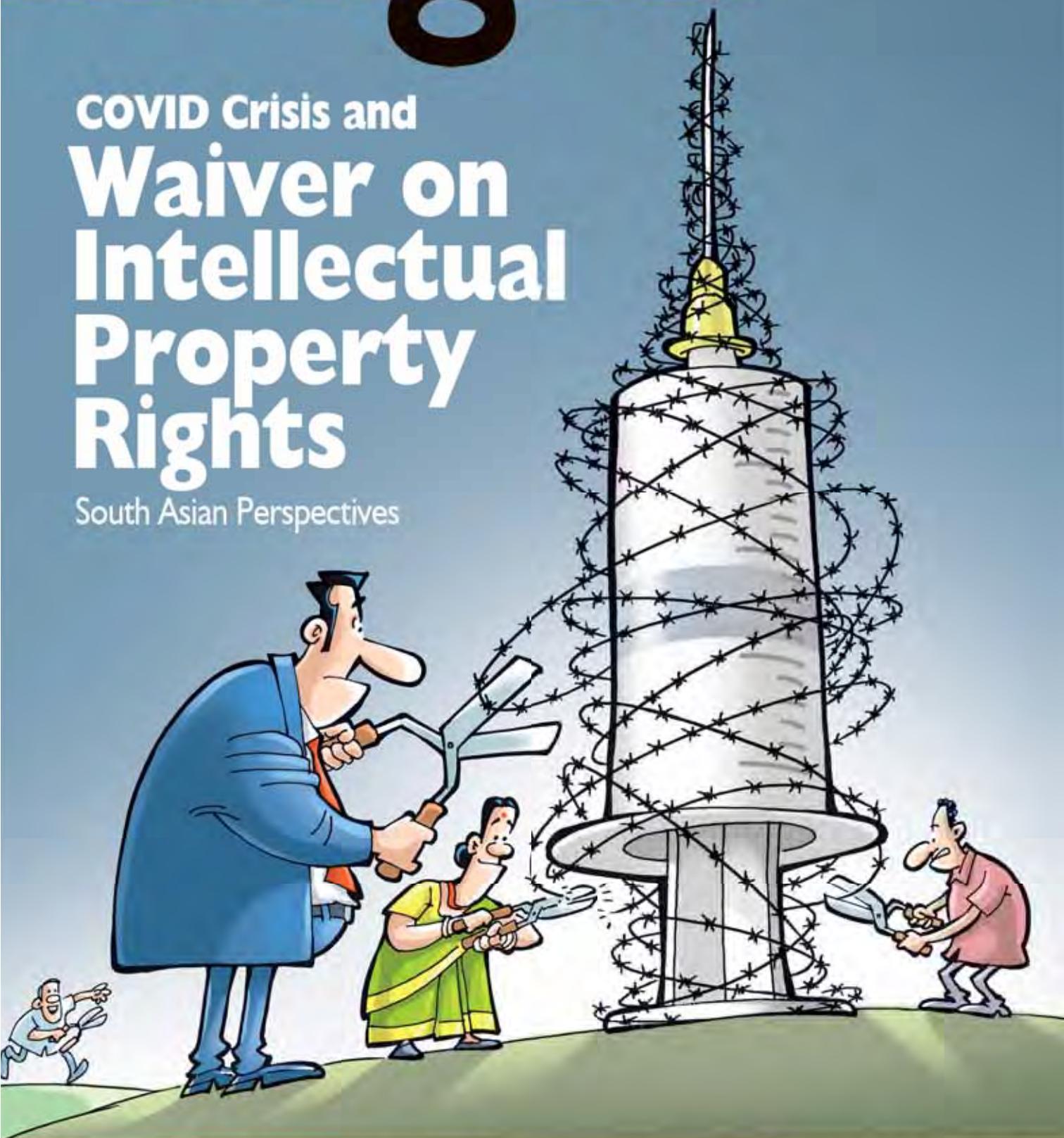


● TRADE ●

# insight

## COVID Crisis and Waiver on Intellectual Property Rights

South Asian Perspectives



**PUBLISHED BY**

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

**REGIONAL ADVISORY BOARD**

**Bangladesh**

Dr. Debapriya Bhattacharya

**India**

Dr. Veena Jha

**Nepal**

Dr. Posh Raj Pandey

**Pakistan**

Dr. Abid Qaiyum Suleri

**Sri Lanka**

Dr. Dushni Weerakoon

**EDITOR-IN-CHIEF**

Dr. Puspa Sharma

**ASSOCIATE EDITOR**

Dikshya Singh

**ASSISTANT EDITOR**

Kshitiz Dahal

**DESIGN**

Bipendra Ghimire

**COVER & ILLUSTRATION**

Abin Shrestha



P.O. Box: 19366

Tukucha Marg

Baluwatar, Kathmandu, Nepal

Tel: +977-1-4424360/4444438

Fax: +977-1-4444570

E-mail: [sawtee@sawtee.org](mailto:sawtee@sawtee.org)

Web: [www.sawtee.org](http://www.sawtee.org)

Regd. No. 208/070/071 (Kathmandu)

# Will pandemic change IPR regime?

**ISSUES** with development of and access to vaccines against COVID-19 have once again revealed how unequal the world is. A major reason for this inequality is the protection accorded to vaccines through the use of intellectual property rights (IPRs) that are held mostly by individuals and organizations in developed countries. Such IPR protection is ensured by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO).

The world is facing acute shortages in the supply of vaccines, yet developing countries barring a few, which have the capacity to produce vaccines, are unable to produce them, mainly due to the protection of vaccines by IPRs. Moreover, the exorbitant prices of vaccines, such as those developed by Pfizer-BioNTech and Moderna, have made them unaffordable to governments and people in developing countries. IPRs are major reasons for these exorbitant prices. Many developing countries, including least-developed countries, have built their capacity over the years to produce vaccines and medicines.

A number of scholars and developing country governments have argued that providing IPR waivers in vaccines would help increase production of vaccines in developing countries, and thus increase their supply, while also reducing their price. India and South Africa have submitted a proposal in the WTO to waive certain obligations of WTO members under the TRIPS Agreements to make COVID-related vaccines, medicines and medical products available at affordable prices.

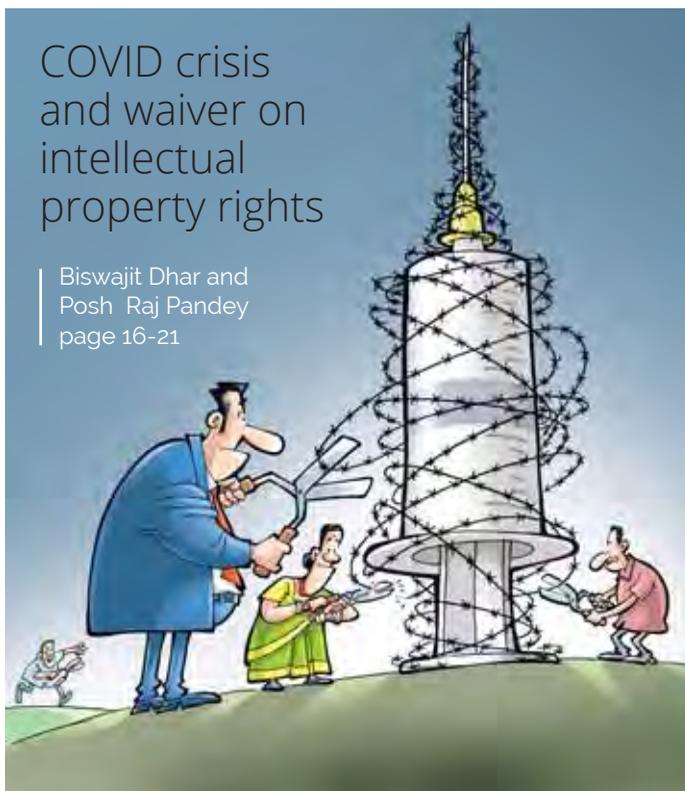
Those against the Waiver Proposal argue that there are flexibilities in the TRIPS Agreement and developing countries can make use of this mechanism in the current context of the pandemic; hence, providing a separate waiver is not necessary. However, the TRIPS flexibilities have been hardly used by countries in the past, mainly due to the complicated procedural requirements that has made the mechanism unattractive. Hence, in the current case of the pandemic, the possibility of making use of the TRIPS flexibilities to address the concerns related to vaccine access is almost nil. The Waiver Proposal submitted by India and South Africa is of utmost importance to ensure timely vaccine access at affordable prices by developing countries.

As the cover article in this issue contends, “the importance of the Waiver Proposal arises from the fact that the pharmaceutical companies, which are at the forefront of developing vaccines and medicines for overcoming the pandemic, have repeatedly shown their inclination to use their market power, derived from their control over the technology market, using their patent rights”. Therefore, it is urgently necessary to lend voice to the Waiver Proposal. Several member countries of the WTO, including those in South Asia—Bangladesh, Nepal and Sri Lanka—have provided support to the Proposal. Learning from the past, additional like-minded countries and organizations should come forward to build a strong coalition and strengthen the support for the Waiver Proposal. This is one way, and an important one, of fighting the current pandemic together. ■

# Content

## COVID crisis and waiver on intellectual property rights

Biswajit Dhar and  
Posh Raj Pandey  
page 16-21



Tough road ahead for LDCs  
Report, 8

Climate causing distress migration  
Report, 9

Overview of Nepal's  
pharmaceutical sector  
and its response to COVID-19  
Puspa Sharma and Avinash Gupta, 10-12

Leveraging Bangladesh's pharma-  
ceutical industry in COVID-19 vac-  
cine supply chain  
Abdur Razzaque, Rabiul Islam Rabi and Md  
Shahiduzzaman Sarkar, 13-15

Possible investor-state dispute  
settlement claims due to COVID-19  
Prabhash Ranjan, 22-23

Pakistan's pharmaceutical trade in  
COVID-19 time  
Shahid Mehmood, Naseem Faraz and Gh-  
ulam Samad, 24-27

Nepal's chronic fertilizer  
shortage  
Dikshya Singh, 28-29

Has Nepal broken out  
of its trend of export  
stagnation?  
Kshitiz Dahal, 32-34

Knowledge platform  
COVAX and its importance  
in the fight against the global  
pandemic  
Alabhya Dahal, 36-37

## India's new (harsh) rules of origin requirements

M S Siddiqui, 30-31



Book review  
Food as national security agenda  
Shaleen Khanal, 35

in the news, 4-7  
network news, 38-39

### MEMBER INSTITUTIONS OF SAWTEE

**BANGLADESH** 1. Bangladesh Environmental Lawyers' Association (BELA), Dhaka; 2. Unnayan Shamannay, Dhaka; **INDIA** 1. Citizen consumer and civic Action Group (CAG), Chennai; 2. Consumer Unity & Trust Society (CUTS), Jaipur; 3. Development Research and Action Group (DRAG), New Delhi; **NEPAL** 1. Society for Legal and Environmental Analysis and Development Research (LEADERS), Kathmandu; 2. Forum for Protection of Public Interest (Pro Public), Kathmandu; **PAKISTAN** 1. Journalists for Democracy and Human Rights (JDHR), Islamabad; 2. Sustainable Development Policy Institute (SDPI), Islamabad; **SRI LANKA** 1. Institute of Policy Studies (IPS), Colombo; 2. Law & Society Trust (LST), Colombo

Views expressed in *Trade Insight* are of the authors and do not necessarily reflect the official position of SAWTEE or its member institutions.

# Nepali traders shift to exporting soybean oil as palm oil loses lustre after India's restriction

**SOYBEAN** oil has become the largest export of Nepal displacing palm oil as traders changed tack to keep exploiting trade preferential loopholes after the Indian government squeezed palm oil imports.

According to the Department of Customs of Nepal, soybean oil export increased four and a half times year-on-year to NPR 13.5 billion from NPR 3 billion in the five-month period from mid-July to mid-December in the current fiscal year. In the whole of the last fiscal year 2019-20, Nepal's soybean oil exports amounted to NPR 12.69 billion, the statistics show.

Nepal produces very little soybean oil of its own, and the heady growth is achieved by importing raw oil and re-exporting it after processing.

Tariff exemptions on Nepali exports to India under the Agreement on South Asian Free Trade Area (SAFTA) give Nepali exporters an advantage. Countries outside of South Asia are



Wikimedia Commons

slapped with tariffs of 54 percent on palm oil and 45 percent on soybean oil.

The figures show that Nepali traders imported crude soybean oil worth NPR 14.67 billion in the review period—mostly from Argentina, Brazil and Paraguay. An examination of the import and export values shows that the overall value addition of the product is just over NPR 1 billion.

The SAFTA agreement, to which Nepal is a party, stipulates that goods

not in the sensitive lists are eligible to be imported and re-exported with lower duty rates or at zero rates if the requirements are met.

For Nepali exports to India to be eligible for tariff exemptions under this agreement, imported goods need to have at least a 30 percent value addition. Nepali trade experts have been saying that Nepali traders do not meet the 30 percent value addition requirement. (*www.kathmandu-post.com*, 27.12.2020) ■

## Bangladesh, Bhutan sign preferential trade deal

**BANGLADESH** and Bhutan on 6 December signed the first ever preferential trade agreement (PTA) to boost bilateral trade.

The agreement comes at a time when the two South Asian countries are also marking the 50th anniversary of diplomatic ties. Bhutan recognized Bangladesh's independence on 6 December 1971, becoming the first

country in the world to accept it as a sovereign nation.

Under the PTA 100 products from Bangladesh and 34 from Bhutan can find duty-free entry into each other's markets.

Bangladesh's Foreign Minister AK Abdul Momen said the agreement is a new chapter in bilateral ties, urging businessmen of both the countries to take advantage of the accord.

He said there is a possibility of "robust trade" and cooperation in many areas including education, health, shipping, information technology, and agriculture in the near future.

According to official figures, trade between Bangladesh and Bhutan was US\$12.77 million in the fiscal year 2008-09, which rose to US\$49.65 million in 2018-19. (*www.aa.com.tr*, 06.12.2020) ■

# Gwadar port huge trade opportunity for Central Asia, Afghanistan

**ADVISER** to Pakistan's Prime Minister on Commerce and Investment, Abdul Razak Dawood, has said that Gwadar Port will provide energy-rich Central Asian Republics (CARs) and Afghanistan huge opportunities for regional trade connectivity.

He said that the Pakistani government is prioritizing the economic integration to promote regional trade and connect important regional trade players with the deep sea port.

The PM's adviser said that Gwadar's geostrategic location, making it a possible railway link to Kandhar and other parts of Afghanistan, multiplies its economic importance.

He also informed that Afghanistan has requested Pakistan to provide a Cross-Stuffing Facility at the port. He said that Pakistan is actively participating in regional forums of

Central Asia Economic Cooperation (CAREC) and Quadrilateral Traffic in Transit Agreement (QTTA) so that the country can maximize on benefits once Gwadar Port begins operating at full capacity.

According to Dawood, improvement in trans-shipment facilities at Gwadar will change the dynamics of regional connectivity as it is a strategic location giving China and Central Asia access to the Gulf region and the Middle East. The port will also act as the main sea gate for Central Asia, making it easier for Xinxiang and Central Asian countries to send products to other regions.

The port is likely to reduce transport time for goods from Gwadar to Western China and CARs by 60-70 percent, respectively. (*profit.pakistan-today.com.pk/*, 17.12.2020) ■

## India, Bangladesh ink seven pacts

**INDIA** and Bangladesh on 17 December sealed seven agreements to expand cooperation in diverse areas, and restored a cross-border rail link which was in operation till 1965.

The restoration of the Chilahati-Haldibari railway link and signing of the pacts, providing for cooperation in areas of hydrocarbons, agriculture and textiles, among others, came at a virtual summit between Prime Minister Narendra Modi and his Bangladeshi counterpart Sheikh Hasina.

The inauguration of the Chilahati-Haldibari rail link is expected to enhance connectivity to Assam and West Bengal from Bangladesh. It was part of the broad gauge main route from Kolkata to Siliguri till 1965. (*economictimes.indiatimes.com*, 17.12.2020) ■

# Delays in customs clearance crippling India's import-export industry

**CUSTOMS** clearance delays continue to cripple the Indian industry as they have risen from the earlier 15-20 days to 25-30 days, and in some cases clearance is being given after over a month. The industry and custom brokers are citing the poor rollout of faceless assessment for the delays.

The sectors that are being impacted by the delay have increased. Earlier, delays were faced primarily by automobiles, auto ancillary, electrical machinery, metals, chemicals and medical equipment. Now labour intensive sectors and domestic man-

ufacturing are also getting impacted, due to the delay in release of goods.

According to export agencies, the delay is worsening the situation as it is the peak business time ahead of the Christmas break. Export agencies have claimed that there are no containers available and freight rates have shot up substantially. They believe that there is an urgent need for regulatory body to regulate the operations. Moreover, exporters have said that the farmer protest in Punjab has held up 5,000 containers, which is creating a lot of issues for the sectors involved.

The customs clearance delays and unavailability of containers at the port are impacting the export sector negatively. The food and beverage industry is getting huge orders from across the globe despite the reeling teething time, but the unavailability of containers at ports is leading to delays beyond the tolerance threshold of food and beverage, food processing industry, clothing, leather, pharmaceutical products, medical equipment, chemicals, etc. (*www.cnbctv18.com*, 20.10.2020) ■

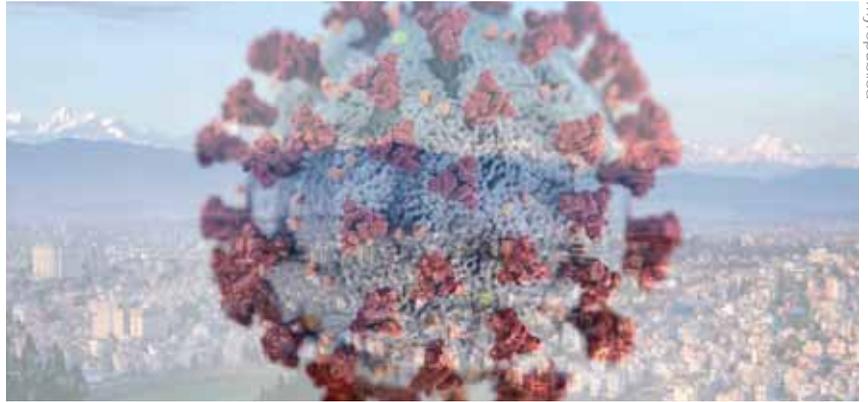
# Severe air pollution can heighten COVID-19 risk in South Asia

**EXPERTS** warn that bad air could worsen the spread and severity of the coronavirus pandemic in the winter of 2020 as South Asia descends into its annual smog season. Pollution levels peak every autumn and winter, when agricultural waste burning, industries, vehicle fumes and brick kilns combine to create a toxic soup.

Emerging studies, currently undergoing peer review, suggest that long-term exposure to air pollution before the pandemic is associated with severe symptoms from COVID-19 and a greater risk of death.

Academics at Harvard University looked at fatalities from the virus and historic levels of dangerous particulate matter across the US. They found that high levels of particulate pollution in the years before the pandemic were associated with an 8 percent rise in COVID-19 death rates.

Bangladesh, India, Nepal and Pakistan have overtaken China and



myrepublica

become home to the most polluted cities in the world. Millions of people die every year from breathing in poisonous air, with life expectancy cut by five years on average. This rises to more than eight years in the most polluted areas of northern India.

But governments have failed to act. In India, activists have rejected

the government's National Clean Air Programme as insufficient. While some real-time data is available in India, cities in Bangladesh, Pakistan and Nepal still lack basic equipment for monitoring air pollution, let alone a robust strategy to address the sources. ([www.indiaclimatedialogue.net](http://www.indiaclimatedialogue.net), 13.10.2020) ■

## India's new customs rules to take toll on Bangladesh's exports

A new rule framed by India on determining the country of origin of a product is going to hurt Bangladesh's exports to India and undermine the efforts to narrow large trade imbalance between the two neighbours, according to two government agencies.

The views came after the Indian authority issued a notification termed 'Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020' in August.

Following the notification, the commerce ministry sought opinions from the Bangladesh Trade and Tariff Commission (BTTC) and the Export Promotion Bureau (EPB).

Both the agencies find that the new measure on rules of origin (RoO) are inconsistent with the trading agreements, particularly the Agreement on the South Asian Free Trade Area (SAFTA).

The move would affect Bangladesh's exports to India, which

enjoyed a US\$4.68 billion surplus, they said.

It comes at a time when Bangladesh's exports to the larger neighbour are gradually increasing.

Officials of the commerce ministry said the BTTC scrutinized the new rule in light of the SAFTA's RoO and the Operational Certification Procedures (OCP). The BTTC found that some of the provisions contradict with those in the SAFTA RoO and OCP. ([www.thedailystar.net](http://www.thedailystar.net), 08.11.2020) ■

# Nepal, India to amend bilateral transit treaty to expand trade and connectivity

**NEPAL** and India have agreed to amend the bilateral transit treaty in a bid to boost trade and connectivity during a meeting of the Inter-Governmental Committee (IGC) on Trade, Transit and Cooperation to Control Unauthorized Trade.

As of now, only government-owned railway services transport cargo to Nepal, and under the proposed amendment, private operators will also be allowed to serve in Nepal, said Baikuntha Aryal, Commerce Secretary at the Ministry of Industry, Commerce and Supplies (MoICS).



The amendment will also allow Nepali railway to be used for trade purposes. A comprehensive review of the transit treaty was undertaken that includes the use of waterways and railway services between the two countries. The date for signing the amended agreement was yet to be fixed.

Nepal also requested the Indian side to extend railway services up to the Integrated Check Posts (ICPs) in Birgunj and Biratnagar, both of which were constructed with the support of the Indian government. According to MoICS, the Indian side announced that the construction of an ICP in Nepalgunj had already started, and that work on the facility in Bhairahawa would begin soon.

The Nepali side also requested its counterpart to allow Nepali traders to use Asian Highway 2 of India for trade with Bangladesh as the existing Phulbari-Bangladesh trade route had become congested. (*www.kathmandupost.com/*, 08.12.2020) ■

## Climate change will continue to widen gaps in food security



pxl/jx

**IN** a new study published in *Nature Food*, researchers assessed global yields for 18 of the most farmed crops—wheat, maize, soybeans, rice, barley, sugar beet, cassava, cotton, groundnuts, millet, oats, potatoes, pulses, rapeseed, rye, sorghum, sunflower and sweet potatoes—that, all together, represent 70 percent of global crop area and around 65 percent of global caloric intake.

The authors found that climate change will not only hamper farmers' abilities to maintain current harvests, but that countries already facing food insecurity will be disproportionately affected. The researchers investigated temperature variations, but did not examine climate impacts to precipitation patterns or other weather phenomena like flood or drought.

The most negatively impacted countries across most crops, their models found, were those in sub-Saharan Africa, and certain countries in South America and South Asia like India, Brazil, Indonesia, and Venezuela, among others. (*www.ehn.org*, 01.10.2020) ■

# Tough road ahead for LDCs

**THE** world economic crisis brought by the COVID-19 pandemic may affect the previously planned graduation of least developed countries (LDCs), according to the latest United Nations Commission on Trade and Development (UNCTAD) report on LDCs.

The COVID-19 pandemic is estimated to contract the GDP per capita of LDCs by 2.6 percent in 2020 from already low levels, as these countries are forecast to experience their worst economic performance in 30 years. At least 43 out of the 47 LDCs will likely experience a fall in their average income. Similarly, extreme poverty in LDCs is projected to expand by 32 million in 2020, to reach 377 million people. The poverty rate will rise from 32.5 percent to 35.7 percent in 2020, due to the COVID-19-induced economic crisis.

While the pandemic had, at least initially, a less than catastrophic health impact, its economic repercussions have been ruinous. LDC economies experienced their strongest economic shock in several decades; this, in turn, resulted in a sharp economic downturn, brought about by the combined effects of a deep world economic recession, and the consequences of the domestic containment measures adopted by LDC governments. Worse still, these consequences are likely to linger in the medium term.

Between October 2019 and October 2020, the economic growth forecast for LDCs was revised sharply downwards from 5 to -0.4 per cent. This is the worst economic outcome in 30 years for this group of countries, and represents a significant reversal of the economic and social progress achieved in recent years, includ-

ing in terms of poverty and social outcomes. It also makes reaching the Sustainable Development Goals by 2030 a more distant prospect.

A protracted recession could lead to permanent job destruction, threaten enterprise survival with related losses in terms of productive capacities and tacit knowledge and could have a long-term effect on potential output. Avoiding this dramatic outcome will be particularly crucial in LDCs because of the structural characteristics of the entrepreneurship that are prevalent in these countries. A prolonged crisis would further deteriorate an already weak LDC entrepreneurial landscape as currently characterized by a plethora of mainly informal

The LDCs that have better weathered the pandemic are those with a broader and more sophisticated base of productive capacities in their economy.

traditional and non-innovative businesses; a structure of firms largely skewed towards micro, small and medium-sized enterprises (MSMEs); and a private sector with limited access to credit.

The impact of the world economic recession on LDC economies has probably been stronger than the domestic demand shock. This, in turn, brought about a sharp downturn in the external demand for LDC goods and services; depressed the prices of their main exports; and caused a slump in inflows of external resources (e.g. remittances, capital). The widening trade deficit in goods and services and the contraction in remit-

tance receipts in 2020 are expected to lead to a further expansion of the total current account deficit of LDCs as a group; this is forecast to deepen sharply from 4.6 percent of their combined GDP in 2019 to 6.8 percent of GDP in 2020. This will be the highest ever (or second highest) collective current account deficit for LDCs, and will continue the sequence of swelling current account deficits experienced by the LDCs since the last global financial crisis.

Countries that have been able to develop a denser and more diversified fabric of productive capacities have shown greater resilience and have been better prepared to weather different types of shocks. The long-standing development challenges faced by LDCs pre-date the COVID-19 crisis. While the economic, social and political context that gives rise to extreme forms of vulnerability and poverty are complex, these phenomena have a common underlying factor, namely the low level of development of LDC productive capacities. Expanding, upgrading and better utilizing productive capacities result in overcoming the structural features which are at the origin of vulnerability. These imperatives have only been strengthened by the COVID-19 pandemic. Against this background, it is all the more vital to highlight the continued relevance of the LDC category, not only during the "great lockdown" and its immediate aftermath, but also importantly for the new decade, which will witness the overlap between the remaining horizon of the 2030 Agenda for Sustainable Development and the next programme of action for LDCs. ■

*This piece is excerpted from UNCTAD's The Least Developed Countries Report 2020: Productive Capacities for the New Decade.*

# Climate causing distress migration

**MORE** than 62 million South Asian people will be forced to migrate from their homes due to climate disasters by 2050, according to the findings of ActionAid International and Climate Action Network South Asia research.

The report, *Costs of climate inaction: displacement and distress migration*, assesses climate-fuelled displacement and migration across five South Asian countries, Bangladesh, India, Nepal, Pakistan and Sri Lanka, and calculates a devastating likelihood of more than 60 million people being homeless and displaced by 2050 in South Asia.

Political failure to limit global warming to below 2°C, as per the Paris Agreement goal, is already driving 18 million climate migrants from their homes in 2020. This analysis estimates climate migration will treble in South Asia alone, a region badly affected by climate disasters, including floods, droughts, typhoons and cyclones. South Asia is particularly prone to climate disasters and has some of the highest levels of climate-fuelled displacement.

The country-level research in these five countries shows that climate change is either directly displacing people or accentuating hardship resulting in distress migration. Rivers eroding banks in Bangladesh, flooding in Pakistan and India, melting glaciers in Nepal, rising seas in India and Bangladesh, periods of unusually dry months followed by heavier than normal rains on rice and tea estates in Sri Lanka, or cyclones and inhospitable temperatures across all countries are contributing to climate-induced migration.

South Asia is already experiencing some of the highest fatalities due to extreme weather conditions. Future projections see

South Asia as an epicenter of extreme weather, afflicted by a combination of unsurvivable heatwaves, chronic droughts, rising sea levels, and intensified cyclones.

The report says that these numbers do no justice to the individual stories of loss and devastation that follow displacement and distress migration. Millions of people will continue to be displaced regardless of climate action, and this requires strong social policies to protect the right to move with dignity. These movements have largely taken place without targeted support, which must also be redressed. Millions of people will continue to be displaced regardless of climate action, and this

Climate migration will treble in South Asia alone, a region badly affected by climate disasters including floods, droughts, typhoons and cyclones.

requires strong social policies to protect the right to move with dignity

This is almost as many people as are forced from their homes globally due to war and conflict, raising the alarm that climate can no longer be overlooked as a major factor driving displacement. Climate migration could easily surpass conflict as a driving force of displacement if political leaders continue to renege on their commitments to reducing greenhouse gas emissions in line with the Paris Agreement. Communities can be made resilient to climate change, slow onset climate disasters, such as sea-level rise, drought, failed harvests and loss of biodiversity, but this takes money and political will.

The research reveals that in all five countries, women are left dealing with the negative fallout from climate migration. They are left behind to take care of household chores, agricultural activities, children and elderly, and manage livestock. Women who migrate to urban settlements are often then forced to take up work in precarious settings where workers' rights violations are rife.

The report calls for strong leadership and ambition from developed countries to cut emissions and support for developing countries to adapt to climate change and recover from climate disasters. It recommends a holistic approach that places the onus on rich countries to provide support and urges developing countries to scale up efforts to protect people from climate impacts. Similarly, the report suggests increasing the effectiveness of an universal access to social protection measures to ensure resilience to disasters and to mitigate the climate-induced distress.

The report also calls to ensure that climate-induced migration is on the agenda of inter-governmental bodies such as South Asian Association for Regional Cooperation (SAARC), Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation (BIMSTEC) and other Asia-Pacific forums. They should monitor the migration triggered due to extreme and slow onset disasters within the region and prepare policy responses to secure human rights of such migrants, in accordance with the recommendations of the UN Human Rights Committee. ■

*This is excerpted from Costs of Climate Inaction: Displacement and Distress Migration by ActionAid International and Climate Action Network South Asia.*

# Overview of Nepal's pharmaceutical sector and its response to COVID-19

Although domestic pharmaceutical manufacturing capacity in Nepal has expanded over the years, the domestic industry is still far from fully meeting the country's needs.

Puspa Sharma and Avinash Gupta

Domestic production of modern medicines started in Nepal in the early 1970s with the establishment of Chemidrug, a private company, in 1971, and Royal Drugs, a public company, in 1972. But it was in the last two decades that Nepal witnessed a significant rise in the number of pharmaceutical companies. Today, there are more than 60 operational pharmaceutical manufacturing units in Nepal.

Over the past two decades, Nepal's pharmaceutical market has grown five-fold to an estimated NPR 45 billion. This includes both domestic production and imports of pharmaceuticals. The top 20 pharmaceutical firms, in terms of their share in Nepal's pharmaceutical market, account for 60 percent of the market. Of these 20 pharmaceutical firms, 13 are domestic pharmaceutical manufacturing units. This shows the growing clout of domestic pharmaceutical manufacturers in Nepal. The government of Nepal has also envisaged becoming self-sufficient in essential medicines—medicines enlisted in the Essential Drugs List that are crucial to meet the needs of the health system. Currently, of the 390 medicines enlisted in Ne-



Wikimedia Commons

pal's Essential Drugs List 2016, only 80 percent are produced in Nepal.

In this article, we provide an overview of Nepal's pharmaceutical sector, focusing on the domestic production and trade of modern medicines. We also assess the sector's response to the COVID-19 pandemic.

## Domestic production

Domestic pharmaceutical manufacturers cater to about 50 percent of Nepal's pharmaceutical market in terms of the volume of medicine. In monetary terms, according to industry insiders, the share of domestic pharmaceutical manufacturers is only

about 45 percent. This is 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. Nevertheless, Nepal's current pharmaceutical import share of 55 percent against the share of 70 percent in the early 2000s<sup>1</sup> shows an expansion of domestic pharmaceutical production in recent years.

According to the Association of Pharmaceutical Producers of Nepal (APPON), 7 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.<sup>2</sup> Of these, 9,940 were foreign brands and the rest 9,166 were domestic brands.

Despite the enhanced production capacity of Nepali pharmaceutical manufacturing firms in recent years, the capacity utilization rate of most of the firms is still relatively low according to APPON. Firms producing tablets are operating at 55 percent of the installed capacity while those producing capsules, syrups and ointments are operating at 40 percent, 35 percent and 50 percent capacity, respectively.

Most of the medicines produced in Nepal are generic medicines. However, there are some firms that produce generic versions of medicines still protected by patents in foreign jurisdictions. There is a lack of organized database on medicine production in Nepal classified into patent and generic groups. Communications with domestic pharmaceutical manufacturers reveal that a dozen or so dominant firms, which currently capture about 60 percent of the domestic producers' share of the pharmaceutical market in Nepal, have been producing generic versions of some medicines patented abroad.

Four of these top firms suggest that such medicines account for 10–30 percent of their annual sales. Drugs such as those in the Gliptins category

(oral medicines for diabetes) and Sofosbuvir (a new drug for Hepatitis C), both of which remain(ed) under patent abroad, are being produced in Nepal. One Nepali firm also produced Favipiravir, which is being used in treating COVID-19 infection. The drug is under patent in Japan (till August 2024) and Brazil (till November 2023).<sup>3</sup>

Backward linkages in the pharmaceutical sector remain mostly underdeveloped in Nepal. The pharmaceutical industry imports virtually all inputs from Active Pharmaceutical Ingredients (API) to excipients, suspending agents, preservatives, packaging materials and other agents and colours. Two major factors that are highlighted for the lack of backward linkages are: i) absence of policy support for the development of ancillarization, and ii) issue of scale and sophistication (especially in producing API). Regarding

The production of Favipiravir, which is used to treat COVID-19 infections in some cases, by a Nepali pharmaceutical company is a sign of growing strength of the Nepali industry.

the first, there are areas wherein there is scope to develop ancillary units and clusters, such as establishing special zones for ancillary activities, but the same would require active industrial policy support that incentivizes and guides such activities. In terms of the second, according to some industry insiders, producers from China and India supply inputs at unit prices that will be difficult to achieve unless the government institutes relevant policy measures and provides incentives.

Despite minimal backward linkages, the industry association estimates that there is a 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 API and NPR 2.2 billion of packaging materials).

### Pharmaceutical trade

Although domestic pharmaceutical manufacturing capacity in Nepal has expanded over the years, the domestic pharmaceutical industry is still far from fully meeting the country's pharmaceutical needs. Nepal relies on imports of several therapeutic categories of drugs and almost all the APIs. There are currently more than 100 registered importers that import modern 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.<sup>4</sup>

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 only about 2 percent.<sup>5</sup>

The top therapeutic categories that are imported into Nepal are anti-infectives, cardiac (including hypertension), respiratory, gastrointestinal and dermatological products. Vaccines, anti-cancer medicines, HIV drugs (antiretroviral or ARVs), injectables, insulin and metered-dose inhalers are sourced completely through imports.

Regarding imports of patented medicines in Nepal, according to a senior executive of a dominant firm, which also features in the list of top 10 firms in terms of its share in the Nepali pharmaceutical market, about 90 percent of the imported medicines in Nepal are generic medicines with expired patents.

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 compared to earlier years. However, in the last fiscal year 2019/20, Nepal's exports of modern medicines rose significantly to US\$5.5 million, of which almost 98 percent was 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, drugs related to cardiac and anaesthesia were also being exported, such as to Uganda.

### COVID-19

In the initial days of the spread of COVID-19 in Nepal, the country had enough stock of medicines for about 6–7 months.<sup>7</sup> Because pharmaceutical production is an essential activity, pharmaceutical manufacturing was allowed to operate during the lockdown imposed to curb the spread of COVID-19 infection. However, pharmaceutical companies operated at reduced capacities because of the disruptions created by the lockdown such as transportation disruptions and workers' inability to travel between their homes and production sites. It was estimated that during the initial period of the lockdown, pharmaceutical production in Nepal decreased by around 50 percent. Similarly, sales of medicines declined by around 60–70 percent due to limited access to hospitals and clinics, limited operation of retail pharmacies and barriers in internal transportation, among others. Sales were reduced also because there had been a sharp rise in sales of many common medicines immediately before the lockdown as the fear of crisis compelled people to maintain stocks of necessary medicines.

According to APPON, during the initial weeks of the lockdown, India imposed export bans on some 26 types of medicines and raw materials. The export ban was lifted soon, yet Nepal's

import of pharmaceutical inputs was only around 60–70 percent of the normal level.

As stated earlier, Nepal's pharmaceutical industry does not have the capacity to produce vaccines. Nepal has to rely on imports of vaccines against COVID-19. Nevertheless, the production of Favipiravir, which is used to treat COVID-19 infections in some cases, by a Nepali pharmaceutical company is a sign of growing strength of the Nepali pharmaceutical industry.

### Conclusion

Nepal's pharmaceutical industry has shown remarkable progress over the years. The share of domestically produced medicines in total medicine consumption in Nepal has been steadily rising. More importantly, the domestic pharmaceutical industry has been contributing significantly by producing medicines used to treat non-communicable diseases such as hypertension and diabetes, which are the leading causes of deaths in Nepal. The capacity of a Nepali pharmaceutical manufacturer in producing a drug to potentially treat COVID-19 infection also speaks of the enhanced strength of Nepal's pharmaceutical sector. Lately, the industry has also been showing promise in the area of export. Whether this will sustain over the long term is an important question. Moreover, the performance of Nepal's pharmaceutical industry pales in significance when compared to the performance of Bangladesh—another least-developed country in South Asia.

Nepal's pharmaceutical industry mostly produces generic drugs with expired patents, although some firms have been producing generic versions of drugs that are still under patents in foreign jurisdictions. One reason for Nepal's ability to produce patented medicines is the waiver it has received as an LDC member of the WTO. After Nepal ceases to be an LDC in the near future, it will no longer be able to make use of the waiver. Nepal's pharmaceutical sector also needs to develop its capacity to produce relatively technologically complex prod-

ucts such as vaccines and inhalers so that it could rise up to the occasion at times of urgent need, such as the COVID-19 pandemic. This is possible only through active and meaningful cooperation between the public and private sector to invest in research and development, use of industrial policy tools such as subsidies and tax exemptions for a certain period, and extensive deliberations on the possible implications of Nepal's LDC graduation and measures necessary to stem them, among others. ■

*Mr. Gupta was Research Officer at SAWTEE.*

*This article draws on a research on Nepal's pharmaceutical sector in the context of Nepal's planned LDC graduation that the authors have undertaken for the Third World Network.*

### Notes

- 1 SAWTEE and Matrix. 2005. Study of the Nepalese Pharmaceutical industry in the context of Nepal's newly acquired WTO membership. Kathmandu: SAWTEE.
- 2 DDA. 2019. *Drug Bulletin of Nepal*, vol. 30, no. 3. Kathmandu: Department of Drug Administration, Ministry of Health and Population, Government of Nepal.
- 3 Schwamborn, Miriam, Christiane Emmerich, and Thomas Stengel. "Favipiravir, a drug candidate against COVID-19—a FIZ Karlsruhe case study exploring the patent situation". *Leibniz Institute for Information Infrastructure*. [http://www.stn-international.de/sites/default/files/STN/Generell%20pdfs/Report-Favipiravir-20200529\\_STN.pdf](http://www.stn-international.de/sites/default/files/STN/Generell%20pdfs/Report-Favipiravir-20200529_STN.pdf).
- 4 This includes products in the 4-digit HS code groups 3003 and 3004 but excludes items such as Ayurvedic and Homeopathic medicines within these groups to cover only modern/allopathic medicines.
- 5 Dhakal, N.P., B.S Poudel, T.R Bhatta, V.L Shrestha, B Poudel, D Dahal, APPON Representative, and Sanotshi K.C. 2016. "Report of the Consultative Committee on Development and Promotion of Nepali Pharmaceutical Industry."
- 6 New Spotlight Online. 2020. "Nepal Has Enough Stock of Medicines: Pharmaceutical Association Nepal". *New Spotlight Magazine*, 6 March. <https://www.spotlightnepal.com/2020/03/06/nepal-has-enough-stock-medicines-pharmaceutical-association-nepal/>



# Leveraging Bangladesh's pharmaceutical Industry in COVID-19 vaccine supply chain

It is extremely important to integrate more capable manufacturers such as Bangladesh into the supply network to ensure mass availability of vaccines.

Abdur Razzaque, Rabiul Islam Rabi and Md Shahiduzzaman Sarkar

The COVID-19 pandemic has wreaked havoc on health services, economic activities, and employment prospects. After almost a year of fighting against the virus through physical distancing measures, discussions on COVID-19 vaccines have taken centre

stage as countries have started their immunization campaign. Countries across the world are facing the mammoth task of inoculating their population in what could be the largest immunization drive that humanity has ever experienced. However, the

capacity-constrained developing countries' access to vaccines is still ambiguous. How to bring their most vulnerable population groups under immunization coverage constitutes one of the most pressing challenges for these countries.

Indeed, fair and equitable access to affordable tests, treatments, and vaccines are now under the spotlight in countries with under-resourced healthcare systems. There are challenges for efficient procurement, delivery and effective administration of immunization programmes. In this initial phase of vaccine production and distribution, massive demand is outstripping supply. There is thus an apprehension that populations in resource-poor countries could be left behind, at least temporarily. A study by the Duke Global Health Innovation Center indicates that many people in low-income countries may not get vaccines until 2024.<sup>1</sup>

COVID-19 has exposed the extent of global supply chains' vulnerability when relying on a small number of manufacturers for raw materials and final products. Therefore, it is extremely important to integrate more capable manufacturers into the supply network to ensure mass availability of vaccines. An estimated three billion people in low-income countries are likely to lack access to a COVID-19 vaccine for years. According to the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), the global vaccine manufacturing capacity today is five billion doses per year. IFPMA estimates also reveal that to achieve sufficient level of immunity of the global population

with a two-dose vaccine, the world would need between 12 billion and 15 billion doses—more than twice the world's current vaccine manufacturing capacity. As of December 2020, 12 COVID-19 vaccine manufacturers had shared their plans to produce 10 billion doses of vaccines by the end of 2021.<sup>2</sup> However, this figure is perhaps an overestimate because it does not consider some important factors. For example, some vaccine manufacturing candidates might not be licensed by the end of 2021, some might be dropped due to lower efficacy, and vaccine production chains could suffer unexpected delays.<sup>3</sup> Furthermore, pharmaceutical firms moving to exclusive manufacturing of COVID-19 vaccines is also not an option as it will cause shortages of other vaccines such as those for preventable childhood diseases (e.g., measles, mumps, and rubella). Prioritizing COVID-19 could affect other health objectives. Establishing new vaccine manufacturing plants is also not possible in the near-term since it takes between 5 to 10 years to establish such plants. Therefore, existing vaccine manufacturing capacity should be aptly utilized to address the immediate need.

Bangladesh is a least-developed country (LDC) with notable pharmaceutical manufacturing capacity. An estimated 97 percent of the demand for medicines in Bangladesh is

met through domestic production.<sup>4</sup> According to available estimates, the value of annual pharmaceutical production in the country is about US\$3 billion. The industry has developed end-stage (known as fill-finish) production capacities. It is worth mentioning that in May 2020, Bangladesh became the first country in the world to produce the generic version of the medicine 'Remdesivir'—a direct acting antiviral drug which was originally developed by the US-based Gilead Sciences and approved by the United States Food and Drug Administration for emergency use authorization for treating severe COVID-19 infections. Bangladesh exported the medicine to many other countries as well. Making this crucial drug accessible and affordable to patients in many middle- and low-income countries was a significant milestone for Bangladesh's pharmaceutical industry. However, when it comes to vaccines, Bangladesh has largely been dependent on the rest of the world.

Currently, two Bangladeshi firms have vaccine production capacity. One of these companies, Incepta Vaccine Ltd, has the capacity of producing vaccines from the molecular stage to the final stage, while the other, Popular Pharmaceuticals Ltd, is equipped with vaccine fill-finish operations. These two companies have a combined capacity of supplying close to 220



ResearchAmerica

Currently, two Bangladeshi firms have a combined capacity of supplying close to 220 million vials of vaccines each year.

million vials of vaccines each year. According to industry experts, local manufacturers are currently using only one-tenth of their capacity. If these two companies undertake full-fledged operation, they can export vaccines to other countries too, playing an important part in the global vaccine supply chain.

However, initiatives taken so far in Bangladesh regarding COVID-19 vaccines have mainly focused on importing ready-to-push vaccines, not on manufacturing them in the country. Local drug manufacturers wanted the government to involve them in negotiations to enable them to produce vaccines in the country. But they failed to act persuasively.

Experts insist that the process for approving, importing and rolling out the immunization programme for the most susceptible groups may take the first quarter of 2021. Bangladesh expected to procure Oxford-AstraZeneca COVID-19 vaccines through the Serum Institute of India. The Oxford-AstraZeneca vaccine does not require preservation in ultra-cold temperature like the vaccines produced by Moderna and Pfizer-BioNTech.

In early 2021, Bangladesh received 20 million doses of the Oxford-AstraZeneca vaccine as a 'gift' from India. With this, 10 million people (or about 6 percent of the population) is estimated to be vaccinated. By May-June 2021, Bangladesh plans to add another 60 million vaccines through the World Health Organization's COVAX programme.<sup>5</sup> While these initiatives will partly address the immediate need of immunization, such pursuits are expected to be short-lived. Due to the nature of the novel coronavirus, there is a possibility that vaccination programme against the coronavirus could become a yearly routine rather than a one-off inoculation campaign, requiring a long-term, sustainable solution.

In the early stage of the pandemic, Bangladesh refused to participate in the clinical trial of the vaccine developed by Sinovac Biotech Ltd, a Beijing-based private firm with a track record of developing vaccines. Many industry experts consider this

as a missed opportunity.<sup>6</sup> They claim that since Sinovac has a long-standing commercial relationship with several leading Bangladeshi pharmaceutical manufacturers, such clinical trials might have paved the way for technology transfer besides ensuring vaccines for local people. Getting Bangladesh's private pharmaceutical companies involved in a joint-venture to produce a vaccine will require a government-to-government (G2G) involvement to seal a firm-level agreement on vaccine manufacturing. Such an initiative will not only act as a catalyst for capacity building of the local pharmaceutical industry and cater to domestic demand; it can also facilitate the country's integration into the global supply chain. It is important to note that Indonesia has leveraged such an opportunity to ensure technology transfer from Sinovac. As mentioned above, efforts are underway through G2G engagements to secure vaccines. When only private manufacturers engage with vaccine innovators without the involvement of governments, prices could be much higher.

At this stage, pharmaceutical manufacturers in Bangladesh are of the view that in the absence of a clearly articulated vaccination policy, securing vaccines in an efficient manner will become extremely difficult. A vaccination policy needs to outline how the government is going to engage with the innovators and purchase vaccines, to what extent private pharmaceutical companies can be involved in this process, what will be the number of doses to be purchased, etc.

For a sustainable solution to address the crisis, a practical idea could be opting for a long-term solution. In this regard, there are two policy options that Bangladesh can pursue.

First, G2G-backed firm-level collaboration with international vaccine manufacturers could be a major way forward. Under such arrangements, working closely with local manufacturers the government can play a key role in negotiating bulk import and fill-finish of vaccines. Two pharmaceutical manufacturers say they are ready to act immediately and another local

pharmaceutical company, Healthcare Pharmaceuticals Ltd, is expected to be ready for vaccine production by mid-2021. This will secure vaccines for domestic population and reduce pressure on global vaccine suppliers. In this regard, Bangladesh should not single out any vaccine candidate and should keep options open to negotiate any strategic collaboration.

Another policy option is to incentivize private initiatives to produce vaccines through contract manufacturing. Local firms have longstanding commercial relationships of contract manufacturing in many segments of pharmaceutical products. Exploiting the same for vaccine production can help. Indeed, the erstwhile success of the local pharmaceutical industry in providing generic medicines to the mass population should call for focusing on long-term capacity building in vaccine production. ■

*Dr. Razzaque is Chairman, Research and Policy Integration for Development (RAPID) and Research Director, Policy Research Institute (PRI) of Bangladesh; Mr. Rabi is a Research Economist at RAPID and Mr. Sarkar is a civil servant and an independent researcher.*

## Notes

- 1 Duke Global Health Institute. 2020. "Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?". <https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive>
- 2 Wang, W., Wu, Q., Yang, J., Dong, K., Chen, X., Bai, X., Chen, X., Chen, Z., Viboud, C., Ajelli, M. and Yu, H., 2020. "Global, regional, and national estimates of target population sizes for covid-19 vaccination: descriptive study". *BMJ* 2020;371:m4704.
- 3 *ibid.*
- 4 Razzaque, M. A., Rabi, R. I., and Akib, H. 2020. "Bangladesh's Pharmaceutical Exports: Trends, Market Prospects, and Policies". In *Navigating New Waters: Unleashing Bangladesh's Export Potential for Smooth LDC Graduation*, edited by M. A. Razzaque. Dhaka: Bangladesh Enterprise Institute.
- 5 See Knowledge Platform Page 36-37 of this issue for the information on COVAX.
- 6 According to reports, Sinovac had asked Bangladesh government to co-fund the clinical trials and the government refused to do so.

# COVID crisis and waiver on intellectual property rights

The question of providing equitable access to healthcare technologies, including vaccines, to all countries, remains unresolved despite flexibilities provided in the WTO Agreement on TRIPS.

Biswajit Dhar and Posh Raj Pandey

COVID-19, caused by a new strain of coronavirus, was declared a pandemic by the World Health Organization in March this year. The speed and scale of the spread of COVID-19, the severity of infection it causes and the social and economic disruptions created by the measures to fight it have been dramat-



ic.<sup>1</sup> Without expanding access to health technology, including diagnostics, medical devices, therapeutics and vaccines, inequalities within and between countries are set to escalate, the recovery of the global economy will be delayed<sup>2</sup> and negative spillovers from the current crisis will be felt across the 2030 Agenda for Sustainable Development.<sup>3</sup> But the question of providing equitable access to healthcare technologies, including vaccines, to all countries, remains unresolved despite flexibilities provided in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the launch of new initiatives such as COVID-19 Vaccines Global Access, abbreviated as COVAX, and COVID-19 Technology Access Pool (C-TAP).

### Flexibilities in TRIPs Agreement

Access to medicines at affordable prices has been a global concern ever since the TRIPS Agreement was adopted as one of the agreements covered under the WTO. The TRIPS Agreement introduced significantly higher global standards for protecting intellectual property rights (IPRs). Since its enforcement in 1995, there have been several instances when holders of intellectual property have exercised their rights to extract exorbitant rents from the users of proprietary products. The most glaring of such examples was exceptionally high prices that several large pharmaceutical companies had charged during the outbreak of HIV/AIDS, last of the major pandemics that had worldwide ramifications. In South Africa, where the per capita gross domestic product (GDP) was US\$3,550, a year's treatment using the HIV anti-retroviral medicines marketed by these companies would cost the South African health service US\$10,000.<sup>4</sup>

The Government of South Africa amended its Medicines and Related Substances Control Act 1965, in response to the growing incidence of HIV/AIDS. The amended act included several provisions that were aimed at ensuring that medicines were available at affordable prices. These included controlling the prices of medicines

and granting of compulsory licences for medicines production in South Africa. Forty major pharmaceutical companies challenged the amendments, arguing that they violated South Africa's constitution and the country's commitments under the TRIPS Agreement.<sup>5</sup> The contention of the pharmaceutical companies was that the rights enjoyed by the patentees in the regime introduced after the implementation of the TRIPS Agreement would be severely undermined if the provisions of the South African law for providing affordable medicines were used by the government.<sup>6</sup> Facing mounting public pressure, the pharmaceutical companies withdrew the case in 2001.<sup>7</sup>

This case propelled many developing countries led by India, South Africa and Brazil to speak against such excessive rent seeking by the pharmaceutical companies. These countries

Access to medicines at affordable prices has been a global concern ever since the TRIPS Agreement was adopted.

proposed that the existing flexibilities in the TRIPS Agreement must be expanded so as to enable WTO member countries to address public health concerns. The outcome of this initiative was the proposal on TRIPS Agreement and Public Health that was backed by more than 60 developing countries, including 41 belonging to the African Group. Consequently, 'Declaration on the TRIPS Agreement and Public Health' was adopted at the Doha Ministerial Conference in 2001.<sup>8</sup> In 2003, a waiver from the TRIPS Agreement was agreed for the implementation of the Declaration. Amendment to the TRIPS Agreement was agreed only in December 2005<sup>9</sup> and the amendment was ratified in 2017.<sup>10</sup>

The Declaration was important for several reasons. First, it recognized the

"gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". Second, the Declaration emphasized the need for the TRIPS Agreement to be part of the wider national and international action to address the health problems. Third, while it recognized that intellectual property protection is important for the development of new medicines, the Declaration voiced concerns about the effects of the Agreement on the prices of medicines. Finally, WTO Members emphasized that the "TRIPS Agreement does not and should not prevent Members from taking measures to protect public health ... and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".<sup>11</sup>

In operational terms, the Declaration gave the WTO members three sets of instruments to address the problem of high prices of medicines arising from the exercise of IPRs: i) the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; ii) the right to determine what constitutes a national emergency or other circumstances of extreme urgency; and iii) freedom to establish their own regimes for exhaustion of intellectual property rights without challenge, subject to the most favoured nation and national treatment provisions. Further, for the WTO Members with insufficient or no domestic manufacturing capacities in the pharmaceutical sector, who could face difficulties in making effective use of compulsory licensing to produce the necessary medicines in order to meet their needs, the Declaration provided a window, in Para 6, through which these countries can import cheap medicines from any country. This window was finally provided through an agreed decision to implement Para 6 that was adopted in 2003<sup>12</sup>, and the TRIPS Agreement was subsequently amended<sup>13</sup> to allow "eligible" countries to import the

medicines and for potential exporters to export them.

However, the procedural requirements were made so complicated that the mechanism was rendered unattractive for the users. The mechanism was used only once in 2007 when Rwanda invoked it in order to import the triple combination anti-retroviral drugs, Zidovudine, Lamivudine and Nevirapine from the Canadian generic drug manufacturer, Apotex Inc.<sup>14</sup> The usefulness of this window was reduced considerably as the supplier could provide the medicines after two years.<sup>15</sup> In other words, the Doha Declaration was not able to fulfil its objective of ensuring that affordable medicines can be delivered to the countries that need them the most.

### New initiatives

In the wake of the COVID-19 pandemic, the international community has taken few initiatives to ensure adequate and timely supply of vaccines to poor and needy countries. The most relevant and significant are COVAX and C-TAP.<sup>16,17</sup> COVAX is a multibillion-dollar alliance of international health bodies and non-profit organizations, established to coordinate international resources to enable low-to-middle income countries' equitable access to COVID-19 tests, therapies and vaccines. However, COVAX covers only about a fifth of the global population and leaves a significant proportion of the needy population outside its coverage. It has not only failed in meeting the stated target but is also struggling to get adequate doses of vaccines. In fact, COVAX is at the mercy of wealthy nations and pharmaceutical companies as rich countries have become rivals in the vaccine-buying race, paying premiums to secure their own shots while moving slow in providing financial support to COVAX. In addition, it has also become a victim of vaccine nationalism and export ban.<sup>18</sup>

The C-TAP, established by emulating the UN-backed Medicines Patent Pool model, is a technology transfer hub that is supposed to provide manufacturers in low- and middle-

income countries financial, training and logistics support necessary to scale up vaccine manufacturing capacity. An mRNA Vaccine Transfer Hub Facility is also being established in the same model.<sup>19</sup> The key aspect of these initiatives is that recipient manufacturers acquire the necessary technologies protected by IPRs from the patent holders to produce vaccines. The sad part is that the pool/hub has not received any formal support from the IPR holders, thus making the initiatives defunct.<sup>20</sup>

Due to the failure of the TRIPS Agreement in ensuring equitable access to health technologies and disappointing performance of the new initiatives in ensuring equitable vaccine access necessary to fight COVID-19, India and South Africa put forward the proposal on TRIPS waiver

WTO members should work together to ensure that IPRs do not create barriers in timely access to affordable medical products.

in October. They have proposed that WTO members should work together to ensure that IPRs such as patents, industrial designs, copyrights and protection of undisclosed information do not create barriers in timely access to affordable medical products, including diagnostics, medical devices, therapeutics and vaccines or to scaling up research, development, manufacturing and supply of medical products essential to combat COVID 19.<sup>21</sup>

### Waiver Proposal of India and South Africa

The joint proposal tabled by India and South Africa seeks waiver from certain obligations under the TRIPS Agreement for the "prevention, containment, and treatment of COVID-19". The major task for India and South Africa is to ensure strong backing for

the Waiver Proposal from within the WTO and outside. The most important first step towards this end is to garner the support of like-minded countries, as was done in case of the TRIPS and Public Health proposal. It seems some ground has already been made since, till date, eight other WTO members have also supported the Proposal.<sup>22</sup> Further, in the TRIPS Council Meetings, several WTO members, including India's South Asian neighbours—Bangladesh, Nepal and Sri Lanka—fully supported the proposal, while 14 others, including China and Nigeria, gave provided qualified support. The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) were also fully supportive of the proposal.

The Waiver Proposal uses the provisions of Article IX of the Marrakesh Agreement Establishing the WTO and makes a request to the General Council of the WTO to waive the implementation, application and enforcement of four forms of IPRs covered by the TRIPS Agreement for some years for the containment or treatment of COVID-19. The forms of IPRs mentioned in the proposal are copyright and related rights, industrial designs, patents and trade secrets. It should be noted that the waiver of legal obligations under WTO agreements is not new. Since 1995, of the waivers that were granted, three are related to TRIPS obligations.<sup>23</sup>

The India-South Africa proposal has been tabled in the backdrop of the cautionary note issued by the WTO that the "COVID-19 pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe". The two countries have argued that it is "important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, develop-

ment, manufacturing and supply of medical products essential to combat COVID-19". Given the large increase in demand for access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment, and ventilators, as well as vaccines and medicines for the prevention and treatment of patients, it becomes imperative that supply-side shocks are eliminated. At the same time, critical shortages in these medical products have also put patients suffering from other communicable and non-communicable diseases at grave risk.

The *raison de'tre* of the Waiver Proposal could be established with the following concerns.

First, exercise of IPRs have impeded or are threatening to impede availability of medical products at affordable prices. It has been reported that AstraZeneca charged South Africa more than double (US\$5.25) the price per dose it charged EU countries.<sup>24</sup>

Second, during negotiations for the implementation of the Doha Declaration on Public Health, the developed countries demanded new and additional conditions and safeguards against the flexibilities provided by the compulsory license. As a result, the

TRIPS flexibilities became more cumbersome, complex and unworkable as was experienced by Rwanda in the import of generic HIV medicines from Canada.<sup>25</sup> Hence, many countries refrained from invoking the flexibilities. In view of the tardy implementation of this mechanism, the United Nations Secretary General's High-Level Panel on Access to Medicines had recommended that "WTO Members should revise paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform".<sup>26</sup> In addition, the Waiver Proposal allows pharmaceutical companies to produce vaccines and drugs without fear of being persecuted or the country being included in the watch list.

Third, a global response to COVID-19 includes the development, testing, and production of safe and effective vaccines to prevent COVID-19, together with new therapeutics for the treatment of prophylaxis.<sup>27</sup> These complex nature of vaccines, biologics, diagnostic tests and medical devices are not only covered by multiple pat-

ents but also by additional intellectual property protections in the form of copyrights, industrial designs, trade secrets, clinical trial data, manufacturing knowhow and other information.<sup>28</sup> For example, the vaccine developed by Pfizer-BioNTech used technologies in which at least six patents have been granted and another seven patent applications are pending. BioNTech has further suggested that its vaccine "relies on trade secrets and confidential know-how to protect aspects of ... [the] manufacturing technologies".<sup>29</sup> The scope of the Waiver Proposal is beyond patent protection and covers the production of diagnostics, medical devices, and therapeutics and vaccines.

Third, many WTO Members, such as Nepal and Sri Lanka, among others, have not introduced the required amendments to their national intellectual property legislation to give effect to Article 31bis of the TRIPS Agreement, and thus, they do not have clear provisions to procure vaccines under parallel imports. In addition, the implementation of the Declaration varies from country to country and has created uncertain and unpredictable environment for the manufacturing and supply of vaccines and drugs. The



pixabay



building production capacity, and so on, as detailed below.

*Stringent rules for export restriction:* WTO members should refrain from imposing restrictions on exports, including export taxes. If it is extremely necessary to restrict export, they should ensure that any export restrictive measures relating to health products are targeted, transparent, proportionate, temporary and consistent with WTO obligations.

*Flawless supply management:* Vaccine supply chains are complex and global. It has been reported that the Pfizer-BioNTech vaccine contains more than 280 ingredients and components, sourced from 19 countries. To streamline the supply management, the global community should agree to take initiatives on mapping the entire supply chain, identifying critical actors and processes, eliminating trade barriers and streamlining regulatory procedures as well as committing to support the supply chain through public policy actions.

*Effective trade facilitation measures:* Apart from the commitments on export restrictions and adoption of effective trade policy measures, WTO Members can contribute to faster and better production and distribution processes with appropriate national policies. They could adopt best trade facilitation practices and develop modalities for regulatory cooperation among trading partners.

*Support for production capacity:* Building production capacity, not only to produce vaccines and therapeutics but also ancillary products such as vials, syringe, refrigeration equipment, etc. would be crucial to fight current and future pandemics.<sup>32</sup> This can be achieved if developed countries agree for lenient licensing agreements, knowledge and know-how sharing, and investment in manufacturing facilities in needy countries. In addition, they can provide technical and financial support for enhancing production capacity to produce vaccines and other medical products, skills development, supply chain management and strengthening regulatory framework.

Waiver Proposal would help remove such legal vacuum and minimize uncertainties.

Fourth, some countries have argued that voluntary sharing and transfer of technology or technology transfer under bilateral agreements could be alternatives to the Waiver Proposal. However, practices of such mechanisms have shown to be selective, non-transparent and arbitrary, and thus, they cannot be substitutes for the Waiver Proposal.

Fifth, the Waiver Proposal is crucial for the successful implementation of the new global initiatives to fight COVID-19.

There are, therefore, important pointers that WTO members must take decisive steps, which can ensure that the rights conferred under the TRIPS Agreement are not exercised to the detriment of the urgent needs of humanity. In other words, it is imperative to go beyond the existing flexibilities for addressing public health concerns arising from the exercise of patent rights over medicines, and to cover, as the Waiver Proposal does, all medical products, including diagnostics, therapeutics, vaccines, and medical equipment required exclusively for preventing the spread of and to cure COVID-19. Thus, the Waiver Proposal does not seek waiver of Members' obligations with regard to IPRs on all other medical products.

### Beyond waiver

It is reported that Moderna, one of the key producers of vaccines against COVID-19, has announced that it will not enforce its COVID-19 related patents against those making vaccines intended to combat the pandemic despite its technology is protected by seven patents.<sup>30</sup> The company has further added that in order "to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request [it is] also willing to license [its] intellectual property for COVID-19 vaccines to others for the post pandemic period".<sup>31</sup> It means the waiver could be one of the contributing factors but not a panacea to fight against the pandemic and ensure health equity. It requires very close cooperation between governments, regulators and the private sector and demands that the international community agrees to collaborate on many fronts: trade policy, supply chain management, trade facilitation,

The waiver could be one of the contributing factors but not a panacea to fight against the pandemic and ensure health equity.

## Conclusion

The COVID-19 pandemic has taught us a few lessons. There exist strong linkages between public health, global economic growth, people's well-beings, sustainable development and human security. Individual countries, irrespective of their levels of income, need to build their capacity to produce essential drugs for public health purposes and reduce their dependence on their external trading partners. Health security should be treated as a human right and achieving healthcare resilience and health security should be the strategic direction of the country. The global intellectual property rules must be supportive of research, production, technology transfer, and equitable access in relation to essential drugs, diagnostic methods and medical information, equipment and devices. The proponents of the Waiver Proposal should build a strong coalition of like-minded developed, developing and least-developed countries to ensure that the Proposal gets through in the forthcoming 12th WTO Ministerial Conference. ■

Dr. Dhar is Professor of Economics, Jawaharlal Nehru University, New Delhi. Dr. Pandey is Chairperson, SAWTEE.

## Notes

- 1 United Nations. 2020. *Shared responsibility, global solidarity: Responding to the socio-economic impacts of COVID-19*.
- 2 World Bank. 2021. *Global Economic Prospects, January 2021*. Washington DC: The World Bank.
- 3 OECD. 2020. Coronavirus (COVID-19) vaccine for developing countries: An equal shot at recovery, February 2020.
- 4 *The Guardian*. 1999. "How drug giants let millions die of Aids." *The Guardian*. 19 December, 1999.
- 5 High Court of South Africa. 1998. Pharmaceutical company lawsuit (forty-two applicants) against the Government of South Africa (ten respondents)." Case number: 4183/98.
- 6 Dhar, Biswajit. 2001. "Patents and Licensing." *The Economic Times*, 6 July, 2001.
- 7 Swarns, Rachel L. 2001. "Drug Makers Drop South Africa Suit over AIDS Medicine." *The New York Times*. 20 April, 2001.
- 8 World Trade Organization. 2001. "Declaration on the TRIPS Agreement and Public Health: Adopted on 14 November 2001." WT/MIN(01)/DEC/2. 20 November, 2001.
- 9 World Trade Organization. 2005. Amendment of the TRIPs Agreement. WT/L/641, 8 December 2005.
- 10 Abbot, Frederick, and Reichman, Jerome. 2020. Facilitating access to cross-border supplies of patented pharmaceuticals: The case of the COVID-19 pandemic, *Journal of International Economic Law*, 2020, 23, 535–561.
- 11 *ibid* Note 5.
- 12 World Trade Organization. 2003. "Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement Public Health: Decision of 30 August, 2003." WT/L/540. 2 September, 2003. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/L/540.pdf&Open=True>.
- 13 World Trade Organization. 2015. "Protocol Amending the TRIPS Agreement: Expected benefits of the Paragraph 6 System of Special Licences for export of medicine." WT/GC/W/696. 23 February, 2015. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W696.pdf&Open=True>.
- 14 World Trade Organization. 2007. "Notification under Paragraph 2(A) of the Decision of 30 August, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Rwanda." IP/N/9/RWA/1. 19 July, 2007. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/N/9RWA1.pdf&Open=True>.
- 15 South Center. 2011. *The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. Policy Brief. No. 7*. Geneva: The South Centre.
- 16 Information available here: <https://www.who.int/initiatives/act-accelerator/covax>
- 17 S Geiger and A McMahon. 2021. "Too many Cooks or Too Many Recipes? An analysis of the institutional landscape and proliferation of proposals for global vaccine equity for COVID-19". *UCD Geary Institute Working Paper 8/21*.
- 18 Check Knowledge Platform on this issue (Page 36-37) for details on CO-VAX.
- 19 Information available on the WTO published Expression of Interest on 16 April 2021. Available here: <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>
- 20 Parsa Erfani, Lawrence O. Gostin and Vanessa Kerry. 2021. Beyond a symbolic gesture: What's needed to turn the IP waiver into Covid-19 vaccines. *Stat News*, 19 May, 2021.
- 21 World Trade Organization. 2020a. "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa." IP/C/W/669. 2 October, 2020. <sup>22</sup> Countries supporting the proposal are, Kenya, Eswatini, Mozambique, Pakistan, Bolivia, Venezuela, Mongolia and Zimbabwe.
- 23 World Trade Organization. 2016. *Waivers – 1995-2015: Note by the Secretariat*. WT/GC/W/718. 28 June, 2016. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W718.pdf&Open=True>.
- World Trade Organization. 2019. *Waivers – 2019: Note by the Secretariat*. WT/GC/W/795. 18 December, 2019. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W795.pdf&Open=True>.
- 24 Ismail, Faizel. 2021. *The WTO TRIPS Waiver Should Help Build Vaccine Manufacturing Capacity in Africa. South Centre Policy Brief No.97*. Geneva: The South Centre.
- 25 Marumo Nkomo. 2013. Rwanda's intellectual property law and compulsory licensing for export under the WTO: Not quite a panacea. *African Journal of International and Comparative Law*. 21.2: 279-294.
- 26 United Nations. 2016. "Secretary-General's High-Level Panel on Access to Medicines, 2016: Promoting Innovation and Access to Health Technologies".
- 27 Peter J. Hotez, Carolina Batista et. al. 2021. "Global public health security and justice for vaccines and therapeutics in COVID-19 pandemic". *EClinicalMedicine*. 39: 1-10.
- 28 Wawda, Yusuf. *The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property. Policy Brief No 99*. Geneva: The South Centre.
- 29 Gaviiria, Mario and Burcu Kilic. 2020. "BioNTech and Pfizer's BNT162 Vaccine Patent Landscape." *Public Citizen*. 16 November, 2020.
- 30 Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic as reported on 8 October 2020 available here: <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>
- 31 Also known as "messenger" Ribonucleic Acid vaccine, this is a new vaccine to protect against infectious diseases Centers for Disease Control and Prevention. 2020. "Understanding mRNA COVID-19 Vaccines."
- 32 OECD. 2021. *Access to COVID-19 vaccines: Global approaches in a global crisis*. Paris: Organisation for Economic Co-operation and Development.

# Possible investor-state dispute settlement claims due to COVID-19

India should be prepared for claims by foreign investors alleging breach of different bilateral investment treaties during lockdowns ensued by COVID-19.

Prabhash Ranjan

COVID-19 has rattled the entire world. Several countries, including India, have taken a number of steps to halt the spread of COVID-19. When the dust settles, some apprehend, that foreign investors may bring claims against India for these regulatory measures alleging breach of different bilateral investment treaties (BITs). Investors would rely upon the investor-state dispute settlement (ISDS) provisions in these BITs to bring these claims. Although India has unilaterally terminated several BITs, these treaties continue to bind India due to the survival clause that keep certain provisions in treaties valid even after their termination. In this article, I discuss the types of ISDS claims that may be brought against India by foreign investors and whether India will be able to defend its regulatory measures against these claims.

## India's measures to fight COVID-19

The most important step that India took to stop the spread of COVID-19 was to announce a nation-wide lockdown on 24 March 2020 under the Disaster Management Act. The lockdown was further extended on 15 April 2020 and then again on 1 May 2020 and lasted till 31 May 2020. From 1 June 2020 onwards, the government started opening up the economy gradually. The national lockdown was a herculean task given the size of the population. As part of this national lockdown, several other regulations were adopted such as prohibiting e-commerce services, including Amazon, to deliver goods barring essential items. The reason for this was to stop the spread of the virus through the movement of personnel who deliver goods directly to people. Likewise,

taxi services were banned, interrupting the business of companies like Uber that provide mobile phone application-based cab services. India also imposed certain export restrictions on active pharmaceutical ingredients (APIs) and other medical products such as gloves, masks, etc., though it was relaxed later.

India's lockdown was one of the severest in the world. All modes of connectivity— road, air and rail— were suspended completely. The nationwide lockdown vastly dislocated supply chains and brought several economic activities to a grinding halt, which severely affected several domestic and foreign investments. The lockdown caused a mass exodus of migrant workers in India, which in turn, massively unsettled the labour markets. According to the international rating agency Standard & Poor,

the Indian economy will contract by 5 percent in the current fiscal year 2020-21 due to the COVID-19 crisis and the national lockdown that followed.

### Threats of investor dispute claims

The lockdown and the forced suspension of business activities could leave the Indian state at risk of getting sued by foreign investors. In the context of the COVID-19 crisis, foreign investors may contend violation of the fair and equitable treatment (FET) standard, which is the most-invoked substantive treaty standard in BIT claims. Foreign investors may complain about arbitrariness in host State action or failure to follow due process and thus a potential breach of FET.

Foreign investors can also complain about the violation of national treatment provision if they are able to show that a COVID-19 related regulatory measure discriminates between a foreign and a domestic investor. Likewise, foreign investors can also bring claims of expropriation of foreign investment, especially of indirect expropriation, against several COVID-19 related regulatory measures. In this regard, the foreign investors may argue that the COVID-19 related regulatory measures have led to severe deprivation of their property rights, thus constituting indirect expropriation.

### India's defence

In case such ISDS claims are brought, India should be able to defend its regulatory measures for the following reasons. First, several BITs that India has signed allow the host State to deviate from the treaty obligations in situations of 'extreme emergency'. COVID-19 has been declared a global pandemic that has caused millions of deaths globally. Thus, the pandemic clearly falls in the category of 'extreme emergency'.

Furthermore, some BITs specifically allow the host State to adopt measures for the protection of public

health. India can use this provision to justify its COVID-19 regulatory measures. India will have to prove that these measures were necessary to protect public health.

So, if the nationwide lockdown is challenged, to pass the necessity test, India will have to prove two things. First, the lockdown had a rational connection or a causal link with stopping the pandemic from spreading. Second, there was no other less restrictive alternative measure reasonably available to achieve the said objective. Since 'social distancing' and 'isolation' have been recognized globally as effective and essential to combat the propagation of COVID-19, it will not be difficult for India to prove that



the lockdown was necessary. In some situations, there may be an additional requirement to prove that the regulatory measure adopted was not excessive or disproportionate. Thus, India will have to show evidence to prove that the benefits of the national lockdown or any other regulatory measures adopted to combat the pandemic outweigh the costs incurred by the foreign investors due to these measures.

Second, in case a claim of indirect expropriation is brought, India can make an arguable case that the measures adopted to combat the pandemic are part of the State's police powers. Many ISDS tribunals have held that States do not violate their BIT obligations when they act in the exercise of their police powers. For instance, in the *Philip Morris v Uruguay* case, the

tribunal held that "State's reasonable bona fide exercise of police powers in such matters as the maintenance of public order, health or morality, excludes compensation even when it causes economic damage to an investor and that measures taken for that purpose should not be considered expropriatory." Thus, India can make an arguable case that national lockdown or other regulatory measures are part of a bona fide exercise of India's police powers to achieve an important health objective. In any case, indirect expropriation means substantial or total deprivation of investment, which none of these measures would have caused.

Third, ISDS tribunals grant a margin of appreciation to host States while judging their regulatory measures pertaining to public health, environment, national security, etc. As it was held by the *Philip Morris* tribunal: "the responsibility for public health measures rests with the government and investment tribunals should pay great deference to governmental judgments of national needs in matters such as the protection of public health". Thus, expectedly, an ISDS tribunal shall be deferential to the Indian State in judging its

COVID-19 related regulatory measures, especially given the severity and the scale of the disease.

India need not worry about ISDS claims in its fight against COVID-19. Still, it is important that India's executive branch—central and state governments—remain conscious of such a possibility and ensure that their actions are not arbitrary, discriminatory or disproportionate and are adopted in good faith following due process. ■

*Dr. Ranjan is a Senior Assistant Professor at Faculty of Legal Studies, South Asian University, New Delhi. Views expressed are personal. Some parts of this article draw from author's previous paper "Covid-19, India and Investor-State Dispute Settlement: Will India be Able to Defend its Public Health Measures?" (with Pushkar Anand as the second author), Asia Pacific Law Review 28(1): 225-247, 2020.*

# Pakistan's pharmaceutical trade in COVID-19 times

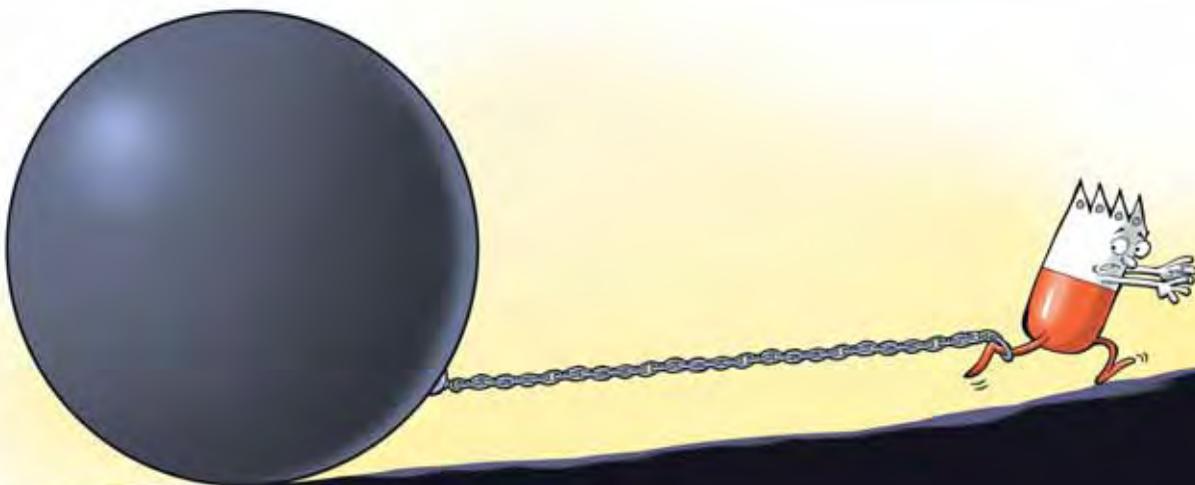
Pakistan's pharmaceutical industry is performing below its potential due to regulatory issues plaguing the performances.

Shahid Mehmood, Naseem Faraz and Ghulam Samad

The COVID-19 pandemic has affected all economic sectors and triggered a slowdown in economic activities globally, including in Pakistan. Measures adopted to stem the spread of COVID-19 such as lockdowns and social distancing have disrupted economic activities and severely impacted all aspects of society and economy. It appears that the virus might not be

eliminated completely and therefore, we have to learn to live with it. Lockdowns and social distancing are temporary measures; they cannot be the solutions forever. Vaccines against COVID-19 and drugs that can treat the infections are the only hope that can ensure our return to normalcy. This has been the case in the past pandemics too.

This re-emphasizes the importance of pharmaceutical research and development, which, so far, has been dominated by developed countries. It is high time that developing and least-developed countries feel the urgency of providing all possible support to the pharmaceutical sector and help it grow. In this article we discuss the various aspects of Paki-





stan's pharmaceutical sector, its role in the current pandemic and some way forward for the sector.

### Pakistan's pharmaceutical industry

The pharmaceutical industry of Pakistan consists of around 750 pharmaceutical units, with a market size of slightly more than US\$3 billion, which is less than 0.3 percent of the global pharmaceutical market. It employs an estimated 150,000 individuals directly, and 300,000 indirectly. Of the total, there are 24 multinational corporations (MNCs), while other firms are domestic manufacturers. The market is highly skewed, with the top 50 firms commanding a market share of 80 percent and the top 100 firms commanding a market share of 95 percent. Similarly, domestic manufacturers' market share stands at 70 percent. The industry imports 98 percent of the raw material and Active Pharmaceutical Ingredients (APIs), mainly from India and China. The lead regulator of the industry, Drug Regulatory Authority of Pakistan (DRAP), was founded in 2012 as an autonomous body. Before that, the industry was governed by the Drugs Act, 1976.<sup>1</sup> Provinces have their own regulatory authorities that

work in tandem with DRAP. The majority of the pharmaceutical firms are concentrated in the south of the country, specifically in its commercial and industrial hub, Karachi.

Although there are no precise figures available on domestic consumption of medicines, pharmaceutical industry acknowledges that the demand for medicines have been on a decline. In terms of exports, Pakistan's pharmaceutical exports of US\$113.9 million between July and November 2020 reflected an increase in exports by 22.87 percent compared to the same period in the preceding fiscal year (US\$92.7 million). The import of medicinal products stood at US\$439.1 million in the period between July and November 2020, which is a slight increase (2.65 percent) compared to the import in the previous fiscal year for during same time period (US\$427.7 million).

Imports significantly outweigh exports, which has been the usual trend for many decades, but the gap between imports and exports has been narrowing a bit. This could be explained by higher tariffs on imports of pharmaceuticals since the Pakistan Tehreek-e-Insaf government took over in 2018, and the decline in aggregate

demand due to the reduced economic activity, which has lessened demand for overall imports. Some of these trends have been depicted in Figure 1.

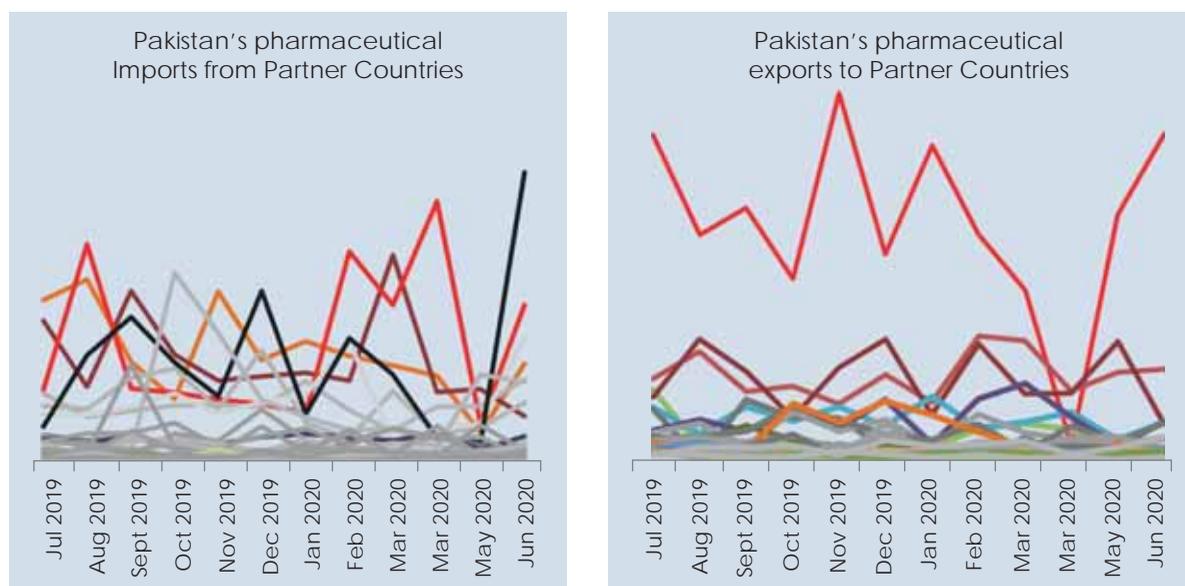
### Issues confronting the industry

Pakistan's pharmaceutical industry is performing below its potential due to the presence of several issues that have plagued its performance for a long time. A majority of these issues are related to the government's regulatory measures.

Perhaps the biggest issue is related to the pricing of medicines, a fact readily admitted by both industry and government officials. Historically speaking, pricing has always been a political decision rather than one based on market forces of supply and demand, or of competition between pharmaceutical firms. The pharmaceutical industry, arguably, is the most regulated industry in Pakistan, and unlike industries such as textiles, it enjoys no public subsidies. The most heavily regulated aspect is the final retail price of medicines, which only the cabinet can decide. This aspect has caused tremendous problems for the industry.

The industry went through a 'price freeze' between 2001 and 2013

**Figure 1**  
Trends in Pakistan's exports and imports of pharmaceuticals



Source: Author's compilation

when the cabinet approved the price increase of only limited medicines ('hardship cases') in spite of the growing manufacturing costs. The pharmaceutical companies took this matter to the Supreme Court, after which two new pricing strategies (2015 and 2018) were approved. The new strategies take recourse to 'reference pricing' and allow companies to raise prices by a certain percent against the Consumer Price Index (CPI). The cabinet approved increase in prices of a few medicines last year.

Stringent price controls have resulted in negative repercussions such as non-availability of life-saving medicines. Simply put, the government-mandated prices make it financially unfeasible to produce medicines given that the cost of manufacturing and distribution often exceeds the final approved retail price. An apt reflection of this is that out of 70,000 registered medicines, only 10,000 are produced domestically.<sup>2</sup> Similarly, a survey carried out in twin cities of Rawalpindi and Islamabad found that several categories of life-saving med-

icines were not available. Besides the non-availability of medicines, another fallout of the rigid pricing policy is the production of only those drugs that can garner a higher margin<sup>3</sup>, meaning that low-cost, life-saving drugs were not produced. Although, after the intervention of the country's Supreme Court, pricing of drugs is based on 'reference pricing' rather than a government-mandated price, there is still a doubt about the government's commitment in the long run.

There are other issues too that hamper the efficient working of the industry. 'Toll' or contract manufacturing of drugs is a norm around the world. For example, in India, toll manufacturing constitutes manufacturing worth US\$34 billion.<sup>4</sup> However, Pakistan does not allow toll manufacturing of pharmaceuticals without cogent reasons. Similarly, there are issues regarding delays in registration and approval of new medicine production. Although the process has sped up compared to what it was earlier, it is still considered slow by industry standards.

Haphazard political decisions and taxation issues also plague the working of this sector. In the wake of tensions with India in August 2019, Pakistan suspended all bilateral trade with India. This put the industry and the market in a difficult situation as India is a major source of raw material for manufacturing medicines.<sup>5</sup> The government had to exempt pharmaceutical products from the import ban as the production of many medicines suffered due to the non-availability of raw materials and hospitals had to cope with severe shortages (like cancer drugs, many of which are imported from India). This step, taken without any discussion with the industry or without considering ground realities, was a reflection of the government's general attitude towards this sector.

Similarly, the government has been charging 1 percent of gross industry sales as tax to contribute to the Central Research Fund since 1976. Not much is known about the amount of funds that have been collected or where they have been spent. However, there is not a single Federal Drug Adminis-

tration (FDA)-approved laboratory in Pakistan, which is considered the gold standard for drug testing around the world. There are 12 drug testing laboratories in the country at the moment, but they do not necessarily meet international standards.

There are also issues related to administrative bottlenecks in the pharmaceutical sector. For example, it takes a long time to get clearance for pharmaceutical raw materials at ports, especially during congestion. The pharmaceutical industry has raised this issue several times and has put in efforts to resolve it, but without much success. Similarly, Pakistani pharmaceutical products have been losing their overseas markets. A case in point is the loss of the Afghan market to Chinese and Indian pharmaceutical products, where Pakistani pharmaceutical products once held a monopoly. A major reason for this is the frequent closure of the border between Pakistan and Afghanistan, which has caused persistent shortages of medicines in Afghanistan. Thus, to ensure a smooth supply of medicines, Afghanistan turned to India and China. Hence, a lucrative export destination for Pakistan's pharmaceutical exports was lost because of procedural obstacles at the border.

Last, but not the least, capacity of the Pakistani regulator is quite limited, especially in terms of human resources and low financial outlays. There are not more than 30 drug inspectors at the federal level, which is grossly inadequate to cover the whole country. This results in several issues, such as delayed inspection and prevalence of ineffective/counterfeit drugs (although at a small scale than is usually believed).

### Pakistan's pharmaceutical industry during COVID-19

The spread of COVID-19 and the development and distribution of vaccines have brought to the fore the importance of having a pharmaceutical industry that can rise to such monumental challenges. The Pakistani government appears to have noted this fact and thus it has taken a

step back from strictly regulating the pharmaceutical industry to incentivize the growth of Pakistan's pharmaceutical sector. The most notable sign in this has come in the form of granting multiple price increases of medicines, something that has rarely happened before. Similarly, there are efforts to streamline and resolve the other outstanding issues. However, it remains to be seen whether steps like granting multiple price increases would constitute a continuing trend or a temporary phenomenon.

Despite the fact that the top 50 pharmaceutical firms in Pakistan are well placed to compete with international firms, there is no or little incentive to do that. Consistency in policies that make for certainty in the business environment is still missing as there is a little guarantee (and confidence)

Pakistan's pharma industry lost Afghanistan as a lucrative export market due to procedural hassles at the border.

that the government will not reverse a particular decision (like increasing medicine prices). Similarly, the issue surrounding 'toll manufacturing' persists, something that could make outsourced manufacturing of critical medicines within Pakistan possible.

Since the pandemic is still unfolding, it is difficult to ascertain what changes, if any, this challenge has brought to the public-level policymaking in Pakistan with regard to the country's pharmaceutical industry.

### Conclusion

Pakistan's pharmaceutical industry is well placed to cater to the demands for pharmaceutical products within the country, as well as meeting the demands for pharmaceutical products in the immediate neighborhood (such as Afghanistan) as well as other low

and middle-income regions. Yet, its full potential has not been realized in the face of adverse regulations. Successive governments in Pakistan have resorted to reversing or cancelling policies of the preceding government, and policies related to the pharmaceutical sector are no exception in this regard. On DRAP's website, for example, one can still find a plethora of Statutory Regulatory Orders, which in general reflects a lack of continuity in policies. Application of intellectual property rights, a critical determinant in pharmaceutical research, is still non-existent, which makes it easier to manufacture low-quality drugs. Similarly, the government still extracts billions of rupees every year from the pharmaceutical sector in the name of research, yet there is none, and the country still lacks quality infrastructure like FDA-approved laboratory.

COVID-19 provides Pakistan an opportunity to change its policies for good with regard to the development of the pharmaceutical sector. Whether the government can seize this moment and change regulations that can boost the pharmaceutical industry, only time will tell! ■

*Mr. Mehmood is Research Fellow, Pakistan Institute of Development Economics (PIDE), Islamabad; Dr. Faraz is Research Economist at PIDE; and Dr. Samad is Senior Research Officer, Central Asia Regional Economic Cooperation (CAREC) Institute, Islamabad.*

### Notes

- 1 Mehmood, Shahid. 2020. "Time to Get the Pharmaceutical Industry Policies Right". *COVID-19 Bulletin No. 8*. Islamabad: Pakistan Institute of Development Economics (PIDE).
- 2 Junaidi, Ikram. 2018. "Pharmaceutical firms set to increase prices of 10,000 drugs." *DAWN* 25 June 2018.
- 3 Dawani, Kabeer, and Asad Sayeed. 2020. "Anti-corruption in Pakistan's pharmaceutical sector: A political settlement analysis." *ACE Working Paper no. 25*. <https://ace.soas.ac.uk/wp-content/uploads/2020/07/ACE-WorkingPaper025-PakistanPharma-200701.pdf>.
- 4 *ibid.* Note 1.
- 5 Ahmed, Khurshid, and Mehreen Zahra-Malik. 2019. "Pakistan exempts pharmaceutical industry from India trade ban". *Arab News* 3 September 2019.

# Nepal's chronic fertilizer shortage

Regional and bilateral procurement mechanisms should be taken as back-up preparations for the fertilizer procuring agencies.

Dikshya Singh

Besides dealing with COVID-19 pandemic, Nepali farmers in 2020 monsoon cropping season had to struggle with acute fertilizer shortage. Delayed fertilizer procurement is even expected to create shortages well into the winter cropping season. However, the recent agreement signed between Nepal's state-owned fertilizer distributing agency and Bangladesh's government-owned chemicals factory to import urea from Bangladesh may help tackle the imminent shortage.<sup>1</sup>

The repeated failure of Nepal's government-backed apparatus in procuring and distributing the vital agriculture input has created an urgency to look for alternative solutions to work as stop-gap measures to prevent crippling shortages. Having a government-to-government purchase mechanism in place as a back-up option through putting them in the bilateral or regional treaties could be a viable step. The absence of any institutional mechanism in place between Nepal and Bangladesh with regard to such government-to-government procurement had delayed the purchase

despite the process being started in late August.

Nepal is fully dependent on imports to meet fertilizer demand. In Nepal, any enterprise can import fertilizer but only two state-owned companies—Agriculture Inputs Company Ltd (AICL) and Salt Trading Corporation (STC)—are granted subsidies for the cost of transportation by the government. Subsidy on transportation means only the public sector authorities are able to import fertilizer into Nepal and distribute it through their own depots and via agricultural groups and cooperatives across Nepal.

Delays in fertilizer procurement and inefficient distribution leading to shortages of essential fertilizers—urea, diammonium phosphate (DAP) and potash—during the major cropping season are regular occurrences, making it just another instance of the inefficiency in agricultural policy delivery. On top of the existing bottlenecks, this year's pandemic and the measures such as lockdown aggravated the shortages.

According to official estimates, Nepal requires about 700,000–800,000 MT

of fertilizers annually.<sup>2</sup> Nepal imports less than half of the estimated requirement.<sup>3</sup> The government had planned to buy 450,000 MT fertilizer in the fiscal year 2019-20.<sup>4</sup> The amount was estimated based on the plans prepared a year earlier and announced during the annual government budget in July 2019. Despite the AICL and STC inviting bids from private suppliers for the urea and DAP by the beginning of 2020, farmers could not get the required fertilizer, especially urea, during the entire monsoon cropping season of paddy.<sup>5</sup> Paddy is the major crop in Nepal as it accounts for 20 percent of Nepal's agricultural gross domestic product and 53 percent of total food grain production.<sup>6</sup>

Considering the time required to conclude the procurement contract and the arrival of the shipment, the AICL and STC should have started the process at the end of 2019. However, according to the press statement issued by MoALD<sup>7</sup>, the lockdowns imposed in late March 2020 caused delays in procurement resulting in the shortage. Some reports blame

the AICL awarding fertilizer import contracts to inexperienced importers for the delays. The contracts awarded to Nepali contractors were later cancelled due to their inability to get the consignments delivered on time.<sup>8</sup> This meant restarting the process all over again. COVID-19-related disruptions and cyclone in India also affected the transit and transport of Nepal-bound fertilizer. For example, cyclone Amphan and lockdown in India's West Bengal forced the ship carrying 21,000 MT of urea and 20,000 MT of DAP for STC to reroute to Kandla Port in Gujarat from Kolkata Port.<sup>9</sup> The shipment had to be moved to Kolkata again since Kandla Port is not authorized to process Nepal-bound cargoes.

This year's fertilizer shortage caused by COVID-19-related disruptions was felt more acutely by Nepali farmers living in areas close to the border with India. Since they are dependent on the informal supply of fertilizer from India, the closure of the border to contain the COVID-19 spread had shut off all the major border points, making informal imports quite difficult.

Despite the fertilizer shortage, MoALD update on paddy production for 2020 monsoon season shows that production has slightly increased compared to last year.<sup>10</sup> Although paddy production increased by 1.2 percent to 5.3 million MT, the yield had increased slightly by 0.28 percent. This year's increase in paddy production is attributed to an increase in the area of cultivation, ample monsoon, use of improved seeds and, importantly, availability of labour as the lockdown measures caused reverse migration from cities to villages. Hence, it can be expected that the timely availability of fertilizer could have improved yield and production significantly.

Recurring fertilizer shortage is one of the major issues debated in the policy circle in Nepal. The government is promoting the idea of establishing a fertilizer plant to address the shortage. However, it appears that fertilizer plant will be resource-intensive requiring an enormous amount of energy. On the other hand, considering the need to produce a large quantity of

fertilizer to make its production financially viable and the limited domestic demand fertilizer production in Nepal may not be a sound decision. Instead, the focus should be on improving the existing mechanism with alternative sources to prevent crippling shortages like the one experienced this year.

The agreement to import fertilizer from Bangladesh shows that strengthening regional cooperation could be one way to go about it. Similarly, the existing mechanism with India, based on Nepal-India Trade Treaty, which has the provision of India supplying a certain quantity of fertilizers to Nepal at import parity price (technically extending a subsidy), was helpful in meeting the demand during peaks. However, the arrangement was discontinued in the last couple of years for India is not willing to sell fertilizer at subsidized rates to Nepal.<sup>11</sup>

This year's fertilizer shortage caused by COVID-19 related disruptions was felt more acutely by Nepali farmers living in areas close to the border with India

This issue needs to be included in the ongoing negotiations between the two countries regarding the renewal of the trade treaty. An arrangement needs to be decided so that Nepal can access a certain volume of fertilizer from India at the rate acceptable to both the countries. Timely availability of fertilizer at a reasonable rate can also help in dealing with the informal import of fertilizers from India. Although essential, the widespread practice of informal imports of fertilizer from India has weakened Nepal's position at the negotiating table with India and could be one of the reasons for India unwilling to provide Nepal fertilizer at a lower rate. A similar formal arrangement needs to be made with

Bangladesh. This will ensure that farmers will be able to access the essential agriculture input on time.

However, regional and bilateral procurement mechanisms should not be taken as the go-to arrangement for the fertilizer procuring agencies in Nepal but as back-up preparation when in need. The advantage of awarding short-term contracts to commercial procurers is that it allows the state to buy fertilizer at best prices. The repeated shortage is the result of inefficient management of buffer stocks and imprudent procurement decisions by the state authorities. Unless these issues are resolved by the state and public procurers, fertilizer shortage will persist, affecting overall agriculture productivity. ■

## Notes

- 1 United News of Bangladesh. 2020. "Bangladesh to provide 50,000 mt fertilizers to Nepal." *United News of Bangladesh*, September 01, 2020.
- 2 Ministry of Agricultural Development. 2015. "Agriculture Development Strategy 2015 to 2035." Kathmandu: Government of Nepal.
- 3 Ministry of Agriculture and Livestock Development. 2020. "Statistical Information on Nepalese Agriculture 2018/19." Kathmandu: Government of Nepal.
- 4 My Republica. 2020. "Only urea fertilizer is insufficient, not Potash and DAP: Agriculture Minister." *Republica*, June 27, 2020.
- 5 Press Release on "Appeal regarding chemical fertilizer import and distribution system" (in Nepali). Ministry of Agriculture and Livestock Development, August 17, 2020.
- 6 Crop Development and Agriculture Biodiversity Conservation Center. 2020. "About Crop Development and Agriculture Biodiversity Conservation Center".
- 7 *ibid.* Note 5.
- 8 Himalayan News Service. 2020. "Agriculture Inputs Company cancels contract with fertilizer importers." *The Himalayan Times*, September 6, 2020.
- 9 *ibid.* Note 5.
- 10 Press Release on "Rice Production" Ministry of Agriculture and Livestock Development, December 28, 2020. (in Nepali).
- 11 Prasain, Sangam and Anil Giri. 2020. "Nepal's fertilizer conundrum-governments ponder over it every paddy season and then forget harvest." *The Kathmandu Post*, September 3, 2020.

# India's new (harsh) rules of origin requirements

India's recent changes in Rules of Origin enforcement may have a detrimental impact on the India-bound exports of other South Asian countries.

M S Siddiqui

Current global trade regime is governed by bilateral, regional and multilateral trade agreements. As per World Trade Organization (WTO) statistics, there are 305 bilateral and regional trade agreements in force as of 2020. These include the bilateral and regional trade agreements between countries in South Asia.

India is a major trade partner of most of the countries in South Asia. Trade between India and other South Asian countries is governed either by the bilateral trade agreement between India and the respective country or the Agreement on South Asian Free Trade Area (SAFTA).

Rules of Origin (RoO), which prescribes the criteria that must be fulfilled for goods to attain 'originat-

ing status' in the exporting country, is a major component of any free trade agreement (FTA). Such criteria are generally based on factors such as domestic value addition and substantial transformation in the course of manufacturing/processing. For instance, in the SAFTA agreement, the general RoO criteria are Change in Tariff Heading (CTH) plus domestic value addition of 30 percent for least-developed country (LDC) members and 40 percent for non-LDC members.

Recent changes made by India regarding the new norms for enforcing RoO may have a detrimental impact on India-bound exports of other South Asian countries.

The Indian government, through Finance Act 2020, amended the

Customs Act 1962, putting forth new rules on the administration of RoO for preferential tariff treatment regime under various trade agreements. The new rules, called Customs (Administration of Rules of Origin under Trade Agreements) Rules 2020 (CAROTAR 2020),<sup>1</sup> was introduced on 21 August and were to be implemented from 21 September, giving importers and other stakeholders only 30 days to familiarize themselves with the new provisions. It looks like CAROTAR 2020 will affect exports to India made by countries that have FTA or a Preferential Trade Agreement (PTA) with India.

The amendments provide for "a basic level of due diligence" on the part of an importer to satisfy



himself that the claimed originating criteria have been met, and that mere submission of a Certificate of Origin (CoO) along with the customs documents may not be sufficient. For this purpose, the importer is required to possess 'sufficient' origin-related information. The first point of query into the origin of goods, in case of doubt, will now be the importer, thus shifting verification-related activities from a government-to-government model to a business-to-government model. Hence, now the onus is on the importer to prove the accuracy of the information about the origin and value addition of the imported products. Accordingly, an importer needs to possess sufficient information about the origin of goods, where preferential tariff treatment is claimed.

Likewise, CAROTAR has empowered the customs officers to use their discretionary authority to deal with 'doubt' on the authenticity of the CoO provided by the exporters. The officers are also empowered to send a verification request to the designated authority in the exporting country through a nodal officer in the importing country if the importer cannot provide a satisfactory response. Moreover, Section 28DA of CAROTAR empowers Indian customs officers to impose a temporary suspension of preferential treatment and even reject the submitted certificate.

Since importers are supposed to possess all the necessary information about the origin of imports, where preferential tariff treatment has been claimed, they need to enter the information in a form. An importer is not required to submit the said form at the time of filing customs declaration. However, when there is a doubt on the declared origin details, the customs officer may ask the importer to submit origin-related details, in which case the importer will have to submit the form along with supporting documents.

The form requires information regarding the process to attest the origin of the good, i.e., whether the good is produced entirely from inputs from the exporting country (that has access

to preferential treatment from India) or also includes inputs from a third country. Likewise, the form requires information about each input, including constituents that occupy an insignificant weightage such as preservatives. Furthermore, each input, no matter how insignificant its presence is, should be incorporated into the cost of materials (by value or weight). Furthermore, if a supplier/producer declares that the exported goods have non-originating components but meet the RoO criteria, it is advised to check if the claimed originating criteria applies to that specific tariff heading. Importers are expected to ask these questions to the exporter to ensure that the claim is valid and to diminish the chances of erroneous claims. Also, the importer is required to keep origin-related information specific to each bill of exchange (BE) for a minimum of five years from the date of filing BE. Furthermore, it mandates the inclusion of specific origin-related information in the BE to provide for scenarios wherein verification from the exporting country can be initiated. Moreover, importers are expected to exercise 'due diligence' in verification of the information provided by exporters.

The new regulation gives discretionary power to Indian customs officials, who can investigate the origins of the commodities on their own volition. Another issue with the new regulation is related to the protection of some confidential information. For instance, some information that needs to be filled in the form such as compositions and formulations of products can be confidential, which are protected as trade secrets or intellectual property. Hence, producers may not want to divulge the exact quantities of the ingredients and inputs used, as required by the new regulation.

Given that countries in South Asia have limited capacity in producing all the necessary inputs, they use imported materials to manufacture finished products. In case they fail to satisfy the Indian customs officials that their products meet the domestic value

addition and CTH criteria, they may not receive the deserved preferential treatment. Worse, this uncertainty will remain up to five years after the import.

According to the new regulation, the request for verification may be sent within five years from the date of claim of preferential tariff treatment, unless specified otherwise in the trade agreement. The preferential tariff treatment to the goods can also be temporarily suspended pending verification. Furthermore, according to amendments in Section 111 of the Customs Act, relating to the confiscation of goods, if the goods imported under the claim of preferential tariff treatment were found to be contravening the provisions of the regulation, they could also be confiscated.

Thus, it appears that India's imports under SAFTA might fall drastically due to such stringent RoO requirements and the discretionary authority provided to the customs officials. Bangladesh's newspaper, *Financial Express*, reported that "a government agency has suggested retaliation by issuing similar harsh rules unless India agrees to withdraw its newly enacted customs rules, which are likely to make it tough for Bangladesh to get tariff preferences"<sup>2</sup>. "The Export Promotion Bureau (EPB) also suggested engaging the South Asian Association for Regional Cooperation (SAARC) and the Asia-Pacific Trade Agreement (APTA) secretariats in negotiations with India for the withdrawal of new rules"<sup>3</sup>. Perhaps SAARC countries should take a united stand on this issue. ■

*Mr. Siddiqui is the CEO of Bangla Chemicals.*

## Notes

<sup>1</sup> The Customs (Administration of Rules of Origin under Trade Agreement) Rules, 2020 ('the Rules') have been notified vide Notification No. 81/2020 Customs (N.T.), dated 21 August 2020, effective from 21 September 2020.

<sup>2</sup> Islam, Syful. 2020. "Retaliation suggested for India's customs rules that may hurt Bangladesh exports." *The Financial Express*, 7 November 2020.

<sup>3</sup> *ibid*.



Swastik Aryal

# Has Nepal broken out of its trend of export stagnation?

Nepal's recent increase in exports is rather a result of a sudden surge in exports of a couple of products that Nepal has no real comparative advantage in producing.

Kshitiz Dahal

Nepal's Prime Minister's Office recently unveiled the progress report of the current Prime Minister KP Sharma Oli's three-year reign. Among the many achievements highlighted, one was the increase in country's exports. The progress report points out that Nepal's exports in the first six months of the current fiscal year (FY) 2020-21 increased by 6.1 percent. It also points out an overall increase in exports by 4.5 percent in the period ruled by the current government (since mid-February 2018). While brakes applied to the ever cruising

trade deficit is undoubtedly a relief, much of the optimism is lost when one scratches the surface.

Nepal's exports saw a clear stagnation in the period 2014–2018—total export in 2018 was less than the total export in 2014 (Figure 1). We also see that Nepal's total export has undoubtedly surged in the review period. While total export declined in 2019 relative to 2020, the decline could have been because of restrictions and disruptions caused by COVID-19. Further, if we go beyond the mere export value and delve a little deeper to

look into the composition of exports, a pattern begins to emerge that poses serious questions as to the sustainability of the current export hike. The pattern referred to is a sudden emergence of two commodities—palm oil (HS 15119000) and soybean oil (HS 15079000)—as the top two export products of Nepal.

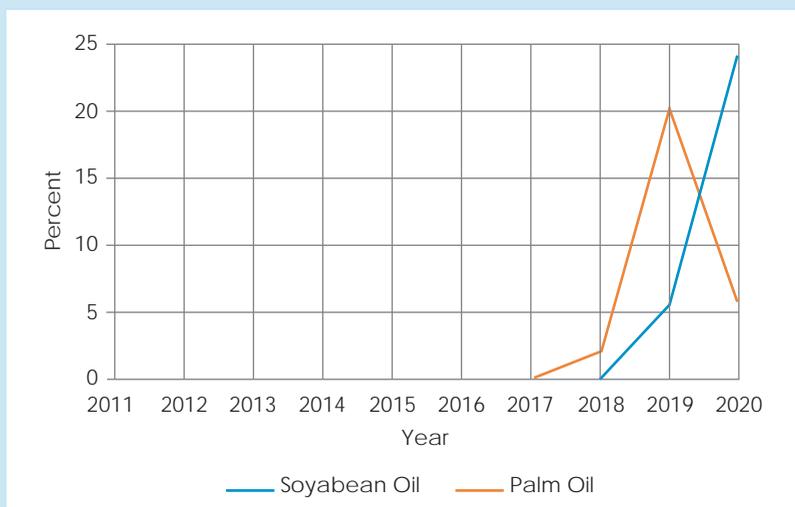
Exports of palm oil and soybean oil did not feature in Nepal's export until 2017. But, their share in Nepal's total export skyrocketed from 2018 (Figure 2). The prominent position of these products in Nepal's export

profile is all the more surprising given that Nepal's production profile does not support any possibility of backward linkages (there is no extensive farming of palm or soybean in Nepal) that would have justified the export of these products. Assessment of trade data reveals that Nepal imports crude oil from third countries and exports their refined forms to India. The activity is profitable to the refineries in Nepal only because India imposes a hefty tariff on crude oils and Nepal gets duty-free access to the large Indian market for refined oils.

Interestingly, the preferential access to the Indian market for the oils refined in Nepal is secured not through Nepal-India Trade Treaty, but through the Agreement on South Asian Free Trade Area (SAFTA), which allows for less stringent rules of origin (RoO). Put briefly, while SAFTA's RoO for refined palm oil and soybean oil are a minimum 30 percent domestic value-addition and a change of tariff-heading (CTH) at the six-digit level, Nepal-India Trade Treaty's RoO requires a minimum of 30 percent domestic value-addition and CTH at four-digit level.

As rapid as the rise in the export of these commodities have been,

**Figure 2**  
Share of soybean oil and palm oil in Nepal's total export



Source: Author, using data obtained from NTIP.

evidence suggests that the export of these products can come down to a grinding halt any minute. India amended its import policy to restrict the import of refined palm oil in January 2020. Consequently, Nepal's export of palm oil collapsed. While soybean oil has stepped up to fill the gap in export created by the collapse

of palm oil exports, it could very well meet the same fate if exports continue to escalate.

Once we deduct the export of palm oil and soybean oil from Nepal's total export, we see that Nepal's export has in fact witnessed a significant decline since 2018 (Figure 3). Decline or stagnation in the export of Nepal's major products is also corroborated by the fact that Nepal's export of products identified in the Nepal Trade Integration Strategy (NTIS) 2016 as major exportable products, and hence worthy of receiving government's promotion, facilitation and support, has witnessed a noticeable decline since 2018 (Figure 4).

As for the claim that Nepal's export increased by 6.1 percent in the first six months of the FY 2020/21, it is once again largely due to the surge in the export of soybean oil. Export of soybean oil in the first six months of the FY 2020/21 increased by NPR 12.7 billion compared to the same period in the preceding fiscal year. This increase was almost large enough to counter the total collapse in the export of palm oil in the period—export of palm oil in the first six months of the FY 2020/21 was down to nothing from NPR 13.9 billion in the first

**Figure 1**  
Nepal's commodity export



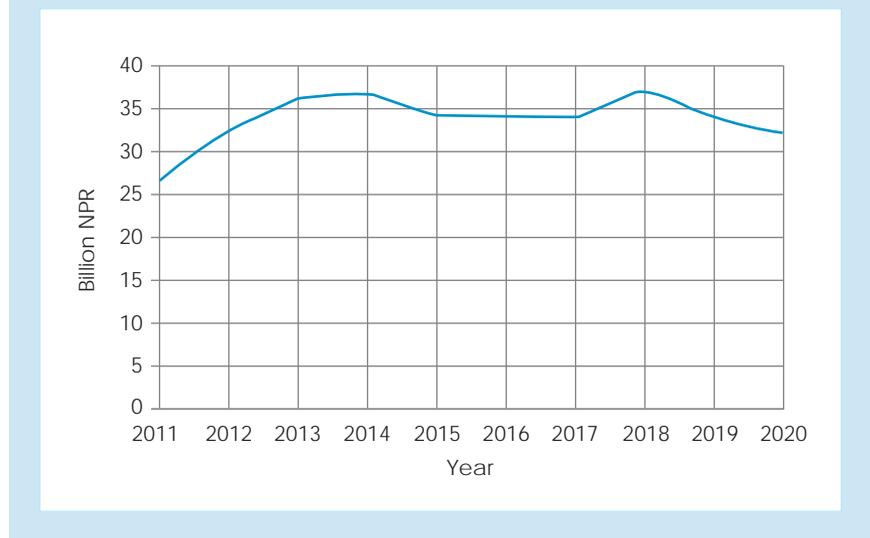
Source: Author, using data obtained from Nepal Trade Information Portal (NTIP).

six months of the FY 2019/20. There have also been some other notable increase in exports in the period. For instance, the export of large cardamom (HS 09083110) increased by NPR 2.53 billion, and export of black tea (HS 09024000) increased by NPR 1.07 billion. On balance, the overall export in the first six months of the fiscal year 2020/2021 has increased by only NPR 4.76 billion if we are to discount the role of soybean oil and palm oil.

However, evidence shows that the rise in export of other commodities in the first six months of the current fiscal year could largely be due to the loosening of COVID-19 disruptions that had restricted exports in the preceding months. The fact that export in the last six months of FY 2019/20 had declined significantly—by NPR 11.3 billion or 21.8 percent—compared to the same period in the preceding fiscal year lends credence to the hypothesis that the increase in exports of other commodities in the first six months of FY 2020/21 is most likely a recuperation of lost exports during peak months of COVID-19 disruptions rather than an emergence of a persistent trend.

Hence, evidence suggests that the increase in export witnessed after 2018

**Figure 4**  
Export of NTIS products



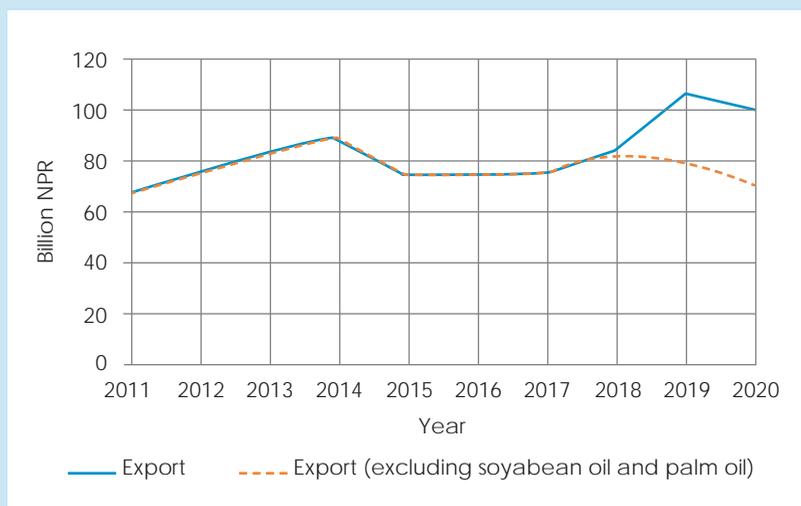
Source: Author, using data obtained from NTIP.

is almost entirely because of the rise in the export of palm oil and soybean oil. Exports have occurred only due to the narrow window of potential created by provisions of tariff differential that exists between India and Nepal (with respect to the import of crude oil) and the provision of preferential market access to Nepali exports in

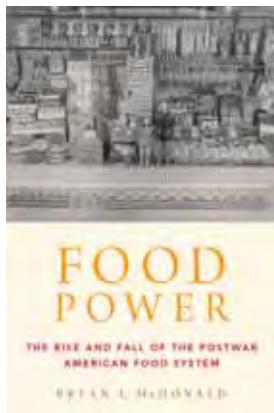
India. Excluding these products, exports of which were insignificant or non-existent before 2017, from Nepal’s export profile shows that the total export of Nepal’s other commodities has seen a decline. Furthermore, the decline in export of NTIS 2016 products is a strong indication that structural problems that hinder Nepal’s export—for instance, low productive capacity, poor implementation of government policies and strategies, lack of coordination among government agencies, inadequate private-public collaboration and dialogue, private sector capacity constraints, issues with quality, standards, and conformity assessment (Sanitary and Phyto-Sanitary and Technical Barriers to Trade issues), poor state of logistics, etc.—are very much intact.

Thus, the current increase in exports, rather than being a trend that can be sustained, is rather a result of a sudden surge in exports of a couple of products that Nepal has no real comparative advantage in producing. Hence, a better strategy is to address the current constraints in industrial development and export promotion rather than to revel in fluke achievements. ■

**Figure 3**  
Nepal’s export (with and without export of soybean oil and palm oil)



Source: Author, using data obtained from NTIP.



# Food as national security agenda

**Title:** Food Power: The Rise and Fall of the Postwar American Food System

**Author:** Bryan L. McDonald

**Publisher:** Oxford University Press

**ISBN:** 9780190600686

Shaleen Khanal

While food security has always been a priority for countries around the world, recent events like trade war and COVID-19 and its impact on supply chain disruptions have put the focus back on food as an important national security agenda. However, understanding food diplomacy and negotiating with today's food system of highly complex networks requires a thorough comprehension of its roots, and Bryan McDonald's *Food Power* is an excellent primer in this regard.

*Food Power* is essentially a book on the US' experience of historic and sustained food surplus post World War II and how it utilized the surplus to create a food system to improve its soft power around the world. It extensively chronicles how internal electoral politics played a key role in generating agricultural surplus over the years and resulted in politicians identifying international markets as key to solving the problem of surplus. Consequently, the US introduced a series of mechanisms to distribute food across the world to its allies and foes, starting with the reconstruction of Europe through the Marshall Plan to institutionalizing food-based organizations such as the World Food Programme and Food for Peace. Mechanisms of support would range from outright aid to sale at subsidized prices. The aim was to demonstrate the superiority of the capitalist system over the socialist one, to make new allies and to support existing ones.

Another fascinating aspect of the

book is its discussion of technology. Recognizing the importance of food as a valuable resource, McDonald argues, the US government invested significantly in food and crop technology. The result was creation of entire new markets. For instance, improvements in food science resulted in emergence of processed and packaged food products, better understanding of nutrition and creation of large marketing industry geared towards selling processed food to increasingly affluent consumers. At the same time, investments in crop technology led to development of hybrid seed varieties and improved fertilizers that resulted in the Green Revolution.

In the latter half of the book, McDonald explains how culmination of years of policy incentives to reduce farm acreage led to eventual end of American surplus. This coupled with global agricultural shocks (including poor weather, and rise in petroleum prices), rise in population in developing countries, and increase in affluence and change in food habits of consumers created a perfect storm to end the American dominance on global food systems. The result was today's amorphous and complex food network.

The book clearly takes a commemorative attitude towards the American dominance of food system, arguing that American surplus was key to stable food markets, low global food prices, and increased investment in agriculture in the aid recipient nations. Even if one ignores the recent debates on influence of food aid on receiving

countries' food systems, McDonald conveniently overlooks the massive distortions that farming assistance caused, including quantitative restrictions and export subsidies, which were directly harmful to farmers in developing countries. Even as late as 1991, it was reported that an American farmer received US\$43 per ton of wheat exported. Notwithstanding the effectiveness of food aid on the recipient countries, its effectiveness as a diplomatic tool is also a matter of debate. While the author provides plenty of examples of the US providing food aid, the impact of aid on increasing American soft power is not made very clear in the book. While significant portions of the chapters focus on internal political struggles regarding food aid, very little attention is paid to its effects on global politics.

Also missing is the discussion on the 'fall' of American power. Although the book goes into some detail on how the food crisis of 70s led to an end of surplus era for the US, very little is said on what emerged afterwards. The author suggests the emergence of global food network, but no explanation is given on why this was so, or why the US could not go 'back' to being a food hegemon.

Overall, the book provides a compelling study on how domestic politics and policies of a superpower can spillover to create an entire global food system. ■

*Mr. Khanal is a PhD scholar at Lee Kuan Yew School of Public Policy, National University of Singapore.*

# COVAX

## and its importance in the fight against the global pandemic

Ensuring that vaccines are distributed equally throughout the world should be the main priority in the fight against the pandemic.

Alabhya Dahal

Past pandemics have shown that bigger and richer nations with the ability to produce and purchase vaccines and medicines have disproportionate access to such products. For example, when the vaccine for swine flu was supplied, almost all the vaccine was bought by a small number of wealthy nations.<sup>1</sup> Usually vaccines go to the people of countries that can afford them rather than reaching those who need them the most. This weakens the collective effort to fight against the global pandemic, especially when the pandemic is highly contagious and difficult to contain, such as COVID-19.

For the most part of 2020, COVID-19 crippled the world. There was a glimmer of hope when vaccines emerged in late 2020 and early 2021. But given the history of vaccine hoarding during swine flu, the fear of 'vaccine nationalism' once again surfaced as rich countries started pre-ordering the vaccines for COVID-19

several times over their population.<sup>2</sup> By early 2021, a number of vaccines against COVID-19 were rolled out for emergency use. But by mid-January, according to the Duke University's Global Health Institution, high-income countries representing only 16 percent of the world's population had purchased about 60 percent of all the vaccines that had been purchased until that time.<sup>3</sup> People Vaccination Alliance reported that rich countries have ordered vaccines enough for three times their population. Canada has secured vaccines for about five times its population. The fate of poorer countries, however, has been left in limbo.

Such vaccination nationalism would mean that a healthy young person from a rich country, living in an area with less risk of infection and having better access to treatment facilities will be more likely to receive vaccination than a poor country's health worker or an individual with

underlying conditions who are more vulnerable to the disease. While this is grossly immoral, this is also not the proper way of tackling the pandemic. There is no certainty that the vaccine will provide a lasting immunity. As a result, rich countries hoarding more than enough doses of the vaccines at the expense of poor countries makes no sense since the danger of reinfection remains if everyone is not immunized. Moreover, if left unchecked, there are possibilities for the emergence of newer variants of the virus that could be resistant to the vaccine, rendering all the efforts made for vaccine development meaningless.

To prevent such a situation, COVAX, formally known as the COVID-19 Vaccines Global Access Facility, was formed in April 2020. It is based on the idea that "no one is safe unless everyone is safe". Objectives of COVAX are to facilitate the vaccine development process, scale-up manu-

facturing and equitably distribute the vaccine around the world as quickly as possible.

COVAX is a global vaccine sharing initiative jointly coordinated by the World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations, and Gavi, the Vaccine Alliance. The WHO states that the COVAX facility aims to “accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.”<sup>4</sup> COVAX has also set up a funding mechanism that pools funds from wealthy participating nations and then facilitates in distributing the COVID-19 vaccines to themselves and less wealthy nations. COVAX will use the funds to invest in the most promising vaccine developers.<sup>5</sup>

COVAX works in development, acquisitions and delivery of COVID-19 vaccines. Research for developing a vaccine requires significant investment. Manufacturers of the vaccine will also be dealing with huge costs for storage facilities and supply. For example, the vaccine developed by Pfizer and the German firm BioNTech requires it to be stored in -70°C. This requires storing the vaccine in ultra-cold-freezers, which can cost US\$10,000 to US\$15,000,<sup>6</sup> increasing logistics costs. Due to huge demand for vaccines from all over the globe, this can create a huge supply constraint and thus an asymmetric distribution of vaccines based on the ability of a nation to pay. To avoid this, COVAX facility will be working with research and manufacturing bodies to get started with manufacturing and distribution of the vaccines as quickly as possible once it is approved.

According to the WHO, 190 countries, so far, already participate in COVAX facilities. This includes 98 higher-income countries and 92 low and middle-income countries. The COVAX facilities have made an advance purchase agreement with the Serum Institute of India for 200 million doses and with AstraZeneca for 170 million doses of the AstraZene-

ca/Oxford vaccine. It has also signed a memorandum of understanding (MoU) with Johnson & Johnson for 500 million doses of the Janssen candidate by December 2020. Under COVAX, all the participating countries will be able to access vaccines to protect the most vulnerable groups in the first half of 2021.

Gavi, the main organization supporting the COVAX facility, is a public-private global health partnership that aims to increase access to immunization in poor countries. Gavi has a history of making an impact on accessibility to immunization. It has immunized more than 822 million children in the world against different diseases, which has prevented more than 14 million

Under COVAX,  
participating countries  
will be able to access  
the vaccines to protect  
most vulnerable groups.

future deaths. Gavi is estimated to have contributed more than US\$150 billion in economic benefits around the world.<sup>7</sup>

In the fight against COVID-19, Gavi has an ambitious plan of rolling out vaccines to 190 participating countries, regardless of their ability to pay. Two billion doses of vaccines are expected to be delivered to the participating countries by the year 2021.<sup>8</sup> This will take place under the COVAX initiative.

Gavi’s ‘interim distribution forecast’, released in early February 2021, outlines the details of the vaccine distribution plans. In the initial phase, 336 million doses will be distributed to some 145 participating countries based on the recipient country’s population profile. Additional 1.2 million doses of the Pfizer-BioNTech vaccine are also expected to be rolled out through COVAX facility within the first quarter of 2021.

Now that multiple vaccines have been developed around the world, ensuring that the vaccines are distributed equally throughout the world should be the main priority for fighting the pandemic. The consequences of unequal distribution of vaccines would be hundreds of thousands of deaths and huge economic losses globally due to a prolonged pandemic. Delays in vaccinating people in all the regions of the world bring the possibility of resurgence of the virus, perhaps in an even stronger form, endangering the world once again.

Vaccinating eight billion people is, surely, a daunting task of unprecedented scale. But with mechanism such as COVAX in place, this could be achieved and everyone, regardless of where they live, can be vaccinated soon. ■

Mr. Dahal is Research Associate at SAWTEE.

## Notes

- 1 DW. 2009. “Rich nations stockpile swine flu vaccines”. *DW* June 27, 2009. <https://www.dw.com/en/rich-nations-stockpile-swine-flu-vaccines/a-4520907>
- 2 Smith, Alexander. 2020. “Covid-19 Vaccines Are Being Hoarded by Rich Countries - Poor Ones Are Missing Out.” *NBCNews.com*. NBCUniversal News Group. December 16, 2020. <https://www.nbcnews.com/news/world/covid-19-vaccines-are-being-hoarded-rich-countries-poor-ones-n1251351>.
- 3 Marcus, Mary Brophy. 2021. “Ensuring Everyone in the World Gets a COVID Vaccine”. *Duke Health Institute* January 20, 2021. <https://globalhealth.duke.edu/news/ensuring-everyone-world-gets-covid-vaccine>
- 4 World Health Organization. 2021. “COVAX.” <https://www.who.int/initiatives/act-accelerator/covax>.
- 5 Gavi. 2021. “COVAX Facility.” Gavi, the Vaccine Alliance. <https://www.gavi.org/covax-facility>.
- 6 Goldhill, Olivia. 2020. “Rural Hospitals Can’t Afford Freezers to Store a Covid-19 Vaccine.” *STAT*. November 11, 2020.
- 7 Gavi. 2021. “COVAX Facility.” Gavi, the Vaccine Alliance. <https://www.gavi.org/covax-facility>.
- 8 Okonjo-Iweala, Ngozi. 2021. “Globalizing the COVID Vaccine.” *Gavi, the Vaccine Alliance*. January 5, 2021.

# SAWTEE webinar Series

SAWTEE, in association with Biruni Institute, Afghanistan, Center for Policy Dialogue (CDP), Bangladesh, Research and Information System for Developing Countries (RIS), India, Sustainable Development Policy Institute (SDPI), Pakistan, and Institute of Policy Studies of Sri Lanka (IPS), Sri Lanka, organized a series of webinars to deliberate on various socio-economic aspects of the COVID-19 pandemic,

how they relate to South Asia and what should be the future course of action for South Asian countries.

The webinar's topic included the impact of the pandemic on labour migration and remittances in South Asia, revival of tourism in the region, foreign investment, tackling climate change amidst the pandemic and the future of development finance in South Asia. ■

# Awareness workshops on gender dimensions of trade facilitation



SAWTEE organized two awareness generation workshops in December on enhancing entrepreneurial capabilities of women entrepreneurs in Karnali Province and Province 1. The workshop in Surkhet, Karnali Province, was organized in association with *Manav Adhikar tatha Grameen Bikas*, on 13 December. The workshop in Province 1 was organized in partnership with Federation of Nepalese Chambers of Commerce and Industries, on 29 December.

The main objective of the workshops was to help women entrepreneurs engaged in micro and small

enterprises understand tax liabilities, bookkeeping, becoming export-ready and looking for new markets, among others. Insights into managing accounts, calculating taxes and becoming credit-worthy, improving product quality and becoming export-ready were provided by experts from Kathmandu. The experts from respective Provinces presented information on the facilities and programmes of the provincial and local governments to women entrepreneurs and how to accrue those facilities. The two workshops hosted around 60 entrepreneurs. ■

# Sustainable Development in the times of COVID-19



THE Sustainable Development Policy Institute (SDPI), Pakistan, organized its Twenty-third Sustainable Development Conference (SDC) with the overarching theme: Sustainable Development in the Times of COVID-19 from 14 to 17 December in Islamabad, Pakistan. Given the COVID-19 pandemic the speakers attended the conference in person taking all the necessary safety precautions including social distancing, while the rest participated through a web-based platform.

The main objective of the conference was to discuss life after COVID-19, development in the midst of a pandemic and how the development process has changed due to the COVID-19 pandemic.

The Conference reflected on what worked and what did not in the fields of health and social safety nets, economy and trade, food security and supply chains, climate change and environment, cultural diplomacy, how it is going to impact our day-to-day life, methods of governance, education, tourism, among others. ■

# Building resilient and sustainable food systems

**THE** Institute of Policy Studies of Sri Lanka (IPS) organized a virtual dialogue on 'Building Resilient and Sustainable Food Systems in the Age of Pandemics' on behalf of the government of Sri Lanka on 3 December. The dialogue was the first in a three-part series of dialogues on the 'Agriculture Value Chain Linkages to Improved Food Systems in Sri Lanka' ahead of the UN Food System Summit scheduled for September 2021 in

Rome. The dialogue was supported by the International Fund for Agriculture Development (IFAD), Food and Agriculture Organization of the United Nations (FAO) and United Nations World Food Programme (WFP).

Mr. R. H. W. A. Kumarasiri, Director-General, Department of National Planning, delivered the opening remarks, and Ms. Hanaa Singer, UN Resident Coordinator in Colombo, delivered the opening

remarks on behalf of the UN. Dr. Tarek Kotb, Country Director (Sri Lanka and Nepal), International Fund for Agricultural Development (IFAD); Ms. Brenda Barton, Representative and Country Director (Sri Lanka), World Food Programme (WFP); and Dr. Xuebing Sun, Representative for Sri Lanka and Maldives, Food and Agriculture Organization of the United Nations (FAO), also addressed the virtual dialogue. ■

# Transforming logistics performance in BBIN Countries

CUTS International (Consumer, Unity & Trust Society) in association with Unnayan Shamannay, Bangladesh, Bhutan Media & Communications Institute (BMCI), Bangladesh and Nepal Economic Forum (NEF), Nepal organized a webinar on transforming logistics performance in BBIN countries towards creating a lasting legacy on 16 December 2020.

The seminar was based on a recently published discussion paper *Transforming Logistics Performance in BBIN Countries: Towards creating lasting legacy*. Authored by Pritam Banerjee, an independent trade and logistics expert, it discusses the concept of freight fluidity and the fluidity of specific economic corridors that could be adopted for future research.

Delivering his presentation, Pritam Banerjee underlined that end-to-end analysis of a corridor using objective

data is rare in the BBIN context. He made a case for this concept by arguing that while the current approaches used in the assessment of logistics quality in BBIN countries have added great value in identifying problems and get a much better visibility of issues, over-used methodologies have diminishing returns after a point in terms of providing more holistic or newer insights.

Reflecting on the presentation, Cecile Fruman, Director, Regional Integration and Engagement, South Asia, The World Bank Group, said that they are fully behind the concept of corridor-wide assessments by leveraging big data and new technologies.

The World Bank is now in the process of developing its Logistics Performance Index 2.0, which will leverage automated and big data to a much greater extent.

However, she argued that there are challenges in corridor benchmarking and monitoring. A key issue to any corridor benchmarking approach is financial sustainability. "The World Bank supported the development of a GPS-based corridor monitoring platform and trucker monitoring system in Southern Africa. Though it entailed a low initial capital investment, operation and maintenance costs become too high to sustain," she said.

Speaking on the occasion, Jan Hoffmann, Chief, Trade Logistics Branch, Division on Technology and Logistics of the United Nations Conference on Trade and Development, reflected on the present logistics conditions in the BBIN countries, and argued that the demand for digitisation and connectivity will only increase. ■



South Asia Watch on Trade, Economics and Environment (SAWTEE) is a regional network that operates through its secretariat in Kathmandu and member institutions from five South Asian countries, namely Bangladesh, India, Nepal, Pakistan and Sri Lanka. The overall objective of SAWTEE is to build the capacity of concerned stakeholders in South Asia in the context of liberalization and globalization.

[www.sawtee.org](http://www.sawtee.org)