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

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

Presentation structure

- Background
- Pharmaceutical Sector and Intellectual Property Regime
- WTO TRIP's Flexibilities
- Some Suggestions

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Background

- Nepal set to graduate from LDC
- Lose flexibilities provided to LDCs in WTO
  - General transition to implement TRIPS until 1 July 2034
  - Need not provide patent protection to pharmaceutical products until 1 January 2033
  - Waiver on mailbox obligation and exclusive marketing rights
- Full freedom to produce generic medicine
- Nations Drug Policy envisages self-sufficiency in medicine- key to access to safe, effective and affordable medicines
- 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.

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Objectives of the Study.

- Analyze the strengths and weaknesses of Nepal's pharmaceutical industry vis- a-vis TRIPs obligations.
- Identify the major legal, policy and institutional issues for the optimal use of TRIPS flexibilities.
- Identify the preparedness to make use of TRIPS flexibilities.
- Develop a set of recommendations/strategies to optimize the use of TRIPS flexibilities for pharmaceutical product patent regime

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Pharmaceutical Sector and Intellectual Property Regime

Brief History of Pharmaceutical Sector and IP System

- Royal Drug Research Laboratory (RDRL) set up in 1964,
- Chemidrug established in 1971
- Royal Drugs Limited established in 1972
- Health Policy rolled out in early 1970s
- IoM introduced Pharmacy Diploma in 1972
- Nepal Pharmaceutical Association set up in 1972
- Drug Act enacted in 1978
- DDA established in 1979
- Association of Pharmaceutical Producers of Nepal (APPON) established in 1991

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Brief History of Pharmaceutical Sector and IP System

- Patent, Design and Trademark Act and Copyright Act enacted in 1965
- Nepal became party 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
- New Copyright Act enacted in 2002 replacing Copyright Act 1965

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Pharmaceutical sector in Nepal

- Constitution provides right to healthcare
- National Drug Policy 1995 and National health policy 2014 stipulate access to safe, efficacious and affordable medicine

But out-of-pocket health expenditure stands at slightly over 55 percent,

- Slightly over one-third health expenditure is on pharmacies and medical good

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Causes of Death

1990		2017		
Disease	**Rank**	**Disease**	**Rank**	**% change**
Lower respiratory infections (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 (CD; 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

Top 10 Causes of Years of Life Lost

1990		2017	
Disease	% of total YLL	Disease	% total YLL
Lower respiratory infections (CNMN)	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	Intracerebral hemorrhage (NCD)	2
Protein energy malnutrition CNMN)	3	Pedestrian road injury (NCD)	2
Neonatal preterm births (CNMN)	3	Drug-susceptible tuberculosis (CNMN)	3
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 (NCD)	1	Tetanus (CNMN)	<1
HIV/AIDS and other diseases (CNMN)	<1	Measles (CNMN)	<1

Top 15 Therapeutic Category, 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)	7
Anti-diabetic	8
Neuro-related	9
Gynecology	10
Ophthalmology	11
Urology	12
Hormones	13
Anti-parasitic	14
Hepatoprotectives	15

Domestic Production

- Pharmaceutical producers- 73, operation in 62
- All operational firm are large
- Based on annual sales, 13 of the 20 dominant, with 60 percent market share, pharmaceutical companies are in Nepal.
- Employs about 15,000 people, including few foreign consultants
- No pharma company has R&D division in real sense
- Domestic company cater about 50 % share in volume and 45% in value
- Top 20 brands sold in Nepal are Nepalese
- Minimum backward linkages
  - Absence of policy supports
  - Issue of scale and sophistication

But industry claims 50% value addition

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Domestic Production

- 30 pharmaceutical company are either GMP-certified or in the process
- Sometimes quality questionable
- Fulfill labeling requirements-expiry date, storage requirements and usage direction
- Nepal health Research Council found supply of substandard medicines
- High price variation for similar products-up to 400 %

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Consumption and Production of Patented medicines

- Lack of organized data on domestic production of generic version of originator medicine,
- About 90 % of domestic consumption is generic version
- High market concentration-dozen or so firms capture about 60 % market share
- Few company started generic version of originator medicine, e.g. Gliptins (oral medicine for Diabetes), Sofosbuvir (drug for Hepatitis C) Favipiravir (use to treat COVID)

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Import and Export

- Import almost all inputs -active pharmaceutical ingredients (API), excipients, suspending agents, preservatives, packaging material, color and other agents, and several categories of drugs
- Major imported drugs 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
- Import market concentrated-both importer and source
- Export is almost nil- exported paracetamol and cardiac and anesthesia to Uganda
- Regulatory barriers to exports
  - have WHO prequalification;
  - obtain recognition from a stringent regulatory body in a developed country;
  - obtain certifications from relevant international bodies such as the UN Children's Fund (UNICEF
- Price regulation for 96 kind of medicines

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Policy Structure

- Patent Design and Trademark Act 1965, no specific provision governing pharmaceuticals, patent rights for 7 years with possibility to renew twice
- IP Policy 2017, which states to take into account TRIPS flexibilities and waiver for LDCs
- Control of patent during the period of national crisis
- Use of compulsory licensing
- Provision of parallel imports
- Draft of IP Act based on IP Policy
  - Lacks provision to effectively avoid secondary patent
  - No provision granting parallel imports
  - No Bolar exemption
  - Inadequate provisions for compulsory license

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Use of WTO TRIP's Flexibilities

Use of TRIPs Flexibilities

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 novelty and non-obviousness standard and broad scope of prior art have an effect on the quantity and quality of patents and the scope for generic production of pharmaceuticals.
Patent examination and opposition procedures	Patent examination, 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.

Use of TRIPs Flexibilities

TRIPS Flexibility	Remarks
Regulatory exception (Bolar exception)	Allows generic 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.

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Use of TRIPs Flexibilities

TRIPS Flexibility	Remarks
Compulsory license	When negotiation for a voluntary license fails, third parties can be authorized to exploit the patent without the consent of the patent holder. Such compulsory licenses may also be granted to remedy anti-competitive practices, even in the absence of a prior negotiation.
Compulsory licenses for export/import	A special regime that permits the export of pharmaceuticals produced under compulsory license 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.


Some
Suggestions

For Government

- Improve data on production, import and export of pharmaceutical sector
- Enhance transparency and accountability mechanism to avoid, among others, frivolous patent
- Incorporate fully and optimally public health related flexibilities in IP legislation
- Hold extensive consultation with stakeholders before presenting to parliament
- Work closely with industry to make it globally competitive
- Continue advocacy for flexibilities to newly graduated LDCs

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For Pharmaceutical Industry

- Convey industry concern to draft IP Bill
- Continue to strengthen capacity to produce generic version of originator medicine
- Build capacity to utilize TRIPs flexibilities

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For Civil Society

- Play active role in the legislative process of IP Law
- Advocate for effective implementation of TIPs flexibilities

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Thank you

For comments and queries

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