BANGLADESH
CAPACITY FOR VACCINE DEVELOPMENT AND ROLL OUT

THE PEOPLE'S VACCINE ASIA
LDC Watch L'Observatoire PMA
South Asia Alliance for Poverty Eradication (SAAPE)
Bangladesh
Capacity for Vaccine Development and Roll Out
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<td>AEFI</td>
<td>Adverse Event Following Immunization</td>
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<td>AESIS</td>
<td>Adverse Events of Special Interest</td>
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<td>ARV</td>
<td>Anti Rabies Vaccine</td>
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<td>BMRC</td>
<td>Bangladesh Medical Research Council</td>
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<td>BPRP</td>
<td>Bangladesh Preparedness and Response Plan</td>
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<td>CRO</td>
<td>Contract Research Organization</td>
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<td>CTD</td>
<td>Common Technical Documents</td>
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<td>DCC</td>
<td>Drug Control Committee</td>
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<td>DGDA</td>
<td>Director General of Drug Administration</td>
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<td>EDCL</td>
<td>Essential Drugs Company Limited</td>
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<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<td>EUA</td>
<td>Emergency Use Authorization</td>
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<td>EUL</td>
<td>Emergency Use Listing</td>
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<td>IPH</td>
<td>Institute of Public Health</td>
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<td>IVL</td>
<td>Incepta Vaccine Limited</td>
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<td>LMICS</td>
<td>Low and Middle Income Countries</td>
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<td>Acronym</td>
<td>Description</td>
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<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
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<td>NOC</td>
<td>No Objection Certificate</td>
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<td>NRA</td>
<td>National Regulatory Authority</td>
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<td>NREC</td>
<td>National Research Ethics Committee</td>
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<td>ORS</td>
<td>Oral Rehydration Saline</td>
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<td>RMP</td>
<td>Risk Management Plan</td>
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<td>SII</td>
<td>Serum Institute of India</td>
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<td>SRAs</td>
<td>Stringent Regulatory Authorities</td>
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<td>TPP</td>
<td>Target Product Profiles</td>
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<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
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<td>WHA</td>
<td>World Health Assembly</td>
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Introduction

Nearly every country in the world is administering COVID-19 vaccines, and over 12 billion doses have been completed so far. It is estimated that approximately 19.8 million deaths were averted in 2021 (WHO 2022b) due to COVID-19 vaccines. However, transmission of the virus continues to be unabated until recently. Even today, there are repeated waves and the mutation of new variants continue to threaten public health security worldwide. It is imperative for every country to respond rapidly to new waves of pandemic and ensure continuity of COVID-19 vaccination even after 2022 to protect health and socio-economic settings. This may be ensured by securing financial and other resources for developing/enhancing capacity of vaccine development and research on new vaccines.

Bangladesh Preparedness and Response Plan (BPRP) for COVID-19 consists several pillars including research (Husain 2021). Though it did not emphasize on vaccine development due to its inherent limitation, it is included in the list (MoHFW GoB 2020). One of the goal of WHO Global COVID-19 Vaccination Strategy is to accelerate development and access to improved vaccines to achieve durable, broadly protective immunity and reduce transmission. The WHO suggested the national and sub-national policy makers to consider increasing financial and technical investment in fundamental innovation towards achieving more durable, broadly protective and transmission-reducing vaccines with prospects for improved delivery. WHO provides guidance for vaccine development through updated target product profiles (TPP) and vaccine composition recommendations. The WHO also encouraged national and sub-national policy makers to explore regional collaboration agreements to create greater manufacturing autonomy (WHO 2022b).

Director-General of WHO, noted that inequitable global distribution of the COVID-19 vaccine will mostly affect low and middle income countries (LMICs), which will be a catastrophic failure of moral obligations of developed countries’ governments as well as big pharmaceutical companies who are not willing to share vaccines or technologies associated with them. To avoid such moral failure, it is critical that high income countries realize the importance of sharing technologies among manufacturers of poor countries. The WHO and public health experts emphasized that the global COVID-19 vaccine supply could be significantly increased if vaccine manufacturers would share their efforts and technological knowledge with external manufacturers capable of vaccine production. This measure could make possible for vaccines to be manufactured locally and contribute to international endeavor of ensuring equitable COVID-19 vaccine supply. South Africa has already shown the impact of such collaboration. They have already developed the capacity to produce mRNA vaccine for COVID-19 (WHO 2022a).

Epidemiology of COVID-19 in Bangladesh

Bangladesh notified the first case of COVID-19 case on 8 March 2020 and the first death was reported on 10 days later. As of 19 November
2022, there were 2,036,343 COVID-19 cases confirmed by RT-PCR, GeneExpert, Rapid Antigen tests; number of deaths were 29,430 (Case Fatality Rate 1.45).

Out of cumulative cases, 1,984,604 (97.46%) recovered. As of 19 November 2022, 6 (six) person was in isolation in last 24 hours. As of 19 November 2022, 15,065,368 samples were tested. Among the samples 66% were tested in government facilities, among all samples 88.2% were tested by RT-PCR, 0.9% by GeneExpert, and 1.8% by Rapid Antigen Test.
COVID-19 Vaccination Situation in Bangladesh

The vaccination commenced on 27 January 2021 and nationwide rollout was on 7 February 2021. Till 14 November 2022, first dose of COVID-19 vaccine was taken by 84.5%, two doses by 73.1% of the total population. Booster dose was taken by 58,669,048 person, lagging far behind (47%) the number of two doses (124,751,844 person).

Challenges for COVID-19 Vaccine Roll Out

Bangladesh achieved its first global milestone of vaccinating 10% of its total population by the end of September 2021. At the time, it was not a smooth journey, to say the least. Bangladesh faced challenges with the availability of vaccines in the first six months of introduction of COVID-19 vaccination. One of the reasons was that due to surge of the pandemic in India, Oxford-AstraZeneca vaccine supply was stopped by India to other countries including Bangladesh. The number of vaccine available had to be cut off to its half to ensure vaccine is saved for the recommended second dose for those who received first dose with recommended schedule. The target was only achieved when vaccine from China arrived.

Bangladesh was also struggling to achieve its second global milestone of vaccinating 40% of total population by the end of December 2021. The major challenge was receiving multiple vaccine in tranches with different quantity and its recommended schedule.
for two doses to achieve full vaccination. It took almost 7 months to vaccinate the country’s 10% of population with two doses with the vaccine supplies constraints, limited availability of logistics and huge operational cost. However, Bangladesh achieved the 40% of the total population coverage (NDVP Bangladesh 2022).

**Few key challenges in vaccine deployment:**

a) Human resource gap at the national and sub-national levels for service delivery, monitoring, vaccine distribution and logistics management.

b) Human resources gap for data management at national and sub-national level.

c) Multiple vaccines with different schedule and shelf life.

d) Registration on digital platform for vaccination.

e) Cold chain space at national and sub-national level.

f) Evidence generation through survey, evaluation and research.

The National Immunization Technical Advisory Group (NITAG) is a government constituted body of independent experts. The NITAG Bangladesh has been guiding the government since the start of the pandemic to develop COVID-19 vaccination strategy including plan of action. They provided recommendations on the prioritization of target populations for COVID-19 vaccine introduction, recommendation on vaccine choice, planning, and monitoring of the vaccination.

**Regulatory Mechanism of Bangladesh**

**Vaccine regulatory pathway**

Two main regulatory pathway exist for market entry of COVID-19 vaccines in Bangladesh. The Director General of Drug Administration (DGDA) is the national regulatory authority. Both the below pathways are under the jurisdiction of DGDA.

**No objection certificate (NOC)**

The NOC pathway applies mainly to COVAX facility vaccines and other products which have been prequalified by the WHO and imported into Bangladesh for non-commercial purposes. Based on the required documents, DGDA issues a NOC for Customs release of consignments. To expedite the process, human resources have been proposed to be responsible for lot-release and issuance of NOC. All products receiving NOC are listed on the DGDA website www.dgda.gov.bd.

**Registration/ Emergency Use Authorization (EUA)**

For products entering Bangladesh through commercial channels, registration/ EUA is required. Registered products are subject to lot-release from DGDA and testing requirements are specified as per the applicable DGDA standard operating procedures.
Regulatory preparedness

Appropriate regulatory pathways and procedures to prepare for a public health emergency should ideally be done before the emergency occurs.

Emergency regulatory procedure should ensure:

a) An expedited assessment of existing information that supports the best regulatory decision making on COVID-19 vaccine approval

b) Import permits are provided in the minimum possible time

c) Vaccine release for prompt administration to target groups

Ensuring access to COVID-19 vaccines

There are three main objectives for regulatory preparedness for COVID-19 vaccines in Bangladesh:

1. Specify regulatory pathways of the Directorate General of Drug Administration (DGDA) to approve market access for COVID-19 vaccines.

2. Put in place required regulatory instruments and resources in advance to ensure timely decision-making.

3. Put in place required regulatory instruments to ensure reporting on vaccine safety.

In Bangladesh, DGDA has established regulatory and administrative procedures which ensure proper information management, effective communication, and cooperation between different branches of the National Regulatory Authority (NRA) and relevant stakeholders, i.e. public health authorities, customs authorities, procurement, and deployment entities.

Regulatory approval

Four legislative references were identified as referral clause for issuance of emergency use authorization of COVID-19 vaccine by DGDA:

*Drug Act 1940, clause 3 (b) Definition of drugs:

2(b) 'drug' includes—

i. all medicines for internal or external use of human beings or animals, and all substances intended to be used for or in the treatment, mitigation or prevention of diseases in human beings or animals, not being medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic or biochemical system of medicine,

ii. diagnostic, abortive and contraceptive substances, surgical ligatures, sutures, bandages, absorbent cotton, bacteriophages, adhesive plasters, gelatin capsules and antiseptic solutions,

iii. such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals,

iv. any substance, mentioned as monograph in any of the editions of
the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States or the International Pharmacopoeia, whether alone or in combination with any substance exclusively used in the Unani, Ayurvedic, Homoeopathic or biochemical system of medicine and intended to be used for any of the purposes mentioned in subclauses i, ii, iii, and iv and

v. any other substance which the Central Government may, by notification in the official Gazette, declare to be a drug for the purposes of this Act;

National Drug Policy 2016, Clause 4.2 envisages accessibility to efficacious, safe and quality drugs, including equitable access to all kinds of vaccines and other drugs essential for better mother and child health care to be ensured.

Gazette notification published on 17 May, 2020 for inclusion of action to combat COVID-19 pandemic in the clause 4.2 of National Drug Policy 2016:

In the Gazette, section 2, it is noted that -

Due to present COVID-19 pandemic situation, with reference to section 2 of national drug policy, DGDA is authorized as licensing authority to issue NOC/ Emergency use authorization (EUA) in case of necessity for manufacturing, import, distribution and ensuring accessibility of essential drugs, investigational drugs, medical devices in country for detection of corona virus, diagnosis, treatment and prevention of COVID-19.

Import Requirements

The import requirements in Bangladesh will vary based on the origin of the vaccines and the purchase method.

COVAX vaccines:

- Vaccines must be registered/EUA in country of origin (manufacture)
- Vaccines must have lot release certificates
- Vaccine must be included in WHO EUL (Emergency use listing)
- DGHS submits request letter to DGDA for issuing No-Objection-Certificate (NOC)
- Review, verification of documents (WHO EUL, Lot release certificate, vaccine shipment document/ data logger reading for mapping temperature etc.)
- NOC to issue by DGDA
- Process to be expedited due to priority of the product

Required Time for NOC: If all documents have been submitted to DGDA, it will take 2-3 days for issuing NOC

Non-COVAX vaccines (imported)

Registration/EUA requirements:

- Registration/EUA in any of the 7 countries (USA, Australia, Switzerland, France, UK, Germany, Japan) and European Medicines Agency as well as WHO Prequalification
• Applicant must submit application according to Common Technical Documents (CTD) format following DGDA biosimilar registration guideline. (Link: file:///C:/Users/User/Downloads/Documents/Biosimilar%20Guideline_2018.pdf)

• Public Health Emergency Committee authorization (Emergency use)

• Drug Control Committee (DCC) authorization (Market Authorization)

• Vaccine Evaluation Committee (Chemistry Manufacturing and Control- CMC, Toxicology and Clinical Trial Committee) authorization.

Required Time for Registration: If all documents have been submitted to DGDA, it will take 12-15 days for registration

Non-COVAX Vaccines (Local Production)

Registration/EUA requirements:

• Satisfactory Preclinical study

• Clinical study (Ethical clearance from NREC of BMRC)

• Protocol development through CRO (Contract Research Organization)

• For clinical trial - protocol approval from National Clinical Trial Advisory Committee, DGDA

• Phase 1, 2, 3 Clinical trials follow

Upon satisfactory trial results the manufacturer should submit data in CTD formats

• Administrative (CTD Module 1)

• Summary (CTD Module 2)

• Chemistry Manufacturing and control (CMC information) (CTD Module 3)

• Pre-clinical info (CTD Module 4)

• Clinical info (CTD Module 5)

• Registration

Required Time for Registration: If all documents have been submitted to DGDA, it will take 12-15 days for registration

Release of the Vaccine

The deployed vaccines should be released to the immunization programme in the shortest possible time during the COVID-19 pandemic. Testing of vaccines requires sophisticated and complex analytical methods and equipment that should be managed by a team of competent staff.

DGDA will not perform testing on vaccines procured from assured sources, e.g. WHO pre-qualified vaccines, vaccines listed as EUL or approved by stringent regulatory authorities (SRAs), as they have been tested and released already by NRAs with stable formal approaches for vaccine approval. In this case, review of the summary lot protocols will be conducted, and vaccine release will be expedited through the review of the minimum documents as advised by the WHO.

In case of locally produced vaccines or vaccines imported from non-WHO prequalified sources, laboratory testing of the first three batches will be required. Additional
batches may be tested at the discretion of DGDA for monitoring, pharmacovigilance and post-marketing surveillance. DGDA has suitable infrastructure for vaccines testing but technical and financial support is needed to procure additional laboratory equipment and train staff on testing protocols for COVID-19 vaccines.

**Other Considerations**

**Risk management**

As per the marketing authorization / EUA procedures, a risk management plan (RMP) shall be in place to safeguard against any harm associated with use of the products. The RMPs will be submitted by the manufacturer and outline a set of activities designed to identify, characterize, prevent, or minimize risk related to the product; assess the effectiveness of the vaccination; and communicate risk information to the national EPI program and other relevant stakeholders. The RMP may be developed and implemented based on the potential risks, focusing on the published Adverse Events of Special Interest (AESIs).

**Liability/indemnity**

In case of any harm occurring while using the products there should be a clear understanding between the COVAX facility, national authorities and the manufacturer regarding liability and indemnity. According to GAVI, vaccine manufacturers will require all Participants in the COVAX facility to provide an indemnity for all damages relating to or arising from the use and administration of the vaccine within the jurisdiction of the participant. The facility would expect that indemnification would not apply if an injury associated with the approved vaccine resulted from:

- wilful misconduct of the manufacturer; or
- a defect in the approved vaccine due to non-compliance with, for example, terms of the marketing authorization; or
- failure to comply with good manufacturing practices.

Some vaccine manufacturers may require other protections against product liability claims (e.g., that the participant has a no-fault compensation scheme in place or legislative limitations on liability). COVAX facility will be transparent with participants on the manufacturer requirements on these issues and will work with participants on the best approach to liability and indemnity issues. For example, the facility will provide model language for liability and indemnity agreements with manufacturers.

In the present routine immunization policy, there is no system to compensate any cash for any AEFI except free medical treatment.

**Importance of Vaccine Production in a Country like Bangladesh**

The experience of COVID-19 shows the importance of vaccine manufacturing capacity to contain the pandemic on a global scale. Vaccine roll-out in few high income countries do not ensure development of collective population immunity to stop
the transmission. If equity is guaranteed in vaccine production, i.e., most of the countries among LMICs achieve the vaccine production capacity, we may feel comfortable in developing population immunity worldwide.

But the vaccine production capacity should be accompanied by backward and forward linkages. Backward linkages include capacity to provide raw materials and inputs, production of active and inactive ingredients, consumable. Pan-African public health organizations feel that this will be beneficial to achieve self-reliance and health security. They are also confident that such steps will increase the sustainability of vaccine production and reduce production costs. The forward linkage is the rapid vaccine rollout in producing country and other similar countries.

**Vaccine Manufacturing Capacity in Bangladesh in Government Sector**

The government owned Essential Drugs Company Limited (EDCL) has already signed an agreement with a US biotech company to manufacture protein vaccine (TBS 2021). But the EDCL will have to construct the vaccine manufacturing factory. They are progressing to install a pre-fabricated factory within a year. But till date they have no backward linkage, no skilled human resources for mRNA and viral vector vaccine (www.edcl.gov.bd).

Government owned Institute of Public Health (IPH) once produced vaccines, but those plants were dismantled about three decades ago. The institute has a creditable history of producing small pox vaccine. It also produced

vaccines for cholera, typhoid and rabies and tetanus toxoid. The unit used to produce Anti Rabies Vaccine (ARV) of nerve tissue origin. The vaccine was supplied at a subsidized rate to prevent rabies. Considering the scientific development and the drawbacks of nerve tissue vaccines, steps have been taken to switch over for production of tissue culture vaccine.

The Unit used to produce WHO standard tetanus toxoid vaccine to support the EPI programme and other public sectors programmes in the country during 1983-2003. But due to financial and technical reasons, the production was delayed. Earlier it was planned to restart the production of TT and also planned to produce DT vaccine from imported bulk (www.iph.gov.bd accessed on 22/11/22). The experts and public health activists of Bangladesh are now critical of abandoning vaccine production capacity in the government sector, which exposed our vulnerability in a pandemic situation. Our self-sufficiency in vaccine production could avoid the helpless condition, when in 2021, Serum Institute of India (SII) was compelled by the Indian government’s decision to stop vaccine supply to Bangladesh and other countries despite prior agreement and advanced market commitment.

It may be mentioned that, the mission of IPH is to produce vaccines, sera and other biological products, parenteral fluids, diagnostic reagents etc. The IPH is the National Focal Point for the production of biologicals including vaccines, intravenous fluid, oral rehydration saline (ORS), diagnostic reagents and chemicals, blood bags etc. (<www.iph.gov.bd> accessed on 05-10-22). But these capacities were withdrawn by the authorities. Critics complained that it was done to award advantage to multinational pharmaceutical companies.

**Vaccine Manufacturing Capacity in Bangladesh in Private Sector**

Along with securing COVID-19 vaccines from different manufacturers, Bangladesh is trying to become self-reliant in vaccine manufacturing. A biotech company, Globe Biotech, has completed non-human primate trials of its own mRNA-based vaccine and heading towards clinical trial. Other Bangladeshi vaccine manufacturing companies are capable of addressing the gap in vaccine antigen production.

Incepta Vaccine Ltd is the first human vaccine manufacturing private sector company in Bangladesh. The manufacturing unit is situated at Zirabo, Savar which is conveniently located at the outskirts of Dhaka city. It is established with an objective to introduce modern concepts in manufacturing vaccine by acquiring advanced knowledge and technique. Prime objective of this company is to protect vast population of Bangladesh as well as the developing world from various infectious diseases at an affordable cost. It
has a vision to develop novel vaccines against diseases of the developing world (www.inceptavaccine.com). The company maintains and continually improves the effectiveness of the QMS in accordance with the requirements of ISO 9001:2000 and ISO 14001:2004.

Incepta Vaccine Limited (IVL), has signed a memorandum of understanding with Sinopharm, China, for production of the Sinopharm BBIBP-COVID-19 vaccine in Bangladesh. This collaboration will contribute to the efforts of Bangladesh to produce COVID-19 vaccines locally. Along with contract manufacturing, IVL is also developing the capacity of research and development in collaboration with international institutes (Mahmud-Al-Rifat et al 2022). The Managing Director of Incepta Pharmaceuticals stated that his company is ready to produce vaccines if technology were shared (Health Policy Watch 2021). It is a large vaccine manufacturing facility that has the capacity to manufacture 180 million single dose vials and ampoules per year. A large pool of scientists are engaged in different areas of specialties like research and development, quality control, quality assurance, production and other related areas.

An antigen bulk facility compliant with WHO GMP requirements, has been developed providing the appropriate environmental conditions for performing the operations. The facility can manufacture both Bacterial and Viral bulk antigen. Antigen bulk facility is equipped with modern production fermenters with capacity of 1500 L, 750 L and 500 L.

One of the Spokesperson of Directorate General of Health Services of Bangladesh informed that, three local companies—Incepta, Unihealth and Popular pharmaceuticals have
shown their interest in manufacturing Russia’s Sputnik V vaccine. But other public health experts expressed doubt about their capacity to do so. Rather these private companies can import vaccines in bulk from Russia or China for marketing it after bottling or packaging here (UNB 2021). Beximco Pharmaceuticals is also developing capacity for packaging vaccines from imported bulk. It may take one to two years to develop such capacity.

Conclusion

Although Bangladesh undertook a range of measures to enhance domestic production of vaccines, its efforts have not yet been successful. A primary reason for this may be the existing Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. The proposal submitted by India and South Africa to the World Trade Organization (WTO) for a temporary waiver of certain provisions of the agreement on TRIPS, for developing countries to manufacture their own COVID vaccines, has not been accepted till date (Bose 2022). However, the negotiation is going on (MSF 2022). Bangladesh has called for a temporary waiver from certain obligations under the agreement on TRIPS at the 74th virtual session of World Health Assembly (WHA). The demand for the waiver was made for the production of vaccines, medicines and health technologies to face the onslaught of the COVID-19 pandemic. Bangladesh claimed that the pharmaceutical industries in Bangladesh as well as other LMICs, who are capable of producing vaccines, therapeutics, diagnostics, and other medical equipment should get licenses, technology, and technical know-how at free of cost. These are required for responding to COVID-19 pandemic (www.tbsnews.net dated 04/06/2021).

The proposal was that the intellectual property rights such as patents, industrial designs, copyright, and protection of undisclosed information do not make any obstacle to timely access to affordable healthcare including vaccines or limit research, development, manufacturing, and supply of medical products for combating COVID-19 pandemic. Bangladesh has the capability to produce million COVID doses per year, but appropriate technology should be accessed. High income countries are yet to agree to share their technology. So Bangladesh, like other LMICs are waiting to see such collaboration to become self-reliant in vaccine production.

References

- Health Policy Watch (2021): Indonesia and Bangladesh Reveal Massive untapped Vaccine Production Capacity at C-TAP Anniversary. 28/05/2021

• Medecins Sans Frontiers (MSF) (2022): MSF responds to potential compromise on the ‘TRIPS Waiver’. 16 March


• Ministry of Health and Family Welfare (MoHFW), Government of Bangladesh (GoB) (2022): National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines in Bangladesh. Version 3 (draft, personal communication)


• The Business Standard (TBS) (2021): Bangladesh seeks TRIPS waiver to ramp up Covid vaccine production. www.tbsnews.net 04 June

• UNB (2021): Vaccine Production in Bangladesh: Experts ‘vehemently against private sector’s engagement. May 18

• World Health Organization (2022a): The mRNA vaccine technology transfer hub. <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub> accessed on 05-10-22

About SAAPE

South Asia Alliance for Poverty Eradication (SAAPE) is a regional platform of civil society organisations, social movements and people’s networks fighting unitedly against the structural causes of poverty and social injustices in the region and beyond. It was conceived in 2001 against the backdrop of increasing anti-people globalisation marked by privatisation, deregulation, extractivism and capital accumulation. SAAPE’s mission is to facilitate the process for establishing mechanisms to ensure people’s genuine participation in the decision-making processes at all levels to contribute towards poverty eradication and sustainable development. SAAPE facilitates linkages among and between groups in the region, throughout the global South and with like-minded groups in the North.