NATIONAL NON-EPI VACCINE SAFETY SURVEILLANCE STRATEGY 2025 (NEPIV-SSS 2025)

Directorate General of Drug Administration (DGDA)
Mohakhali, Dhaka - 1212

Health Services Division
Ministry of Health and Family Welfare
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PREFACE

The National Non-EPI Vaccine Safety Surveillance Strategy 2025 (NEPIV-SSS 2025) is a critical advancement in strengthening Bangladesh's commitment to vaccine safety across all immunization platforms.

Vaccination remains one of the most effective public health interventions for the prevention of infectious diseases and the protection of communities. While the national Expanded Programme on Immunization (EPI) has long sustained robust safety monitoring mechanisms, the increasing administration of non-EPI vaccines, including those delivered through private, travel-related, occupational, and other specialized services; necessitates a comprehensive and integrated approach to safety surveillance that extends beyond the traditional systems.

The NEPIV-SSS 2025 has been developed to establish a structured, proactive, and responsive framework for the monitoring and evaluation of adverse events following immunization (AEFIs) associated with non-EPI vaccines. This strategy aims to uphold the highest standards of vaccine safety, strengthen public confidence, and support evidence-based policy development. It is aligned with national regulatory frameworks, global vaccine safety initiatives, and the evolving dynamics of immunization practices within Bangladesh.

I commend the dedication and collaboration of all stakeholders, including healthcare providers, vaccine manufacturers, public health experts, regulatory authorities, and development partners; who have contributed to the formulation of this strategy. Their collective expertise and commitment have been instrumental in shaping a forward-looking, practical, and impactful surveillance model.

As we implement NEPIV-SSS 2025, it is imperative that we maintain a culture of vigilance, transparency, and responsiveness. I urge all involved parties to actively engage with this framework, ensuring that the safety of every vaccine administered in Bangladesh remains a shared national priority.

I am confident that the successful execution of this strategy will further reinforce the integrity of our health system and contribute significantly to the health and well-being of our people.

Major General Md. Shameem Haidar
Director General
Directorate General of Drug Administration (DGDA)
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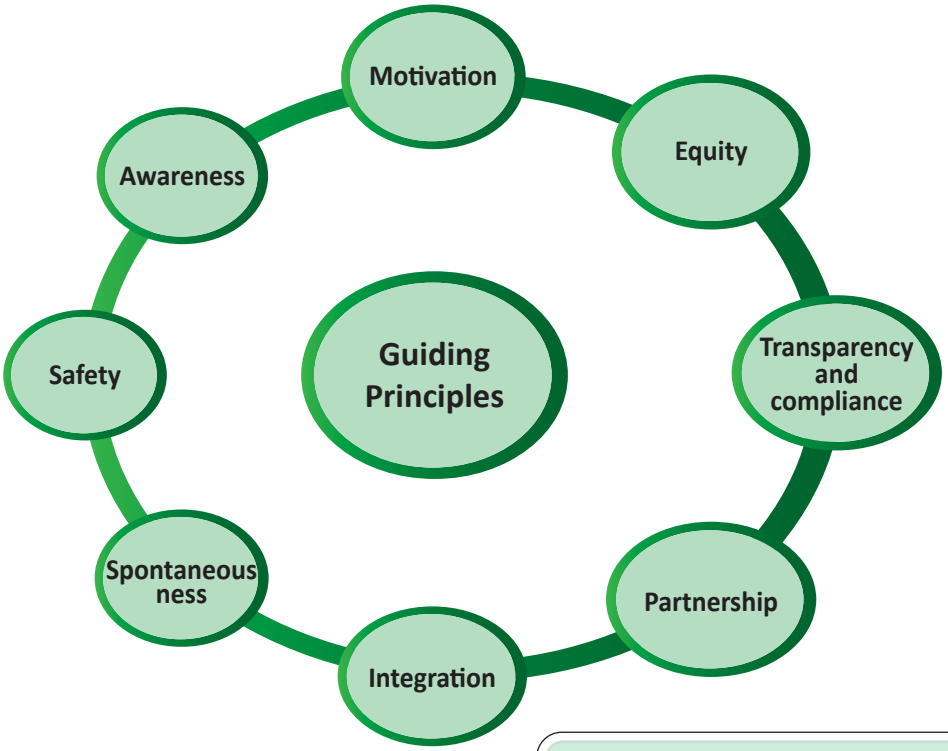
LIST OF ABBREVIATIONS AND ACRONYMS

AEFI	Adverse Event Following Immunization
AEFI-NEPIV	Adverse Event Following Immunization-Non EPI Vaccines
APR	Annual Program Review
BCG	Bacillus Calmette-Guerin
BDHS	Bangladesh Demographic & Health Survey
BHFS	Bangladesh Health Facility Survey
BMDC	Bangladesh Medical and Dental council
BNMC	Bangladesh Nursing and Midwifery Council
COVID -19	Coronavirus Disease 2019
CRM	Cross-Reacting Material
DGDA	Directorate General of Drug Administration
DGHS	Directorate General of Health Services
DGME	Directorate General of Medical Education
DGFP	Directorate General of Family Planning
DGNM	Directorate General of Nursing and Midwifery
DNA	Deoxyribonucleic Acid
DPT	Diphtheria- Pertussis- Tetanus
EPI	Expanded Programme on Immunization
GAVI	Global Alliance for Vaccines and Immunization
HPNSPs	Health, Population and Nutrition Sector Programs
HPV	Human Papilloma Virus
HRH	Human Resources for Health
HWF	Health Workforce
ICT	Information and Communication Technology
IPV	Inactivated Polio Vaccine
MAH	Marketing Authorization Holder
MoV	Means of Verification
MMR	Measles-Mumps-Rubella Vaccine
MOHFW	Ministry of Health & Family Welfare
MR	Measles-Rubella Vaccine
MTR	Mid-Term Review
NEPIVs	Non-EPI Vaccines
NEPIV-AEFI	Non-EPI Vaccines - Adverse Event Following Immunization
NEPIV-SSS	Non-EPI Vaccines Safety Surveillance Strategy
NGO	Non-Government Organization
NIP	National Immunization Program
OPs	Operational Plans
OPV	Oral Polio Vaccine
PA	Protective Antigen

PAP	Priority Action Plan
PCB	Pharmacy Council of Bangladesh
PCV	Pneumococcal Conjugate Vaccine
PHPs	Pharmaceuticals and Healthcare Products
PV	Pharmacovigilance
RABIVAX	Rabies Vaccine
rDNA	Recombinant DNA
ROTATEQ	Rotavirus Vaccine
SDG	Sustainable Development Goal
SEARN	South-East Asia Regulatory Network
TG3	Technical Group 3
TTVa	Tetanus Toxoid Vaccine
UHC	Universal Health Coverage
WG3	Working Group 3
WHO	World Health Organization

GUIDING PRINCIPLES, GOAL AND OBJECTIVES



GOAL

To promote a stronger public health system through strengthening of non-EPI Vaccines safety surveillance with increased reporting of probable adverse events following immunization (AEFI)

OBJECTIVES

- To revisit and suggest the legislative and regulatary aspects related to the safety surveillance of Non-EPI Vaccines with special focus on increased AEFIs
- To generate awareness and motivation among all the relevant stakeholders
- To generate or impove the methodology and tools related to the safety surveillance and increased AEFI reporting in cases os Non-EPI Vaccines
- To train the human resources of the relevant stakeholders on related issues
- To incorporate the Non-EPI Vaccine-related safety surveillance and AEFI issues in the course-curricula and syllabi of the health professionals' education programs
- To stimulate research activities in the relevant areas
- To build capacity among the relevant stakeholders for optimum implementation of the strategic objectives

STRATEGIC ACTIONS

Strategic Action 1: Revisit and suggest the legislative and regulatory aspects of Non-EPI Vaccines

- Review the legislation as relevant to the Safety Surveillance (especially AEFI reporting) of NEPIVs
- Review the documents of Regulatory Agencies as relevant to the NEPIVs (especially AEFI reporting)
- Review the administrative orders as relevant to the safety surveillance and AEFI reporting of NEPIVs
- Suggest, if necessary, the modification of existing legislation, regulatory measures, or administrative steps to improve safety surveillance and AEFI reporting of NEPIVs
- Suggest, if necessary, the introduction of new legislation, regulatory measures or regulatory/administrative steps to improve safety surveillance and AEFI reporting of NEPIVs
- Incorporation of safety surveillance issues of NEPIVs should be ensured in the new rules under Drug and Cosmetics Act, 2023
- Take steps for the modification of the existing or introduction of new legislation, regulatory measures and administrative steps, as appropriate
- Enhance the implementation of the relevant Acts

Strategic Action 2: Generate awareness and motivation among all the stakeholders

- Arrange advocacy programs among relevant Policy Makers, Planners, Senior Administrators
- Initiate large scale awareness campaigns among general people using mass media (electronic and print), social media and community- oriented activities
- Generate awareness and motivation among Providers (like Physicians, Nurses, Pharmacists, and Community Health Workers) using effective tools and channels
- Generate awareness and motivation among Manufacturers, Importers, Distributors and Retailers using effective tools and channels

Strategic Action 3: Generate and improve the methodology and tools related to AEFI reporting of Non-EPI Vaccines

- Review the existing Reporting Forms with input from the various stakeholders
- Redesign, if necessary, the forms with special reference to user-friendliness
- Design, if necessary, new forms with special reference to user-friendliness
- Design short and simple forms, as much as possible, without compromising the quality
- Use (as much as feasible in the Bangladesh context) the digital channels (e.g. Apps in mobile phones) for reporting AEFI for NEPIVs
- Create databases for cumulating the AEFI reports at various levels

Strategic Action 4: Train HR from relevant stakeholders

- Develop training programs with customized course-curriculam and training materials for specific groups of professionals like Regulators, Providers, Manufacturers, Importers, Distributors and Retailers
- Arrange regularly the Fresher as well as follow-up training programs for the relevant professionals
- Review the effectiveness of the training programs following appropriate evaluation projects

Strategic Action 5: Incorporate AEFI issues in the course-curricula of the relevant professional education/training programs

- Create contents and educational materials related to NEPIVs, especially AEFI reporting for providing education and training to the students from physicians, pharmacists, nursing and paramedical disciplines
- Take organized initiatives to incorporate the safety surveillance and AEFI-NEPIV-related education and training in the course-curricula and syllabi of the educational and training programs
- Review the impact of education and training related reforms on the reporting of AEFI of NEPIVs

Strategic Action 6: Strengthen research activities on PV of vaccines

- Identify priority areas and projects for research activities on consultation with various stakeholders
- Develop coordinated mechanism to promote research in the prioritized fields
- Create pool fund to support research in the selected areas

Strategic Action 7: Build capacity in the area of Non-EPI vaccines

- Strengthen the PV Cell of DGDA with relevant inputs on physical infrastructure and human resources
- Create capacity (with appropriate HR and other input) all over the country through the DGDA offices at the district and sub district levels
- Explore the already existing potential infrastructure/facilities for their probable incorporation in the safety surveillance (especially AEFI Reporting) of NEPIVs
- Enhance the ICT infrastructure to use the digital tools and channels for conducting relevant activities like advocacy/ awareness, reporting, education, training, and research
- Build capacity of the suppliers (manufacturers, importers, distributors and retailers) on the maintenance of adequate supply chain and reporting of AEFI of NEPIVs
- Consider the issues of natural calamities like (flood, cyclones, earth quack) and other crisis situations (like epidemics and pandemics) in the capacity building of the different stakeholders

1. INTRODUCTION

Vaccines are considered the most cost-effective means to prevent diseases and it is now a central public health tool used in public health interventions. Vaccination is considered one of the greatest public health achievements of human history.

Each year, vaccines prevent more than 2.5 million child deaths globally. An additional 2 million child deaths could be prevented each year through immunization with currently available vaccines.[1]

Some of the major reasons for special importance of vaccines are as follows:

i. **Promotion of health:** Unlike many other health interventions, vaccines help healthy people stay healthy, removing a major obstacle to human development.

ii. **Expansive reach:** Vaccines protect individuals, communities, and entire populations (the eradication of smallpox is a case in point).

iii. **Rapid impact:** The impact of most vaccines on communities and populations is almost immediate. For example, between 2000 and 2008, vaccination reduced global deaths from measles by 78% (from 750,000 deaths to 164,000 deaths per year).[2]

iv. Impact on lives and costs: Recently, a panel of distinguished economists put expanded immunization coverage for children in fourth place on a list of 30 cost-effective ways of advancing global welfare.[3]

Considering all the above facts, the impact of vaccination on the health of the world population is enormous. With the exception of safe water, nothing else, not even antibiotics, has had such a major effect on the reduction of mortality (deaths) and morbidity (illness and disability) and on population growth.[4]

The history of vaccination may be traced to 2000 years back; however, the initiative got special momentum in 1974 when, based on the emerging success of the smallpox program, the World Health Organization (WHO) launched the Expanded Program on Immunization (EPI). The initial EPI goals were to ensure that every child received protection against six childhood diseases (i.e. tuberculosis, polio, diphtheria, pertussis, tetanus and measles) by the time they were one year of age and to give tetanus toxoid vaccinations to women to protect them and their newborns against tetanus. Since then, new vaccines have become available. Some of them, such as hepatitis B, rotavirus, Haemophilus influenzae type-b (Hib) and pneumococcal vaccines, are recommended by the WHO for global use. Others, such as yellow fever vaccine, are recommended in countries where disease burden data indicate they should be used. By 1990, vaccination was protecting over 80% of the world's children from the six main EPI diseases, and other new vaccines are continually being added to the EPI programs in many countries. In 1999, the Global Alliance for Vaccines and Immunization (GAVI) was created to extend the reach of the EPI and to help the poorest countries introduce new and under-used life-saving vaccines into their national immunization programs (NIPs).

Apart from EPI, newer vaccines were introduced in the market to face the challenges of new diseases. Some of these diseases were endemic, but some were epidemic and even pandemic (like the recent COVID-19) in nature. Few of these vaccines were incorporated into the NIPs; however, most of those remained outside the organized system of the Expanded Program on Immunization (EPI). These vaccines are termed as Non-EPI Vaccines (NEPIV) which are available through both the public and private sector providers. As mentioned before, a few of those are also included in the EPI programs of various countries. Along with the rapid expansion of the private sector healthcare providers in many countries, the portfolio of NEPIV delivery through this sector is increasing parallel.

Vaccines used in NIPs are safe and effective. However, like other pharmaceutical products, vaccines are not completely risk-free and adverse events will occasionally result from vaccination. Although most adverse events are minor (e.g. redness at injection site, fever), more serious reactions (e.g. seizures, anaphylaxis) can occur albeit at a very low frequency.[6] The general public has low tolerance to any adverse events following vaccination, because vaccines are given to healthy persons to prevent disease. For this reason, a higher standard of safety is expected of immunizations compared with medications that are used to treat people who are sick (e.g. antibiotics, insulin). This lower tolerance for risks from vaccines translates into a greater need to detect and investigate any adverse event following immunization (AEFI) than is generally expected for other pharmaceutical products.

In line with the higher standard of safety, the reporting of AEFI has been streamlined in most of the developed countries. However, there is still a need for further strengthening of the reporting system in many countries and regions of the world. Such need is also felt in the SEARN region where the member countries include Bangladesh, Bhutan, the Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Sri Lanka, Nepal, Thailand and Timor-Leste. Considering the low-reporting in the region, which may prevent or delay the detection of serious risks, or hamper adequate analysis and risk minimization measures, the assembly of SEARN adopted on 8 June 2022 the SEARN Work Plan 2022-2023 which includes the action point 10, led by Working Group 3 (WG3) Vigilance: 'Draft a strategy to stimulate reporting in the region, including technical solutions'. While stimulation of reporting is necessary for both EPI and Non-EPI vaccines, the need is especially important for the NEPIVs as organized reporting systems have not been developed in most of the member countries.

Bangladesh has a bright success story in the implementation of the EPI program and it is now recognized as a role model for immunization in the world. The safety surveillance for EPI vaccines in the country, including the reporting system, is fairly streamlined in this country. The safety surveillance, however, still needs to be organized for the NEPIVs with a special focus on increased reporting of AEFIs. The issue is especially important in the context of the rapidly expanding private healthcare sector in the country which is now also involved in the manufacturing, importing and distributing of these non-EPI vaccines. The present Strategy, within the wider Pharmacovigilance (PV) context of the Directorate General of Drug Administration (DGDA), is designed to fulfill this need.

2. VACCINES IN BANGLADESH

2.1 BACKGROUND

In Bangladesh, vaccines are available as both EPI and Non-EPI vaccines and those are imported, distributed and retailed by both the public sector and private sector (with specific authorizations). The pharmaceutical industry in Bangladesh is growing very rapidly, both in quantity and quality, and a few industries have recently started to manufacture some vaccines also.

2.1 a. EPI Vaccines: Bangladesh adopted the EPI program since its introduction by WHO in 1974. Since then the country made outstanding progress in implementing the program and it became one of the first countries to eradicate small pox and polio. Presently, 10 vaccines are provided through the program with universal free access (Table 1). A few of these vaccines are also available as non-EPI vaccines, both in the public sector and private sector facilities.

Table1: Vaccines included in the EPI Program of Bangladesh

Vaccine	Disease
BCG	Tuberculosis
Pentavalent	Diphtheria, Pertussis, Tetanus, Hepatitis B, Haemophilus influenza type-B
PCV	Pneumococcal Pneumonia
OPV, IPV	Poliomyelitis
MR	Measles-Rubella
Td	Tetanus, Diphtheria
HPV	Cervical cancer

2.1 b. Vaccines used beyond EPI Program: A number of Non-EPI vaccines are now available in Bangladesh. Most of those are produced locally (table 2) and some are still imported (table 3). Accordingly, there are diverse stakeholders in this group which include manufacturers, Importers, distributors and retailers. As mentioned previously, few of these vaccines are also included in the EPI program.

Table 2: Locally produced/registered Non-EPI vaccines in Bangladesh (As on 21 January 2025)

Sl	Manufacturer	Trade Name	Generic Name
1	Incepta Pharmaceuticals Ltd	Vaxphoid Vaccine	Typhoid Polysaccharide Vaccine
2		Hepa-B Vaccine (For Adult)	Hepatitis B Vaccine (rDNA)
3		Hepa-B Vaccine (For Paediatric)	Hepatitis B Vaccine (rDNA)
4		Vaxitet Vaccine	Adsorbed Tetanus Vaccine
5		Ingovax ACWY Vaccine (0.5ml)	Meningococcal Polysaccharide Vaccine

Sl	Manufacturer	Trade Name	Generic Name
6		Rabix - VC Vaccine	Rabies vaccine (Human)
7		Influvax Vaccine.	Inactivated Influenza Vaccine
8		Rubavax M Vaccine	Measles and Rubella vaccine
9		Ingovax ACWY Vaccine 5ML	Meningococcal Polysaccharide Vaccine
10		PrevaHAV Vaccine (For Adult)	Inactivated Hepatitis A Vaccine
11		PrevaHAV Vaccine (For Pediatric)	Inactivated Hepatitis A Vaccine
12		Varizost Vaccine	Varicella vaccine (Live, attenuated)
13		Cholvax Vaccine	Inactivated Oral Cholera Vaccine
14		Influvax Tetra Vaccine	Inactivated Influenza Vaccine (Quadrivalent)
15		Papilovax Vaccine	Human papilomavirus bi valent
16		Prenovax 23 Vaccine	Pneumococcal Polysaccharide vaccine 23 serotype
17		Evimar 13 Vaccine	Pneumococcal Polysaccharide conjugate vaccine (13 serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F)
18		Vax HIB Vaccine	Hemophilus Influenzae type B conjugated 10 mcg/0.5ml
19		Propenta Vaccine	Diptheria Toxoid+Tetanus Toxoid+ Bordetella Pertusis+Purified Hepatitis B Surface Antigen+ Haemophilus Influenzae type b
20		Ploivax Vaccine	Poliomyelitis vaccine, Live
21		Measeles Vaccine	Measles vaccine (Live attenuated)
22		Vaxitet Vaccine 5 ml	Adsorbed Tetanus Vaccine
23		Vaxpol 1+3 Vaccine	Poliomyelitis vaccine, Live (oral)
24		Neisseria Meningitidis Group A Purified Polysacharide	Neisseria Meningitidis Group A Purified Polysacharide
25		Neisseria Meningitidis Group C Purified Polysacharide	Neisseria Meningitidis Group C Purified Polysacharide
26		Neisseria Meningitidis Group Y Purified Polysacharide	Neisseria Meningitidis Group Y Purified Polysacharide
27		Neisseria Meningitidis Group W135 Purified Polysacharide	Neisseria Meningitidis Group W135 Purified Polysacharide
28		Hepatitis B (rDNA) Purified Sterile Bulk Antigen	Purified Hepatitis B (rDNA) Antigen
29		V Cholera O1 Inaba Phil 6973, Formaldehyde Inactivated Purified bulk	V Cholera O1 Inaba Phil 6973, Formaldehyde Inactivated Purified bulk
30		V Cholera O1 Inaba Cairo 48, Heat Inactivated Purified Bulk	V Cholera O1 Inaba Cairo 48, Heat Inactivated Purified Bulk

Sl	Manufacturer	Trade Name	Generic Name
31		V Cholera O1 Ogawa Cairo 50, Formaldehyde Inactivated Purified Bulk	V Cholera O1 Ogawa Cairo 50, Formaldehyde Inactivated Purified Bulk
32		V Cholera O1 Ogawa Cairo 50, Heat Inactivated Purified Bulk	V Cholera O1 Ogawa Cairo 50, Heat Inactivated Purified Bulk
33		V Cholera O 139, Formaldehyde Inactivated Purified Bulk	V Cholera O 139, Formaldehyde Inactivated Purified Bulk
34		Inactivated Purified Rabies Bulk	Inactivated Purified Rabies Bulk
35		Typhocon	Purified Typhoid Conjugate
36		Purified Vi Polysaccharide bulk of S. Typhi	Purified Vi Polysaccharide bulk of S. Typhi
37		Purified typhoid conjugate (Vi-DT)	Purified typhoid conjugate (Vi-DT)
38	Popular Pharmaceuticals Ltd	TTVax Injection	Tetanus Toxoid Adsorbed BP as Purified
39		Hepavax-B Injection	Hepatitis B Vaccine (r DNA)
40		RABIVAX injection	Rabies Vaccine (Purified Vero cell Rabies vaccine as Inactivated & Purified Rabies Antigen Concentrate)
41		HPVax Injection	Recombinant Human Papillomavirus Vaccine (Types 16, 18)
42		Mvax ACYW Injection	Meningococcal Polysaccharide Vaccine
43		EasyFive Vaccine	Diptheria, Tetanus, Pertusis, 50 mcg/2.5 ml
44		EasyFive Vaccine	Diptheria Toxoid
45		Polivax Injection	Inactvated Poliomyelitis Virus type 1, USP 40 DU+ Inactvated Poliomyelitis virus type 2 USP 8DU+ Inactvated Poliomyelitis virus type 3 USP 32 DU/0.5ml
46		Hepavax B Injection	rDNA Hepatitis B vaccine, BP 10 mcg/0.5ml
47		Hib Vax Injection	Haemophilus Type b Conjugate vaccine USP 10mcg/0.5ml
48		Rabivax IG Injection	Rabies Immunoglobulin (RIG)
49	Healthcare Pharmaceuticals Ltd.	Teta-fix 0.5 ml vaccine	Adsorbed Tetanus Toxoid
50		HB-fix 10 Vaccine	Hepatitis B Vaccine (rDNA)
51		HB-fix 20 Vaccine	Hepatitis B Vaccine (rDNA)

Table 3: Imported Non-EPI vaccines registered in Bangladesh (As on 21 January 2025)

Sl No	Importer	Trade Name	Generic Name
1	Synovia Pharma PLC	Avaxim 80U Pediatric	Inactivated Hepatitis A vaccine
2		Hexaxim	Diphtheria, tetanus, pertussis (acellular component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine
3		Menactra	Meningococcal (Groups A, C, Y, W-135) polysaccharide diphtheria toxoid conjugate vaccine
4		Tetraxim	Diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous haemagglutinin, poliomyelitis virus (inactivated)
5		Typhim VI	Vi capsular polysaccharide typhoid vaccine
6		VaxigripTetra	Quadrivalent inactivated influenza Vaccine
7		Verorab	Purified inactivated rabies vaccine, prepared on Vero cells
8		Stamaril	Attenuated yellow fever vaccine
9		Vaxigrip	Inactivated Influenza vaccine
10	Janata Traders	Prevanar 13 Suspension for Injection	Pneumococcal Polysaccharide serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V,18C, 19A, 10F,23F conjugate to CRM 197 Carrier Protein and adsorbed on aluminum phosphate
11		Typhibev Typhoid Conjugate Vaccine	Typhoid Vi Polysaccharide Vaccine conjugate to 16mcg to 100 mcg of CRM 197
12		MMR Vaccine (Measles, Mumps and Rubella Vaccine Live) Attenuated	Measles Virus Mumps Virus Rubella Virus
13		Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents	Tetanus toxoid
14		Rotasiil- Liquid	Rotavirus Vaccine, Live Attenuated (Oral) (Liquid), 2ml-1 dose
15	Healthcare Pharmaceuticals Ltd.	GARDASIL	Quadrivalent Human Papillomavirus
16		ROTATEQ	ROTAVIRUS VACCINE, LIVE, ORAI, PENTAVALENT
17		PNEUMOVAX 23	PNEUMOCOCCAL VACCINE POLYVALENT
18		VARIVAX	Oka/Merck Varicella Virus

Sl No	Importer	Trade Name	Generic Name
19	Radiant Export Import Enterprise	Prevenar 13 (Vaccine)	Pneumococcal Polysaccharide conjugate Vaccine (Adsorbed), 13-valent
20		Nimenrix	Meningococcal group A,C,W-135 and Y conjugate vaccine
21		Vaxigrip Tetra	Quadrivalent inactivated Influenza Vaccine
22		Tetraxim	Diptheria toxoid, Tetanus toxoid, Pertusis Toxoid, Filamentus Haemagglutinin

2.2 PHARMACOVIGILANCE OF VACCINES

As per regulations in Bangladesh, vaccines are considered drugs and their PV is included in the National Pharmacovigilance Guideline of the DGDA, which was approved by the Ministry of Health & Family Welfare (MoHFW) in 2018 and updated in 2023. The EPI program has its own organized safety surveillance system with structured reporting. There is no such separate system yet in cases of the NEPIVS. However, in parallel to the reporting of adverse events of the drugs, a system of AEFI reporting has been operating under the management of the PV Cell of the DGDA.

2.3 UNIQUE ARRANGEMENT DURING COVID-19

Although the COVID-19 vaccines are not included in routine EPI Program, the management of the large-scale vaccination initiative was done by the EPI Program. This included the reporting of the AEFIs through the EPI channels and a link was established with the DGDA. Again, COVID-19 vaccination is a global success story for Bangladesh, especially in the context of resource constraints and the safety surveillance experience of those NEPIVs may teach important lessons for generating the safety surveillance system for the Non-EPI vaccines.

2.4 POLICY CONTEXT IN RELATION TO THE SAFETY-SURVEILLANCE OF NON-EPI VACCINES

National Health Policy 2011 in Bangladesh aims to ensure the health of the population through curative and preventive services, and the issue of the public health has been prioritized in this policy. Similar priority has been echoed in the subsequent documents and programs including the Health, Population and Nutrition Sector Programs (HPNSPs) and the Five-year programs of the government. The country is committed to Goal 3 (Health and Wellbeing) of the Sustainable Development Goal (SDG) and, as a prerequisite to achieve the Goal, it is trying hard to achieve Universal Health Coverage (UHC) by 2030. Only through the development of a healthy nation, the 2041 vision of a developed Bangladesh can be achieved. As universally acknowledged and as especially experienced in the context of Bangladesh, vaccines are invaluable tools for achieving the health-related objectives and goals of the nation. The Non-EPI vaccines are now important subcomponents of the vaccination initiatives and a safe implementation of the NEPIV-related initiatives is fully in line with the overall policies and programs of Bangladesh.

2.5 MAJOR CHALLENGES FOR SAFETY-SURVEILLANCE OF NON-EPI VACCINES IN BANGLADESH

Low reporting of the AEFIs is the major challenge to effective safety surveillance of NEPIVs in Bangladesh. The country is part of the SEARN region and the barriers to AEFI reporting (Table 5) as identified in action Point 10 (led by the Working Group 3 or WG3) in the SEARN Work Plan 2022-23, also applies to this country. A systemic analysis reveals the challenges related to legislation and regulation, awareness and motivation, methodology and tools, human resource training, professional education, research, and capacity enhancement of the regulators and other stakeholders.

Table 5: Main barriers to AEFI reporting in the SEARN countries, identified by WG3 in the SEARN Work Plan 2022-23

Sl No	Barriers
1	Lack of time
2	Legal framework, governance and policy
3	Language/ Literacy as a barrier
4	Complexity of reporting form
5	Complexity/ Lack of reporting system
6	Lack of knowledge/ Awareness/ Training
7	Lack of motivation
8	Perception about product safety
9	Guilt/ Shame
10	Fear of consequences
11	Discouraging system
12	Lack of positive feedback to reporters
13	Uncertainties about what to report
14	Uncertainties on who should report
15	Preference for publication rather than PV report

2.5.1 Challenges in relation to legislation and regulation

Most of the issues related to the implementation of the safety surveillance of the Non-EPI vaccines may be covered by the existing legislations (such as the Consumer Protection Act 2009 and TORT Law 1876) of the country. However, the coverage may not be all inclusive and a close inspection is necessary to get a comprehensive legal framework. The recently passed Drug and Cosmetics Act, 2023 has gone a long way in that direction; however, the rules & regulations related to the act are still to be fully formulated and implemented. Especially, the intermixing of drugs and vaccines needs to be especially scrutinized and, due to the higher demand for safety surveillance in the case of vaccines, it should be carefully noted whether the existing laws in the act fully cover the vaccine-related challenges. The health protection Act is now under the process of approval by the Government and it should be explored whether the new Act will also

be helpful in meeting the legislative and regulatory challenges of the safety surveillance of vaccines. Since private sector Providers are also involved in the NEPIV initiatives, the legislative and regulatory issues may pose an extra challenge to the safety surveillance of this subgroup of vaccines.

2.5.2 challenges in awareness and motivation

Among most of the people (even among the relevant professionals and highly educated/ alert subgroups), it is taken for granted that vaccines are safe products and it is not necessary to note any adverse effect after vaccination. This leads to a lack of motivation for AEFI reporting among the stakeholders including the common public (the Consumers), Providers (Physicians, Pharmacists, Nurses, Paramedics etc.), Policy Makers and Suppliers (Manufacturers, Importers, Distributors and Retailers). In line with this attitude, organized initiatives to promote awareness and motivation are lacking in both the relevant public and private sectors.

2.5.3 Under defined methodology and less efficient tools for AEFI reporting of NEPIV

While the PV Cell of the DGDA, within its existing Resource constraints, is providing the maximum possible efforts to get AEFI reports for NEPIVs, the adopted methodology has considerable limitations and the used tools may not be optimally user-friendly. The distribution channels for NEPIVs are not fully streamlined with binding regulations and the capacity- and category-specific authorization of the providing facilities (especially the private pharmacies) are not yet explicitly evident. The incorporation of modern information-communication technology (ICT) is still lacking in the case of NEPIV-AEFI. All these factors play an inhibitory role in the reporting of AEFI for NEPIVs.

2.5.4 Inadequate HR training

The human resources, involved in the providing organizations are not properly trained and motivated in the detection and reporting of NEPIV-related AEFI. Programs for vaccine- and category-specific organized and continued training is lacking among all the stakeholders.

2.5.5 Gaps in professional education

The existing course-curricula of the healthcare professionals (physicians, pharmacists, nurses and paramedics) do not adequately address the PV issues in general. The specific issues related to vaccines are even more marginalized and are thought to be covered in the contents related to drugs. The issues related to AEFI of NEPIVs are hardly mentioned. As mentioned previously, the safety standards of the vaccines are higher (due to involvement of healthy persons) and should be discussed separately.

2.5.6 Absence of locally relevant evidence

Like drugs, vaccines may have special effects on the members of particular ethnic groups due to genetic, cultural and lifestyle reasons. Continued, scientifically valid research activities are required to generate AEFI-related evidence in cases of NEPIVs. These vaccines, in reality, are public health assets. At the same time, the life of even a single person is extremely valuable. Thus,

careful conclusions must be drawn from credible evidence and a balanced inference is necessary for onward actions. In addition, evidence in such cases will have to confront commercial interest in most cases. Thus, the evidence must be reliable and robust. A process for such evidence-based decision-making is still lacking in Bangladesh.

2.5.7 Inadequate capacity among the relevant stakeholders

A comprehensive and effective safety surveillance of NEPIVs requires a high level of capacity and expertise in the regulatory agency. The infrastructure and HR capacity of the present PV Cell in the DGDA is not adequate in that respect. Even the PV initiatives of the drugs are difficult to implement with the present capacity. A dedicated sub cell is not present to address the vaccine-related safety surveillance and focused activities for NEPIVs are not present in a consistent manner.

In addition to the regulators, the capacity of the suppliers is not uniformly optimum in most cases. For example, maintenance of cold chains in the small Pharmacies (from where many vaccines are sold) is not guaranteed. Maintenance of the optimum environment during the storage and distribution steps is also not uniformly standardized.

3. NEPIV SSS 2025: GOAL, OBJECTIVES AND STRATEGIC ACTIONS

3.1 STRATEGY DEVELOPMENT PROCESS

The present strategy was developed through a consultative process involving various stakeholders. The action point 10 of the SEARN action plan 2022-23 (formulated by the TG3) was a major guiding document in framing the present strategy. Through an initial round- table meeting with the relevant officials in DGDA, some of the basic challenges for AEFI-NEPIV reporting were gathered in the context of Bangladesh. Extensive desk review was made and few of the relevant professionals were consulted. A power point presentation, based on the conceptual zero draft, was made in a larger scale workshop (at DGDA Conference Room) attended by diverse stakeholders including experts/officials/representatives from the Health Ministry, DGDA, other relevant Directorates/Agencies, Hospitals and Healthcare providers, Academia and Research Organizations, Development Partners, Suppliers (Manufactures/ Importers/Distributors), and Civil Society Organizations. The present first draft will be further refined with input from the policy makers, other experts and stakeholders.

3.2 GOAL AND OBJECTIVES OF NEPIV-SSS 2025

GOAL

To promote a stronger public health system through strengthening of Non-EPI Vaccine safety surveillance with increased reporting of probable adverse events following immunization (AEFI).

OBJECTIVES

The objectives of the strategy are to suggest strategic actions and operational activities around the following objectives:

- To revisit and suggest the legislative and regulatory aspects related to the safety surveillance of Non-EPI vaccines with special focus on increased AEFIs;
- To generate awareness and motivation among all the relevant stakeholders;
- To generate or improve the methodology and tools related to the safety surveillance and increased AEFI reporting in cases of Non-EPI vaccines;
- To train the human resources of the relevant stakeholders on related issues;
- To incorporate the Non-EPI vaccines-related safety surveillance and AEFI issues in the course-curricula and syllabi of the health professionals' education programs;
- To stimulate research activities in the relevant areas;
- To build capacity among the relevant stakeholders for optimum implementation of the strategic objectives.

3.3 STRATEGIC ACTIONS

Strategic Action 1: Revisit and suggest the legislative and regulatory aspects of Non-EPI vaccines

Legislative basis and associated regulatory frameworks are of central importance in implementing any strategic action. A number of operational activities will be required to ensure the existence of appropriate legislation and regulatory provisions to implement the actions visualized in the present Strategy. The rights of the Consumers will have to be protected in such frameworks, especially in light of the potential involvement of the for-profit private sector in their dispensing. This, in turn, will promote the confidence of the people in these vaccines Relevant administrative procedures will then be made easier.

1.1 Review the legislation as relevant to the safety surveillance (especially AEFI reporting) of NEPIVs

Existing regulations related to the duties and obligations of the health care providers and rights of the consumers (general people in this case) will have to be critically reviewed with support and input from legal experts. The review needs to focus on the safety surveillance of NEPIVs and the protection of all the stakeholders. It should also assess whether the regulations have been formulated to implement the specific Act. Particular attention will be required for the legislations under process (such as the health protection Act) as there is still some scope for improvisation in these acts.

1.2 Review the documents of regulatory agencies as relevant to the NEPIVs (especially AEFI reporting)

It should be critically examined whether the regulatory documents, related to the particular legislation, have been prepared and implemented.

1.3 Review the administrative orders as relevant to the safety surveillance and AEFI reporting of NEPIVs

Administrative steps, related to the implemented regulations (aligned with the ACT), will need to be revisited and gaps in the steps, if any, should be identified.

1.4 Suggest, if necessary, the modification of existing legislation, regulatory measures, or administrative steps to improve safety surveillance and AEFI reporting of NEPIVs

With a view to enhanced safety surveillance and protection of all the stakeholders, if necessary, suggestions regarding amendments will need to be generated. The necessary regulatory and administrative steps should also be suggested.

1.5 Suggest, if necessary, the introduction of new legislation, regulatory measures or regulatory/administrative steps to improve safety surveillance and AEFI reporting of NEPIVs

In case of need, suggestions for new legislation should also be generated. The legislation already under process will need to be expedited. The chain of documents, from legislation to administrative orders will need to be available and any missing link should be rectified.

1.6 Incorporation of safety surveillance issues of NEPIVs should be ensured in the new rules under Drug and Cosmetics Act, 2023

1.7 Take steps for the modification of the existing or introduction of new legislation, regulatory measures and administrative steps, as appropriate

Based on the suggestions of the reviews, appropriate modifications of the existing legislation, regulatory measures and administrative steps will need to be completed. In required cases, legislation, regulatory measures and administrative steps should be initiated.

1.8 Enhance the implementation of the relevant Acts/Enforcement

Particular attention should be given to the relatively new legislations (such as the Drug and Cosmetics Act, 2023) development of the Rules-Regulations will need to be expedited. Based on the review suggestions, other measures will also be taken to implement the relevant Acts.

MAHs, PHPs & facilities (where vaccines are manufactured, distributed and used) must conduct regular AEFI monitoring and reporting through their functional safety surveillance system & PV team/chain/set up following the National Pharmacovigilance Guidelines. PV stakeholders should have their own policy to recruit manpower and allocate budget for pharmacovigilance. Controlled Supply chain/distribution channels for appropriate transportation, storage and use of vaccines with necessary instructions under a supervision of a doctor/pharmacist/trained nurses is important. These professionals can play a vital role in AEFI reporting in the hospitals, clinics, vaccination centers and in the pharmacies. MAHs should have a plan for vaccines sales/distribution to only the enlisted health facilities or model pharmacies to ensure traceability and AEFI reporting.

Qualified Persons of Pharmacovigilance (QPPV) of the vaccine manufacturing & importing companies, health programs and facilities or any other non-EPI vaccination centers in the country should maintain close communication with Pharmacovigilance Department of DGDA in this regard.

Strategic Action 2: Generate awareness and motivation among all the stakeholders

Stakeholders' involvement is an important issue to achieve the goal and objectives in safety surveillance and to stimulate AEFI reporting for Non-EPI vaccines where specific roles and responsibilities should be developed and implemented. So, MAHs (vaccine manufacturers, importers/distributors), vaccine points/retailers, programs, Health facilities, Vaccination centers, Medical, Nursing & Pharmacy educational institutions, Colleges and Universities, Professional councils for registration (e.g. BMDC, PCB, BNMC etc.) should come forward in this regard. The Directorates (DGDA, DGHS, DGME, DGFP and DGNM) of the Ministry of Health and Family Welfare should be brought under a common PV umbrella and work together.

Awareness and motivation are absolutely essential for the safety surveillance of non-EPI vaccines. This is due to the essentially voluntary nature of reporting the AEFIs. All groups of stakeholders – from the Policy Makers to the General Public – should be brought under the campaign of building awareness and motivation. Various techniques/channels (e.g. targeted advocacy, mass awareness, individual/group motivation), as appropriate for the target stakeholders, will need to be applied for effective awareness/motivation initiatives.

2.1 Arrange advocacy programs among relevant Policy Makers, Planners, and Senior Administrators

Focused advocacy, targeted to individuals and groups, will need to be arranged for creating awareness and motivation among the Policy Makers, Planners and Senior Administrators. Leading professionals from the Providers are also included in this group. These professionals are central change makers and they should be approached with well-planned advocacy materials.

2.2 Initiate large scale awareness campaigns among general people using mass media (electronic and print), social media and community-oriented activities

In case of vaccines, the awareness and participation of the general people are central importance. Accordingly, mass campaign, using appropriate channels (such as print and digital mass media, social media platforms, community-oriented activities), will need to be conducted.

2.3 Generate awareness and motivation among Providers (like Physicians, Nurses, Pharmacists, and Community Health Workers) using effective tools and channels

Targeted awareness and motivation programs, designed for specific groups, will need to be conducted among these professionals. Appropriate tools and channels should be used to ensure effective implementation of these programs.

2.4 Generate awareness and motivation among Manufacturers, Importers, Distributors and Retailers using effective tools and channels

Targeted awareness and motivation programs, designed for specific subgroups, will need to be conducted among these professionals. Appropriate tools and channels should be used to ensure effective implementation of these programs.

Strategic Action 3: Generate and improve the methodology and tools related to AEFI reporting of Non-EPI Vaccines

Organized distribution channels for the Non-EPI vaccines should be streamlined under proper regulatory provisions and the methodology for such channels should be clearly defined. On the other hand, the Reporting Systems need to be streamlined with clear definition of the channels from the periphery to the Center. It is of central importance to make the Tools user-friendly and simple as far as possible. The digital tools need to be optimally used.

3.1 Review the existing reporting forms with input from the various stakeholders

With input from the relevant stakeholders (including general people, as appropriate) the presently used reporting forms should be reviewed with special attention to user-friendliness. The rational feedback should be summarized.

3.2 Redesign, if necessary, the forms with special reference to user-friendliness

Based on the rational feedback, as received in section 3.2, the reporting forms should be redesigned, if necessary.

3.3 Design, if necessary, new forms with special reference to user-friendliness

Based on the rational feedback (as received in section 3.2) and also on other review points, new reporting forms should be designed, if necessary. An example of a new form to report AEFI is provided as Annexure 4.

3.4 Design short and simple forms, as much as possible, without compromising the quality

During the redesigning/designing of reporting forms, the issue of simplicity should be given due consideration. However, essential elements in the forms must not be missing and quality should not be compromised.

3.5 Use (as much as feasible in the Bangladesh context) the digital channels (e.g. Apps in mobile phones) for reporting AEFI for NEPIVs

Presently, digital channels are highly important to create awareness and motivation among the stakeholders. In Bangladesh context, mobile phones may be extensively used for this purpose and targeted Apps may be developed for these purposes. However, constraints related to the availability of relevant sets and internet connection should be given due consideration, especially when general people are the targets.

3.6 Create databases for cumulating the AEFI reports at various levels

The AEFI reports should be digitalized as much as possible and proper databases should be used to store the information. Connectivity and compatibility with the regional and international databases.

Strategic Action 4: Train HR from relevant stakeholders

Dedicated human resources for the safety surveillance of NEPIVs should be ensured among all the relevant stakeholders (Regulatory Agency, Suppliers, and Providers). Those groups of HR need to be trained on the safety surveillance issues of NEPIVs and the training sessions should also be used as motivating sessions for increased reporting. The training should be organized with proper planning on course-curricula targeted to specific groups of Providers. The formal acknowledgment of the training programs will create further motivation among the participants.

4.1 Develop training programs with customized course-curricula and training materials for specific groups of professionals like Regulators, Providers, Manufacturers, Importers, Distributors and Retailers

With appropriate professional input, the course curricula and syllabi of the training programs should be designed for periodic upgrading of the knowledge and skills of relevant professional groups. The content must be informative and practical with emphasis on the local context.

4.2 Arrange regularly the Fresher as well as follow-up training programs for the relevant professionals

Fresher as well as Follow-up training should be designed separately. Arrangements for periodic training programs should be planned on discussion with the various executing agencies.

4.3 Review the effectiveness of the training programs following appropriate evaluation projects

The training programs will required to be coupled with evaluation systems which will generate evidence on the effectiveness of the training programs. The feedback collected from the Trainees and their supervisors will be vital to adjust, modify/redesign the trainings, if necessary.

Strategic Action 5: Incorporate AEFI issues in the course-curricula of the relevant professional education/training programs

In the context of the increasing importance of pharmacovigilance, the course-curricula and syllabi of the relevant professional groups (physicians, pharmacists, nurses, paramedics and community health workers) should contain optimum content on the PV of drugs and vaccines. It is important to create customized content targeted to specific professional groups with professional engagement. The relevant regulatory authorities for health professional education will need to be convinced through targeted advocacy. Appropriate teaching-learning techniques will need to be adopted for the effective education of professionals on safety surveillance issues.

5.1 Create contents and educational materials related to NEPIVs, especially AEFI reporting for providing education and training to the students from physicians, pharmacists, nursing and paramedical disciplines

With appropriate professional input, the course curricula and syllabi of the academic programs should be designed for periodic upgrading of the knowledge and skills of relevant professional groups. The content should be target-specific and precise so that the students are not overburdened.

5.2 Take organized initiatives to incorporate the safety surveillance and AEFI-NEPIV-related education and training in the course-curricula and syllabi of the educational and training programs

Development of course-curricula and educational materials does not, automatically, guarantee the inclusion of the issues into the programs of the relevant academic institutions or universities. Special efforts, through awareness and advocacy initiatives, will be required to convince the relevant universities/institutions to include these materials into their regular academic programs.

5.3 Review the impact of education and training related reforms on the reporting of AEFI of NEPIVs

Organization of academic programs may not yield desired outcomes unless proper evaluation and feedback mechanisms are existent. It is important to design an in-built mechanism for evaluating the impact of the training programs and to adjust the contents and methodology of the program based on rational feedback.

Strategic Action 6: Strengthen research activities on PV of Vaccine

Context-specific evidence is crucially important for vaccines and it is especially important for Non-EPI vaccines as these are outside the national immunization programs in most of the cases. Due to racial variations (originating from genetic as well as lifestyle factors) the same vaccines may have some variable effects. An effective safety surveillance program will require continued research on various aspects of NEPIVs including the clinical management and socioeconomic aspects of vaccination. Academia-industrial partnership should be fostered to promote research in these areas.

6.1 Identify priority areas and projects for research activities on consultation with various stakeholders

Though workshops, targeted interactions and other mechanisms, priority research areas will need to be identified based on the context of the country. Some ideas on individual projects may also be generated within the prioritized areas.

6.2 Develop coordinated mechanism to promote research in the prioritized fields

Potential researchers and research groups within the country, as well as potential global collaborating partners, should be identified. A perspective plan for the next few years may also be envisaged. The plan should emphasize on comprehensive and coordinated research involving public as well as private sectors. The need for academia-industry partnership should be highlighted.

6.3 Create pool fund to support research in the selected areas

Initiatives should be taken to generate a pool fund to support research on priority areas. Support from the Government, NGOs, industries and Development Partners may be mobilized to create the pool fund.

Strategic Action 7: Build capacity in the area of Non-EPI Vaccines

Effective implementation of the actions, as visualized in this Strategy, require a parallel capacity in the PV Cell of the DGDA. It now needs to be converted to a Department with dedicated Cells/ Units for drugs, vaccines, medical devices etc. Parallel increase in infrastructure as well as HR capacity will make it possible to ensure health of the population through proper safety surveillance of the pharmaceutical products. At the same time, the capacity of the Suppliers (Manufacturers, Importers, Distributors and Retailers) will need to be enhanced, mainly through planning and supervision by the Regulatory Agency. The Suppliers will need to be encouraged to invest resources to increase their own capacity).

7.1 Strengthen the PV Cell of DGDA with relevant inputs on physical infrastructure and human resources

All the strategic actions require the existence of a resourceful and efficient Pharmacovigilance functional unit in the Regulatory Body (ie DGDA). The presently functioning PV cell in the DGDA may be upgraded to a full-fledged Department with Dedicated Units for Drugs, Vaccines, and Medical Devices. A subunit of the vaccine unit may be assigned for the NEPIV-related activities. Appropriate infrastructure and human resources are the prerequisites for this upgradation.

7.2 Create capacity (with appropriate HR and other input) all over the country through the DGDA offices at the district and sub district levels

Even a strong PV department at the central level will not be successful unless it is supported, in parallel, by peripheral units of the DGDA with enhanced capacity. Again, development of infrastructure and HR capacity in the district and sub district level centers of DGDA is highly important for successful achievement of the strategic objectives.

7.3 Explore the already existing potential infrastructure/facilities for their probable incorporation in the safety surveillance (especially AEFI reporting) of NEPIVs

Some of the public sector agencies may have already functioning facilities which, with relevant input, may be potentially used for some of the actions under this strategy.

7.4 Enhance the ICT infrastructure to use the digital tools and channels for conducting relevant activities like advocacy/awareness, reporting, education, training, and research

The development of infrastructure, as mentioned previously, includes the development of ICT capacity. However, this activity needs separate mentioning due to its special importance in almost all strategic sctions.

7.5 Build capacity of the suppliers (manufacturers, importers, distributors and retailers) on the maintenance of adequate supply chain and reporting of AEFI of NEPIVs

7.6 Consider the issues of natural calamities like (flood, cyclones, earth quack) and other crisis situations (like epidemics and pandemics) in the capacity building of the different stakeholders

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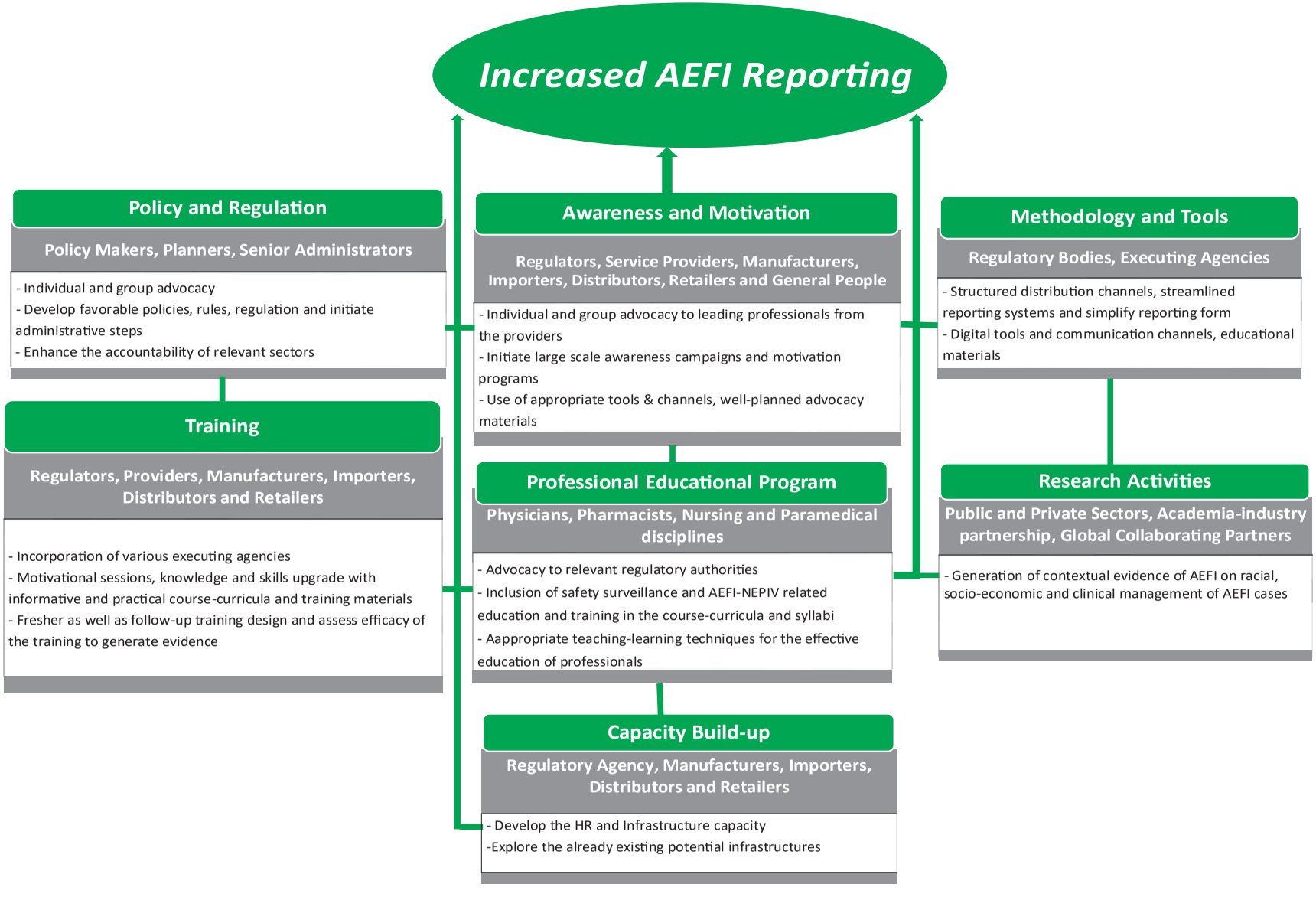
ANNEXURES

ANNEXURE 1


Increased AEFI Reporting
Policy and Regulation
Policy Makers, Planners, Senior Administrators
- Individual and group advocacy
- Develop favorable policies, rules, regulation and initiate administrative steps
- Enhance the accountability of relevant sectors
Awareness and Motivation
Regulators, Service Providers, Manufacturers, Importers, Distributors, Retailers and General People
- Individual and group advocacy to leading professionals from the providers
- Initiate large scale awareness campaigns and motivation programs
- Use of appropriate tools & channels, well-planned advocacy materials
Methodology and Tools
Regulatory Bodies, Executing Agencies
- Structured distribution channels, streamlined reporting systems and simplify reporting form
- Digital tools and communication channels, educational materials
Training
Regulators, Providers, Manufacturers, Importers, Distributors and Retailers
- Incorporation of various executing agencies
- Motivational sessions, knowledge and skills upgrade with informative and practical course-curricula and training materials
- Fresher as well as follow-up training design and assess efficacy of the training to generate evidence
Professional Educational Program
Physicians, Pharmacists, Nursing and Paramedical disciplines
- Advocacy to relevant regulatory authorities
- Inclusion of safety surveillance and AEFI-NEPIV related education and training in the course-curricula and syllabi
- Aappropriate teaching-learning techniques for the effective education of professionals
Research Activities
Public and Private Sectors, Academia-industry partnership, Global Collaborating Partners
- Generation of contextual evidence of AEFI on racial, socio-economic and clinical management of AEFI cases
Capacity Build-up
Regulatory Agency, Manufacturers, Importers, Distributors and Retailers
- Develop the HR and Infrastructure capacity
-Explore the already existing potential infrastructures

ANNEXURE 2

Selected Indicators to Monitor Strategic Actions of NEPIV-SSS 2025

Strategic Action 1: Revisit and suggest the legislative and regulatory aspects of Non-EPI vaccines

No	Indicator	Description
1	Post-review recommendations available regarding legislative-regulatory issues	A thorough review of legislative and regulatory issues as well as administrative orders, related to Non-EPI vaccines, will be done and the review recommendations will address identified gaps and suggest improvement in the existing framework, ensuring robust governance and effective implementation of the Non-EPI vaccines safety surveillance system.
2	Action initiated on expedited implementation of relevant legislation with special focus on the Drug Act, 2023	The Rules of the Drug and Cosmetics Act, 2023 will be formulated and finalized as soon as possible for efficient implementation. Rules-Regulations related to other legislations will also be expedited.

Strategic Action 2: Generate awareness and motivation among all the stakeholders

No	Indicator	Description
3	Awareness, advocacy and motivation campaigns arranged regularly using effective tools and channels	Regular awareness, advocacy, and motivation campaigns will be organized by leveraging digital platforms (print, electronic, and other digital media), workshops, seminars, and targeted communication strategies. These efforts will aim to educate stakeholders, promote understanding of Non-EPI vaccine safety, and encourage participation in surveillance activities.
4	Targeted stakeholder groups participate in the awareness, advocacy and motivation programs	Participation of targeted stakeholder groups (such as policymakers, planners, senior administrators, service providers, suppliers, and the general public) in awareness, advocacy, and motivation programs will be ensured. Through focused communication and interactive sessions, these programs will aim to engage and educate key stakeholders, ensuring their active involvement and commitment to Non-EPI vaccine safety initiatives.

Strategic Action 3: Generate and improve the methodology and tools related to AEFI reporting of Non-EPI vaccines

No	Indicator	Description
5	Post-reviewed redesigned/ newly designed easier and user-friendly Forms available for AEFI reporting of Non-EPI vaccines	The vital need for Easier and user-friendly forms for more AEFI reporting of Non-EPI vaccines will be realized. Following the review of existing forms with input from relevant stakeholders, redesigned or newly designed forms will streamline the reporting process, making it more accessible and efficient.
6	Mobile Apps developed for AEFI reporting of Non-EPI vaccines	User-friendly mobile apps will be developed to significantly improve the quick and accurate reporting of adverse events related to Non-EPI vaccines among the general public. This initiative will enhance surveillance and response systems for AEFI reporting, ensuring convenience and efficiency. Relevant features and uninterrupted connectivity to enable widespread use will be available.
7	Digital databases improved for cumulating AEFI reports on Non-EPI vaccines	Digital database will be available to streamline the reporting systems from the periphery to the central level, for collecting, storing, and analyzing adverse event data. The database will be gradually integrated with regional and international databases to enhance connectivity and compatibility, improving overall surveillance and response capabilities.

Strategic Action 4: Train HR from relevant stakeholders

No	Indicator	Description
8	Regular training programs organized based on stakeholder group-specific customized training curricula and teaching-learning tools	Frequent organization of fresher and follow-up training programs will be arranged tailored to specific stakeholder groups, utilizing customized curricula and teaching-learning tools in collaboration with various executing agencies. The approach will ensure targeted education and skill development, enhancing stakeholder understanding and participation in Non-EPI vaccine safety initiatives.
9	Training programs attended by the targeted stakeholder groups	Training programs will be well-attended by engaging the targeted stakeholder groups and providing relevant, customized content. This will enhance stakeholders' knowledge and involvement in Non-EPI vaccine safety initiatives

No	Indicator	Description
10	Regular monitoring and evaluation process organized to assess the effectiveness of training programs	Evidence on the effectiveness of training programs will be continuously generated by collecting feedback from trainees and their supervisors. The feedback will play a vital role for adjusting, modifying, or redesigning the training programs as necessary, ensuring they remain relevant and effective.

Strategic Action 5: Incorporate AEFI issues in the course-curricula of the relevant professional education/training programs

No	Indicator	Description
11	NEPIV-related academic course-curricula, syllabi and educational materials developed for targeted professional groups	The content and educational materials related to safety surveillance and AEFI-NEPIVs, for the course curricula and syllabi of their educational and training programs, will be developed with appropriate professional input. The importance of pharma-covigilance and AEFI reporting will be emphasized, and upgradation of the knowledge and skills of relevant professional groups will occur.
12	The safety surveillance and AEFI-NEPIV-related education and training integrated into the academic programs of professional groups	Through special efforts (especially awareness and advocacy initiatives among the relevant regulatory authorities) the developed course-curricula and educational materials, related to safety surveillance and AEFI-NEPIVs, will be included into the programs of relevant academic institutions or universities.

Strategic Action 6: Strengthen research activities on PV of Vaccines

No	Indicator	Description
13	Evidence of continued research activities generated in priority areas through independent initiatives and national-international collaborations	Through Health Workforce (HWF) research, within a broader purview of health system reform, continuous generation of evidence will be ensured for the development of rational policies and programs in the health sector with optimum utilization of Human Resource for Health (HRH).
14	A pooled fund created for sustainable research on NEPIVs	Research in priority areas will be conducted for developing effective policies and programs on safety surveillance and AEFI-NEPIVs. To support this, funds will be pooled from the government, NGOs, industries, and development partners.

Strategic Action 7: Build capacity in the area of Non-EPI Vaccines

No	Indicator	Description
15	The infrastructure and human resources capacity of relevant units of the regulatory agencies developed at central, district, and sub-district levels	A resourceful and efficient Pharmacovigilance Unit will be developed within the Regulatory Body for successful achievement of the strategic objectives. This will be done through developing the infrastructure and HR capacity at central, district and sub-district levels. The existing infrastructure and facilities will be incorporated and this will also strengthen capacity in the area of Non-EPI Vaccines.
16	All relevant stakeholders (including Manufacturers-Importers-Distributors-Retailers), take part in the capacity development process	Through multisector involvement, the health and wellbeing of the population will be ensured by comprehensive Non-EPI vaccine safety surveillance. The Suppliers will invest resources in increasing their own capacity can be part of this effort, guided by planning and supervision from the Regulatory Agency.

Means of verification

The official reports/records from the Ministry of Health and Family Welfare (MoHFW) and/or relevant Directorates/Agencies will constitute the major Means of Verification (MoV) for almost all the strategic indicators. In some cases, there will be commissioned surveys/reports like the Annual Program Review (APR)/Mid-Term Review (MTR) documents as well as publications [like the Bangladesh Demographic & Health Survey (BDHS) and Bangladesh Health Facility Survey (BHFS). Independent studies/surveys may supplement these initiatives in selected cases.

For individual activities/sub activities, operational indicators will be required and those will be generated during designing of the Operational Plans (OPs), either through the 5th Health, Population & Nutrition Sector Program (5th HPNSP) or through the other budgetary allocations of the implementing agency. In reality, those will constitute the Action Plan of the present Strategy (as explained in Annexure 2). In those documents the OP indicators and their MoVs will need to be presented under individual log frames.

ANNEXURE 3

Action Plan Schedule for Implementing NEPIV-SSS 2025

1. Preamble

Vaccination remains one of the most effective public health interventions, significantly reducing morbidity and mortality associated with infectious diseases. While the Expanded Program on Immunization (EPI) has achieved considerable success in administering vaccines for common diseases, there is a growing need to address the safety and monitoring of Non-EPI Vaccines (NEPIVs). These vaccines, which include those for newer or less prevalent diseases, are increasingly being used to prevent a broader range of health threats.

Ensuring the safety of Non-EPI vaccines is paramount to maintaining public trust and achieving optimal health outcomes. Adverse Events Following Immunization (AEFIs) must be meticulously monitored, reported, and analyzed to mitigate risks and improve vaccine safety. Effective surveillance systems are essential for the early detection of potential adverse events and for taking appropriate action to safeguard public health.

Incidentally, the next 5-year implementation of the Non-EPI Vaccine Safety Surveillance 2025 (NEPIVs-SSS 2025) and the 5th Health, Population & Nutrition Sector Program (5th HPNSP) will be almost parallel. Accordingly, in practice, the activities conceived under the various strategic actions will be implemented mainly through the various Operational Plans (OPs) under the 5th HPNSP. In addition, the DGDA and some other relevant Authorities/Agencies will need to incorporate many of the activities in their routine operational activities. The implementation of this strategy will require significant budgetary involvement through Operational Plans (OPs) and regular revenue streams. Adequate funding is essential for establishing and maintaining effective surveillance infrastructure, conducting training programs, and ensuring the availability of necessary resources for timely AEFI reporting and response. Financial support will be allocated to various activities, including the capacity buildup, development of digital reporting platforms, data analysis tools, and public awareness campaigns.

To achieve these goals, the activities outlined in this strategy are categorized to ensure a structured and phased approach to implementation. **Short-Term Activities** are to be planned within the first 2 years of the Sector program, focusing on immediate priorities and foundational elements. **Mid-Term Activities** are to be planned within 2030, aiming at building on the initial progress and expanding the scope of the initiatives. **Long-Term Activities** are to be planned with a vision extending beyond 2030, targeting sustained improvements, comprehensive integration of systems and processes, and long-lasting impact.

This categorization ensures that the work is distributed effectively over time, allowing for gradual and consistent advancement toward the overall objectives. Such a distribution of activities is shown in Section 2 (the code number of the activities corresponds to that in the main Strategy). It needs to be noted that the distribution is tentative, the actual scheduling (including the incorporation in the Priority Action Plan or PAP of the individual OPs) will need to be done on detailed discussion during the designing/review of the sector program.

1. Proposed Scheduling of the Activities under the NEPIV-SSS 2025

a. Short Term Activities

Strategic Action 3: *Generate and improve the methodology and tools related to AEFI reporting of Non-EPI vaccines*

3.1 Review the existing Reporting Forms with input from the various stakeholders
3.2 Redesign, if necessary, the Forms with special reference to user-friendliness
3.3 Design, if necessary, new Forms with special reference to user-friendliness
3.4 Design short and simple Forms, as much as possible, without compromising the quality

Strategic Action 5: *Incorporate AEFI issues in the course-curricula of the relevant professional education/training programs*

5.1 Create contents and educational materials related to NEPIVs, especially AEFI reporting for providing education and training to the students from physicians, pharmacists, nursing and paramedical disciplines

b. Short Term/Mid Term Activities

Strategic Action 1: *Revisit and suggest the legislative and regulatory aspects of Non-EPI Vaccines*

1.1 Review the legislation as relevant to the Safety Surveillance (especially AEFI reporting) of NEPIVs
1.2 Review the documents of Regulatory Agencies as relevant to the NEPIVs (especially AEFI reporting)
1.3 Review the administrative orders as relevant to the safety surveillance and AEFI reporting of NEPIVs
1.4 Suggest, if necessary, the modification of existing legislation, regulatory measures, or administrative steps to improve safety surveillance and AEFI reporting of NEPIVs
1.5 Suggest, if necessary, the introduction of new legislation, regulatory measures or regulatory/administrative steps to improve safety surveillance and AEFI reporting of NEPIVs
1.6 Incorporation of safety surveillance issues of NEPIVs should be ensured in the new rules under Drug and Cosmetics Act, 2023.

Strategic Action 2: *Generate awareness and motivation among all the stakeholders*

2.1 Arrange advocacy programs among relevant Policy Makers, Planners, and Senior Administrators

2.2 Initiate large-scale awareness campaigns among general people using mass media (electronic and print), social media and community-oriented activities

2.3 Generate awareness and motivation among Providers (like Physicians, Nurses, Pharmacists, and Community Health Workers) using effective tools and channels

2.4 Generate awareness and motivation among Manufacturers, Importers, Distributors and Retailers using effective tools and channels

Strategic Action 3: *Generate and improve the methodology and tools related to AEFI reporting of Non-EPI vaccines*

3.5 Use (as much as feasible in the Bangladesh context) the digital channels (e.g. Apps in mobile phones) for reporting AEFI for NEPIVs

Strategic Action 4: *Train HR from relevant stakeholders*

4.1 Develop training programs with customized course-curricula and training materials for specific groups of professionals like Regulators, Providers, Manufacturers, Importers, Distributors and Retailers

4.2 Arrange regularly the Fresher as well as follow-up training programs for the relevant professionals

Strategic Action 6: *Strengthen research activities on PV of vaccines*

6.1 Identify priority areas and projects for research activities on consultation with various stakeholder

6.2 Develop coordinated mechanism to promote research in the prioritized fields

6.3 Create pool fund to support research in the selected areas

Strategic Action 7: *Build capacity in the area of Non-EPI vaccines*

7.1 Strengthen the PV Cell of DGDA with relevant inputs on physical infrastructure and human resources

7.3 Explore the already existing potential infrastructure/facilities for their probable incorporation in the safety surveillance (especially AEFI Reporting) of NEPIVs

7.4 Enhance the ICT infrastructure to use the digital tools and channels for conducting relevant activities like advocacy/ awareness, reporting, education, training, and research

c. Short Term/Mid Term/Long Term Activities

Strategic Action 1: *Revisit and suggest the legislative and regulatory aspects of Non-EPI vaccines*

1.8 Enhance the implementation of the relevant Acts

Strategic Action 3: *Generate and improve the methodology and tools related to AEFI reporting of Non-EPI vaccines*

3.6 Create databases for cumulating the AEFI reports at various levels

Strategic Action 4: *Train HR from relevant stakeholders*

4.3 Review the effectiveness of the training programs following appropriate evaluation projects

d. Mid Term/Long Term Activities

Strategic Action 1: *Revisit and suggest the legislative and regulatory aspects of Non-EPI vaccines*

1.7 Take steps for the modification of the existing or introduction of new legislation, regulatory measures and administrative steps, as appropriate

Strategic Action 5: *Incorporate AEFI issues in the course-curricula of the relevant professional education/training programs*

5.2 Take organized initiatives to incorporate the safety surveillance and AEFI-NEPIV-related education and training in the course-curricula and syllabi of the educational and training programs

5.3 Review the impact of education and training related reforms on the reporting of AEFI of NEPIVs

Strategic Action 7: *Build capacity in the area of Non-EPI Vaccines*

7.2 Create capacity (with appropriate HR and other input) all over the country through the DGDA offices at the district and sub district levels

7.5 Build capacity of the suppliers (manufacturers, importers, distributors and retailers) on the maintenance of adequate supply chain and reporting of AEFI of NEPIVs

7.6 Consider the issues of natural calamities like (flood, cyclones, earth quack) and other crisis situations (like epidemics and pandemics) in the capacity building of the different stakeholders

2. Costing Analysis for the Action Plan of NEPIV-SSS 2025

This needs to be done during the budgetary planning phase of the specific OPs to which the individual activities or sub activities of the NEPIV-SSS 2025 will be assigned. The actual scope of the activities and their scheduling (short- or mid-term and long-term) as well as prioritization (inclusion in PAP) will be important determinants of the budget. A similar process needs to be followed in the routine operational planning of the DGDA and other relevant Directorates/Agencies which will also be involved in the implementation of specific activities/sub activities under the present strategy. By systematically implementing these short to mid-term and long-term activities, its aim to build a resilient and effective surveillance system for Non-EPI vaccines. The ultimate goal is to protect the health of the population, ensure the safe use of Non-EPI vaccines, and reinforce the confidence of the public in the National Immunization Program (NIP).

ANNEXURE 4

ভ্যাকসিন এইএফআই (AEFI) রিপোর্টিং ফরম
(রিপোর্টার, রোগী, প্রতিষ্ঠান এবং ঔষধের বাণিজ্যিক নাম অতীব গোপনীয়)

এইএফআই (AEFI) রিপোর্ট নম্বরঃ | অফিস কর্তৃক পূরণীয় | তারিখঃ

এইএফআই রিপোর্টকারী পূরণ করবেন (টিকা পরবর্তী রোগী হাসপাতালে ভর্তি, জীবন ঝুঁকিপূর্ণ বা মৃত্যু ঘটলে তা মারাত্মক ঘটনা)

☐ মারাত্মক ☐ মারাত্মক নয়

টিকা গ্রহণকারীর নামঃ | লিঙ্গঃ ☐ ছেলে ☐ মেয়ে | জন্ম তারিখ (দিন/মাস/সাল)ঃ...../...../..... বয়সঃ.....

মাতার নামঃ	পিতার নামঃ	স্বামীর নাম (প্রযোজ্য ক্ষেত্রে)ঃ
ফোন নম্বরঃ	জন্ম নিবন্ধন নং (যদি থাকে)ঃ	জাতীয় পরিচয়পত্র নং (যদি থাকে)ঃ

ঠিকানাঃ গ্রাম/বাসা ও রোড নং....., পোঃ....., থানাঃ....., জেলাঃ.....

টিকা প্রদানকারী প্রতিষ্ঠানের নামঃ | ঠিকানাঃ

প্রদানকৃত টিকা সংক্রান্ত তথ্যঃ

টিকার নাম (ব্রান্ডের নাম)	ব্যাচ/লট নং	প্রস্তুতকারীর নাম	টিকা প্রদানের তারিখ	টিকা প্রদানের সময়	ডোজ (১ম/২য়)

ডাইলুয়েন্ট (প্রযোজ্য ক্ষেত্রে) সংক্রান্ত তথ্যঃ

ডাইলুয়েন্ট এর নাম	ব্যাচ/লট নং	মেশানোর তারিখ

টিকা পরবর্তী পার্শ্ব/বিরূপ ঘটনা বা এইএফআই (প্রযোজ্য ক্ষেত্রে এক বা একাধিক টিক (✓) চিহ্ন দিনঃ

☐ ফোঁড়া (Abscess)	☐ খিচুঁনি (Seizure) ☐ জ্বরসহ খিচুঁনি ☐ জ্বর ব্যতীত খিচুঁনি	☐ ইনজেকশনের জায়গায় অনবরত রক্তক্ষরণ
☐ জ্বর ১০২° ফা, এবং এর বেশি	☐ গলা (Cervical) এবং/অথবা বগলের (Axillary) গ্রন্থি ফুলে যাওয়া	☐ এএফপি (Acute Flaccid Paralysis)
☐ ইনজেকশনের জায়গায় মারাত্মক প্রতিক্রিয়া: যেমন লাল হওয়া, ফুলে যাওয়া ☐ তিন দিনের বেশি ☐ নিকটবর্তী অস্থিসন্ধি (জয়েন্ট) ছড়িয়ে যাওয়া	☐ অজ্ঞান হয়ে যাওয়া	☐ এনাফাইলেক্সিস (Anaphylaxis)
☐ ইনজেকশনের জায়গায় শক্ত হওয়া (Nodule)	☐ সাময়িকভাবে মূর্ছা যাওয়া (Fainting)	☐ টক্সিক শক সিনড্রম (Toxic Shock Syndrome)
☐ লালচে দানা/ফুসকুরি	☐ ক্রমাগত জোরে জোরে চিৎকার দেওয়া	☐ এনকেফালোপ্যাথি (Encephalopathy)

অন্যান্য (নির্দিষ্ট করে লিখুন)ঃ .....

হাসপাতালে ভর্তি হলে ভর্তির তারিখঃ...../...../..... | ☐ মৃত্যু হলে মৃত্যুর তারিখঃ...../...../..... | ☐ জনসাধারনের মধ্যে মারাত্মক উদ্বেগ

AEFI শুরু হওয়ার তারিখঃ...../...../..... | AEFI শুরু হওয়ার সময়ঃ...../...../..... | AEFI রিপোর্ট করার তারিখঃ...../...../.....

পরিনতি (শুধুমাত্র মারাত্মক এইএফআই-এর ক্ষেত্রে)ঃ ☐ সুস্থ হচ্ছে ☐ সুস্থ হয়েছে ☐ সুস্থ হয়েছে তবে কিছু সমস্য রয়ে গেছে ☐ সুস্থ হয়নি ☐ মৃত্যু ☐ অজানা

রিপোর্টারের নামঃ	পেশাঃ	মোবাইল নম্বরঃ	ইমেইল (যদি থাকে)ঃ

ঠিকানাঃ গ্রামঃ....., পোঃ....., থানাঃ....., জেলাঃ.....