SAWTEE, discussions can be facilitated to raise overall awareness within the government department about intellectual property rights and their significance.

Mr. KM Gopakumar, Senior Researcher and Legal Advisor at Third World Network, stated that incorporating TRIPS flexibilities into intellectual property legislation is important to mitigate the impact of LDC graduation but it should not be an end in itself. It should be complemented by an enabling policy framework to implement the flexibilities, by addressing critical bottlenecks, beginning with a mechanism to monitor the impact of patents on medicine production and affordable access to medicines. In addition, he mentioned that the Intellectual Property Act should come into effect only after the full exemption period available to Nepal is over. Moreover, the Act should allow patents on new molecules invented only after the date the Act comes into force. All such new patented innovations will take 8-10 years to come into the market which will give the domestic industry more time to prepare themselves for the competition coming from the patent regime, he added.

Mr. Shiv Raj Bhatta, trade expert and SAWTEE board member, stated that the Nepali pharmaceutical industry should start looking beyond the domestic market, and seek precise policy support to help it break into foreign markets.

Ms. Ranja Sengupta, Senior Researcher and Head of Third World Network India, concluded the event by citing it as a much-needed discussion that brought together participants from both the government and private sector.

Participants included policymakers, medicine producers, academics, journalists, members of civil society and other experts.