TITLE: Template for Package & Labelling Information and Patient Information Leaflet

<text> signifies text to be selected or deleted as appropriate.

{text} refers to information to be added.

[For further guidance on how to use this template and populate the different sections, please refer to the guidelines on medical information for Summary product characteristics, patient information leaflet, package and Labeling]

PARTICULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

1. **NAME OF THE MEDICINAL PRODUCT**

   {(Invented) name strength pharmaceutical form}
   {active substance(s)}

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

3. **PHARMACEUTICAL FORM AND CONTENTS**

4. **METHOD AND ROUTE(S) OF ADMINISTRATION**

   <Read the package leaflet before use.>

5. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

   <Keep out of the sight and reach of children.>

6. **OTHER SPECIAL WARNING(S), IF NECESSARY**

   <For prescription use only.>

7. **MANUFACTURING DATE & EXPIRY DATE**

   <MFG. :>

   <EXP. :>

8. **SPECIAL STORAGE CONDITIONS**

9. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

   {Name and Address}

10. MARKETING AUTHORISATION NUMBER(S)

MA No. : {000-000-000}

11. BATCH NUMBER<, DONATION AND PRODUCT CODES>

12. INSTRUCTIONS ON USE

13. UNIQUE IDENTIFIER - HUMAN READABLE DATA, IF NECESSARY

SN {number} [serial number]
NN {number} [national reimbursement number or other national number identifying the medicinal product]>

<Not Applicable>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. **NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

   {(Invented) name strength pharmaceutical form}
   {active substance(s)}

2. **METHOD OF ADMINISTRATION**

3. **MANUFACTURING DATE & EXPIRY DATE**
   <MFG. :>

   <EXP. :>

4. **BATCH NUMBER<, DONATION AND PRODUCT CODES>**

5. **CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

6. **OTHER SPECIAL WARNING(S), IF NECESSARY**

7. **SPECIAL STORAGE CONDITIONS**

8. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

   {Name and Address}

PATIENT INFORMATION LEAFLET

{(Invented) name }
{active substance(s)}

[The PIL is intended to provide:

- Key information to the Patients to enable them to adequately take their medicines and to be informed about important safety information
- Key information to registered physicians, pharmacists, nurses, and other healthcare professionals, when the SmPC is not readily accessible.

The following items must appear in the PIL. In exceptional cases, alternative headings may be acceptable. This should not in any case impact on the content required for the section concerned. Applicants should justify the use of alternative headings (e.g. by reference to user testing results). For certain medicinal products not all items may be relevant, in this case the corresponding heading should not be included.

Sections 2, 3, 6, 7, 8, 9, 10, and 12 must be readable for the patient (The current applicable European Commission's Guideline on the readability of the label and package leaflet of medicinal products for human use is a useful reference document)

Standard statements are given in the template which must be used whenever they are applicable. If the applicant needs to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case-by-case basis.]

<text> signifies text to be selected or deleted as appropriate.

{text} refers to information to be added.

1. **PRESENTATION** [as per the information provided in the SmPC in sections 2 and 6.1]

   <Each ….mL contain(s) active substance(s) of ……mg/µg/gm/IU>

2. **DESCRIPTION** [as per the information provided in the SmPC in sections 1, 3 and 5]

   <Pharmaceutical form, strengh & pharmacology of product.>

3. **INDICATIONS AND USES** [as per the information provided in the SmPC in section 4.1]

   <{X} is used for preventing …….. caused by …….>

   <{X} is given to <age population>

4. **DOSAGE AND ADMINISTRATION** [as per the information provided in the SmPC in section 4.2]

   <Dose>

   <Administration>

   <Revaccination>

5. **METHOD OF ADMINISTRATION** [as per the information provided in the SmPC in section 4.2]

<Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. If either of these two conditions exists, the vaccine should not be administered.>

<Use a separate sterile syringe and needle for each individual patient to prevent transmission of infectious agents from one person to another.>

<Administer X intramuscularly or subcutaneously into the deltoid muscle or lateral mid-thigh. Do not inject intravascularly or intradermally.>

6. **CONTRA-INDICATIONS** [as per the information provided in the SmPC in section 4.3]

The vaccine must not be given:
<- If you are allergic to the active substance or any of the other ingredients of this vaccine>

7. **PRECAUTIONS** [as per the information provided in the SmPC in section 4.4]

<Do not freeze as it may cause the vaccine to lose its effectiveness. Discard the vaccine if it has been frozen>

<If a local reaction (e.g. swelling, discoloration, pain, etc.) occurs after vaccination, please contact a registered doctor, pharmacist, or nurse.>

8. **CO-ADMINISTRATION** [as per the information provided in the SmPC in section 4.5]

<Tell your registered doctor, pharmacist or nurse if you are taking, have recently taken or might take, any other medicines or vaccines, including ayurvedic, unani, or homeopathic medicines.>

9. **USE IN SPECIFIC POPULATIONS** [as per the information provided in the SmPC in sections 4.6 and 4.7]

<Pregnancy>

<Breast-feeding>

<Fertility>

<Children and adolescents>

10. **SIDE EFFECTS** [as per the information provided in the SmPC in section 4.8]

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

<Very common>

<Common>

<Uncommon>

Very common: may affect more than 1 in 10 people Common: may affect up to 1 in 10 people Uncommon: may affect up to 1 in 100 people Rare: may affect up to 1 in 1,000 people Very rare: may affect up to 1 in 10,000 people Not known: frequency cannot be estimated from the

available data

If you get any side effects, talk to your registered doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the **DGDA Bangladesh reporting system in http://www.dgda.gov.bd/**. By reporting side effects you can help provide more information on the safety of this medicine.

11. OVERDOSE [as per the information provided in the SmPC in section 4.9]

<Paediatric population>
<No case of overdose has been reported.>

12. STORAGE [as per the information provided in the SmPC in section 6.4]

<For storage conditions after <reconstitution> <dilution> <first opening> of the medicinal product.>

13. {COMMERCIAL PACK}

14. COMPANY NAME, LOGO & ADDRESS