Annexure-9						
	FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier.					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F09-01	02	DEC' 21	DEC' 26		09.11.21	01 of 04

The following information should be included in CTD Dossier

Part-A: Administrative Information:

1. **Name and address of the Manufacturer of the Drug**:

2. **Manufacturing License Number (for locally manufactured drugs):**
   a) Vaccine:
   b) Biosimilar:

3. **Name of the Drug:**
   a) Generic name (use INN name if included in INN List)
   b) Name of the reference product (Innovator Brand)
   c) Meeting reference of Drug Control Committee for approval (for existing product)
   d) Name under which the drug is proposed to be sold (Optional)

4. Summary of **Product characteristic (SmPC) as per WHO format (Annex-1):**
   a) Qualitative and quantitative composition
   b) Dosage form
   c) Clinical particulars
   d) Pharmacological properties
   e) MA holder name and address (In case of imported product)

5. **Registration Status at USFDA, UKMHRA or included in BNF of the product** *(Only for locally manufactured of new/unintroduced product)*

   Documents for Registration status of the product by **United Status Food & Drug Administration (USFDA)** or **United Kingdom Medicine & Health Product Regulatory Authority (UKMHRA)** or inclusion in **British National Formulary (BNF).**

6. **Particulars and signature of qualified personnel for locally manufacturing products** *(Only for locally manufactured of new/unintroduced product)*

   Particulars of (a) Head of Product Development/Research and Development (b) Head of Quality Assurance (c) Head of Production (Full name, Qualifications, Date of Joining in the applicant's company, Total experience in the Vaccine or Biosimilar or Pharmaceutical industries, PCB Registration Number (If any).

   Application has to be duly signed by the above personnel.

10 NOV 2021

Annexure-9

	FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier.					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F09-01	02	JUL' 21	JUL' 26		09.11.21	02 of 04

7. Application for Importation of Product:

The following additional information are to be provided:

a) Name, address, E-mail address, Telephone number, Fax number of the authorized local agent of exporter (Authorization document has to be appended)

b) **Registration status in the country of origin:** Registration status in the country of origin (COPP of one of the countries has to be submitted).

c) **Registration status of human products in advance countries:** Registration status of at least one of the following seven countries with same brand name: **USA, UK, Germany, France, Australia, Switzerland, Japan or EMA/ WHO PQ** (case to case basis) (COPP of one of the countries has to be submitted)

8. Maximum Retail Price (MRP) or Indicative Price:
(Mention the proposed maximum retail rice (MRP) or Indicative Price)

Part-B: Quality Information

9. Active Ingredient:

a) **General Information**
   i) Nomenclature
   ii) Structure
   iii) General properties (Physico-chemical properties)

b) **Manufacture**
   i) Name and address of Manufacturer

c) **Characterization of Active Ingredient**
   i) Host Cell/Master Seed/Cell line (from Bulk antigen manufacturer)
   ii) Elucidation of structure and other characteristics (from Bulk antigen manufacturer or from compendia) (applicable for Biosimilar product)
   iii) Impurities Profile (if applicable) (from Bulk antigen manufacturer)

d) **Control of drug substances**
   i) Specification
   ii) Analytical procedures
   iii) Validation/Verification of analytical procedures
   iv) Certificate of analysis

Annexure-9						
	FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier.					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F09-01	02	JUL'21	JUL'26		09.11.24	03 of 04

v) Reference of specification for compendia Active Ingredient / Justification of specification for non-compendia Active Ingredient

e) Reference/working standards of Active Ingredient
f) Container closure system of Active Ingredient
g) Stability data of the Active Ingredient (From Bulk antigen manufacturer)

10. Finished Product (FP):

a) Description and composition

b) Product Development:

i) Components of drug product (Bulk Antigen & Excipients)
ii) Formulation development and Justification for overage (if any)
iii) Manufacturing Process Development
iv) Container closure system
v) Microbiological attributes

c) Manufacture

i) Batch size with formula (Proposed Commercial Batch)
ii) Manufacturing process and process control (Process flow, Manufacturing steps, process control)
iii) Control of critical steps and intermediates
iv) Process validation (During submission of application manufacturer will give commitment letter that process validation will be done for first three commercial batches and will submitted to DGDA immediately after completion)

d) Control of excipients

i) Specification for excipients (Pharmacopeia reference has to be mentioned for compendial excipients, for non-compendial it is needed)
ii) Analytical procedures used for testing excipients
iii) Excipients of human or animal origin (TSE/BSE)
iv) Novel excipients (if any)

e) Control of FP

i) Product Specification
ii) Analytical Procedures
iii) Validation/verification of analytical procedures
iv) Certificate of analysis
v) Characterization of impurities/Impurities Profile (if applicable)
vi) Reference of specification for compendial product/Justification of specification for non-compendial product

Annexure-9						
	FORM Title: Check list for Registration Application of Vaccine & Biosimilar products as per CTD format Dossier.					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F09-01	02	JUL' 21	JUL'26		09.11.21	04 of 04

f) Reference standard/ Reference materials/ Working standard

i) Name of the Standards
ii) Name of the Manufacturer
iii) Source of the standard
iv) Certificate of analysis

g) Container closure system

i) Primary packaging material
ii) Secondary packaging material

h) Stability study

i) Accelerated Stability Study Data
ii) Long term stability data

(3-month data at the time of submission and six months before registration with commitment for long-term study)

Part-C: Toxicological Information (For new product/unintroduced products in Bangladesh for DCC):

11. a) Acute, sub-acute and chronic toxicity studies in animals
b) Mutagenicity studies
c) Studies on reproductive system and teratogenicity;
d) Other studies

Part-D: Clinical Information:(For new generic/unintroduced products)

12. a) Clinical study reports:

i) Full clinical study

b) Tabular listing and presentation of all clinical studies:

i) Pharmacokinetics and Pharmacodynamics (In case of Biosimilar)
ii) Studies related to intended therapeutic activity (In case of Biosimilar)
iii) Studies related to secondary pharmacological activity (In case of Biosimilar)
iv) Studies on side-effects/adverse reactions in human subjects

Please Note: Information supplied if found wrong will lead to immediate cancellation of application the product.