ADB's Initiatives to Support Vaccine Manufacturing

24 October 2024

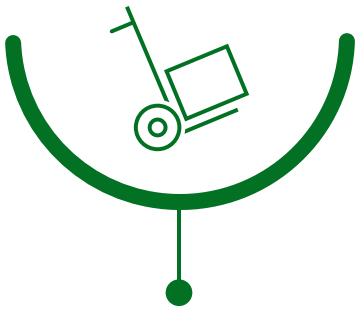
Dr. Dinesh Arora
Principal Health Specialist,
Asian Development Bank

ADB's Support for Vaccine Manufacturing and Regulatory Strengthening in the Asia and the Pacific

During COVID-19

POST COVID-19

Enhancing Vaccine Procurement



Regional Vaccine Advisory Group(RVAG)

Expanding Vaccine Manufacturing and Strengthening Regulators

- New Manufacturing Facilities
- Regulatory Strengthening
- Asia Diagnostics, Vaccines and Therapeutics Network to Counter Epidemics and other disease outbreaks (**ADVaNCE**)
- Strengthening Regulatory Ecosystem for Vaccines, Therapeutics, and Diagnostics in Asia and the Pacific **(REVITALIZE)**

Capacity Building

Building knowledge and skills in vaccine manufacturing

1. RVAG Support to Developing Member Countries

During Covid-19

Expert regulatory advice

- Single dose to multi-dose vials
- Effective tech transfer to DMCs - conditions for success
- Supporting new manufacturing facilities producing COVID and non-COVID vaccines – short, medium, long-term considerations

Access to the latest scientific data

WHO information on vaccines

Information sharing

COVID-19 vaccine implementation experiences related to pharmacovigilance

Post Covid-19

Ongoing role for RVAG?

1. Increasing demand within Asia for regulatory strengthening
2. Emerging regulatory concerns e.g., climate change, digital tools for healthcare
3. Demand for timely regulatory strengthening >> global expertise

Ongoing role for RVAG ?

Asia Diagnostics, Vaccines and Therapeutics Network to Counter Epidemics and other disease outbreaks (ADVaNCE)

Asia Diagnostics, Vaccines and Therapeutics Network to Counter Epidemics and other disease outbreaks (ADVaNCE)

Regulatory Capacity Building

- Training programs to strengthen regulatory oversight and accelerate vaccine approvals during crises.

Harmonization and Regulatory Convergence

- Streamlining approval processes across Asia through regulatory convergence, reducing delays.

Rapid Response to Pandemics

- Supporting rapid production, manufacturing, and distribution of vaccines and therapeutics for future pandemics.

Pooled Procurement of Vaccines and Medical Countermeasures

- Facilitating collective vaccine purchasing, ensuring affordable and reliable supply for ADB member countries.

Innovation and Emerging Issues

- Addressing regulatory challenges with emerging technologies like big data, AI, and digital health.

Composition

- Government Agencies: Ministry of Health (MOH) and National Regulatory Authorities (NRAs) from Asia Pacific
- Manufacturers and Industry Partners
- Academic and Research Institutions
- International Organizations

Bangladesh

Vaccines, Therapeutics, and Diagnostics Manufacturing and Regulatory Strengthening (VTDm-RS) Project

Bangladesh VTD Manufacturing Landscape

Market size and potential

- Large birth cohort (~3 Mn births/ year)
- EPI vaccine market close to USD 90 Mn per year
- Transitioning out of GAVI subsidy by 2029

Regulatory environment

- DGDA classified as ML2
- Weak Pharmacovigilance
- Drugs and cosmetics act passed

Skilled workforce

- Experience in small molecules production
- Recognition of the need for capacity building
- Need to leverage private sector participation

Lessons from COVID-19

- Gaps in VTD availability
- VTD Self-Reliance and Regional Cooperation
- Low JEE score on pandemic preparedness

IP protection

- Patent law reformed in 2022
- IP conflicts reported previously
- IP enforcement needs strengthening

Location

- EDCL has a pharmaceutical manufacturing plant in Gopalganj
- The Gopalganj facility has experience in antibiotic and sterile manufacturing

The Government of Bangladesh has placed high importance on establishing VTD manufacturing facility

- To deal with future pandemics (including COVID-19)
- To support a sustainable supply of vaccines for national immunization program

Bangladesh VTD Regulatory Ecosystem

Pre-clinical and clinical research process

- The specific regulatory framework for preclinical research may not be available
- National Control Laboratory (NCL) requires investments to achieve compliance with Good Laboratory Practices (GLP)
- Limited laboratory infrastructure
- Limited investments in capacity building

Registration and marketing authorization

- Limited availability of clear SOPs for product registration
- Limited uptake of the electronic information management system
- Shortage of qualified inspectors in the DGDA

Manufacturing and quality control

- Challenges related to funding, staffing, and technical expertise
- Unavailability of information in critical regulatory registers

Supply chain management

- Procurement process for importing vaccines experiences delays
- Barriers associated with the logistics
- No identified information on the procedures to perform NRA lot release program

Post-market surveillance

- Inadequacy of existing surveillance and information management systems
- Shortage of IT-trained personnel, hampering data monitoring efforts for pharmacovigilance
- No available information regarding the use of E2B (R3) format for electronic transmission of Individual Case Safety Reports

Strengthening the national regulator will allow Bangladesh to certify the vaccines as safe and efficacious and to export.

VTDm-RS at a Glance

DMC:
Bangladesh

Project Name: Vaccines, Therapeutics, and Diagnostics Manufacturing and Regulatory Strengthening (VTDm-RS)

ADB Financing: $336.47 million

Impact: Disease burden of selected vaccine-preventable diseases reduced in Bangladesh

Outcome: Availability of selected safe and efficacious vaccines, therapeutics and diagnostics (VTDs) improved.

- **Output 1:** Manufacturing facility for vaccines, therapeutics, and diagnostics (VTD) constructed at Essential Drugs Company Limited (EDCL)
- **Output 2:** Capacity for vaccines, therapeutics, and diagnostics (VTD) manufacturing established at EDCL
- **Output 3:** Directorate General of Drug Administration (DGDA) capacity strengthened for VTD regulation

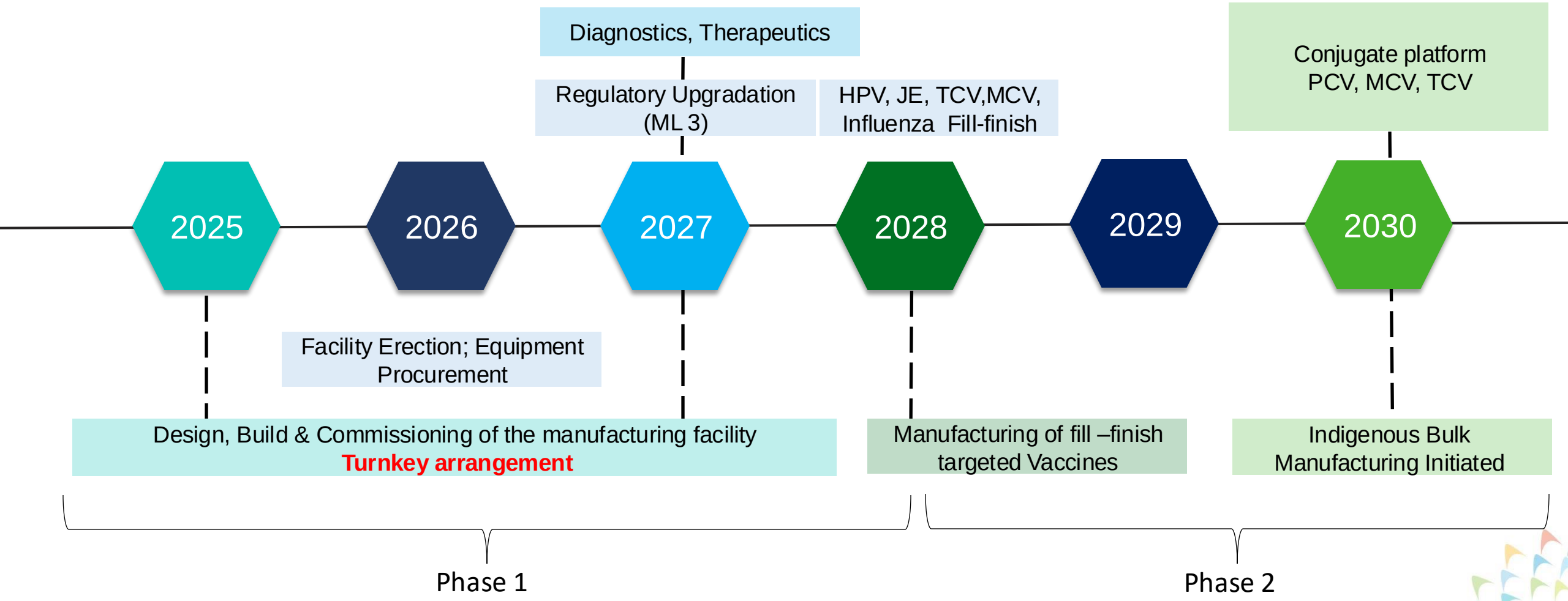
Executing agency
Ministry of Health, Government of Bangladesh

Implementing Agency
Essential Drugs Company Limited (EDCL) and the Directorate General of Drug Administration (DGDA)

Climate financing: Estimated at $37.63 million

Private sector development:
Regulatory upgradation of DGDA will help develop private sector VTD ecosystem

Phased Approach to Vaccine Manufacturing



HPV = human papillomavirus vaccine, JE = Japanese encephalitis, TCV = typhoid conjugate vaccine, MCV = meningococcal conjugate vaccine, PCV = pneumococcal conjugate vaccine.

Climate and Sustainability

Green and Resilient Infrastructure

- Adopting green building design features
- Use of energy efficient equipment and cooling systems
- Proper waste management
- Integrating appropriate risk management measures in facility design and O&M

Sustainable Manufacturing Supply Chain

- Use of foldable packaging, expanded polystyrene instead of borosilicate glass (reducing carbon emissions by 65%), syringes made of COP* plastic (reducing carbon emissions by 50% for storage and transport)
- Use of recycled and/or highly recyclable materials (whenever possible)

Business Resilience and Continuity Planning

- Biosafety level certification
- Biosafety training
- Emergency preparedness and response procedures and training

* Cyclic olefin polymer

Indonesia

Bolstering Product Oversight and Market Regulation in Pharmaceuticals, Therapeutics and Vaccines (BPOM) Project

Prioritization Activities by BPOM

S.No	Proposed Activities	Short Term	Mid Term	Long Term
1	Benchmarking to HSA - Singapore			
2	Benchmarking to South Korean FDA - MFDS			
3	The development of quality standards for advanced Biological Products			
4	Risk Management Plan (RMP) and Environmental Risk Assessment (ERA) evaluation for vaccines			
5	The clinical trials applications evaluations			
6	Periodic Benefit-risk Evaluation Reports (PBRERs) evaluation for vaccines and developing tools/evaluation			
7	RI functions in advanced Biological Products			
8	MC functions in advanced Biological Products			
9	Pneumococcal vaccine testing for post marketing surveillance			
10	Refreshment and training for new laboratory evaluators for lot release			

Strategic Interventions Required by BPOM

S.No.	Parameters	BPOM (NRA-Indonesia)
1	Physical Instructure Requirement	• Construction of a National Control Laboratory. • Setting up and strengthening the regional and district laboratories.
2	Know-how Requirement and Human Resource Skill Enhancement	For graduation to WHO-Listed Authority (WLA) status: • Skill enhancement of the current staff. • IT-enabled systems for seamless and transparent operations.
3	Clinical Trial Support	• Enhancing clinical trial capabilities in terms of conduction, monitoring, and evaluation of full cycle clinical trials locally. • Training, development, and deployment of competent & skilled human resources
4	Research & Development Capabilities	• R&D monitoring capabilities for advanced technologies (Cell & gene technologies, targeted personalized technologies) etc.
5	Regulatory Capabilities	• Strengthening capabilities in alignment of WHO-GBT
6	Business/ Regulatory Strategy	• Strategy for accelerated graduation from current tWLA to a fully operational WLA & strategy for sustenance of WLA status.

Pakistan

Vaccine Manufacturing and Regulatory Strengthening

Vaccine Manufacturing and Regulatory Strengthening in Pakistan

Being a hotbed of infectious diseases, many of them vaccine-preventable, Pakistan needs a sustained vaccine supply.

Population of 250 million and a birth Cohort of 6.5 million

In GAVI Preparatory Transition Phase, and depends highly on UNICEF supplies of EPI vaccines

Private sector unable to sustain since the market is donor driven

National Regulatory Authority (NRA) lacks capacity for a local full-cycle vaccine manufacturing

Pakistan was expected to enter an accelerated transition phase of GAVI in 2021. The population and birth cohort can support a local vaccine manufacturing project encompassing fill and finish in stage 1 and Drug Substance (DS) in stage 2.

Strengthening Regulatory Ecosystem for Vaccines, Therapeutics, and Diagnostics in Asia and the Pacific (REVITALIZE)

Technical Assistance: REVITALIZE

Aim: Support ADB's developing member countries (DMCs) in strengthening their respective regulatory ecosystems for vaccines, therapeutics, and diagnostics (VTD)

Initial Financing: $1 million

DMCs Supported: Bangladesh, Indonesia and Pakistan, with other DMCs to be considered later

Outcome: Strengthened regulatory ecosystem in DMCs, emphasizing climate resilience in vaccine manufacturing, and enhancing regulatory and bio-manufacturing capacities.

- **Output 1:** Roadmaps to strengthen the regulatory system developed in selected DMCs
- **Output 2:** Enhanced capacity of regulatory functions for market entry and post-market control
- **Output 3:** Technology transfer for VTD manufacturing from an advanced pharmaceutical company to a selected DMC facilitated

Implementation Period
January 2025 – December 2027

Implementing Agency
Asian Development Bank

Gender Cosideration: Effective Gender Mainstreaming (EGM)

TA will support the implementation of ADB's Strategy 2030

Regional Capacity Building of Vaccine Manufacturing Workforce

Course by K-NIBRT Yonsei University

Building Knowledge and Skills in Vaccine Manufacturing

8-week intensive course in Incheon, South Korea

Delivered by Yonsei University and Korean National Institute for Bioprocessing Research and Training

Custom made hands-on training facility

Mainstreaming regulatory aspects into vaccine manufacturing training

Linking regulators and manufacturers

90 people trained

13 Countries

Manufacturers, regulators, researchers and trainers

Thank You!