South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

PRE-REGISTRATION CONSULTATION MEETING MATERIAL

The CHECKLIST is to be used for the preparation of a formal request to the office of the Chief Regulatory Officer (CRO)/ South African Health Product Regulatory Authority (SAHPRA) for the purpose of the meeting and should be submitted to the SAHPRA.

NOTE: Information to be submitted as:

- **Covering letter explaining briefly the substance of the application;**
- **1 x Hardcopy of all documents for filing;**
- **1 x Hardcopy of 1 & 2 (below) plus ALL on CDs sufficient for each panel member (Max 6)**

Item		✓
1	**MEETING AGENDA**	
	Indicate Type of Meeting requested e.g. A, B or C (Guideline: 20 minutes for scientific presentation; 30 minutes for discussion; 10 min for Expert Committee Panel Response)	
2	**LIST** of expected participants and personal profile [1 page per person]	
	LIST of the specific objectives of outcome that the applicant expects	
	LIST of specific questions to the Expert Committee	
3	**1. PRODUCT DOSSIER:**	
	• Cover page containing the following information:	
	• Name, Address, and contact information of Sponsor;	
	• Name of the Product;	
	• Date of submission;	
	• Identification of the pre-phase;	
	• Name and title and contact information of the person responsible for monitoring • the progress of the application; and	
	• Signature of the Sponsor of sponsor's authorized representative	
	2. Page 2, Table of Contents	
	3. Page 3 to end, information as required for each Pre-Phase in an accurate and complete English version, created in Arial, font 11, and single spacing.	
	4. Information previously submitted: The sponsor is not required to submit information previously submitted but may incorporate the information by reference. The reference must be identified by name, reference number, volume and page number where the information can be found.	

Item		✓
3.1	**Pre-Phase I** (Limited to 30 A4 pages)	
3.1.1	Description of product, including scientific rationale and chemical or biochemical characterization	
3.1.2	Description of the manufacturing facility *(including status of facility e.g. certified for GMP; ISO 9001, etc.)*	
3.1.3	Summary of the manufacturing process including:	
	a. A flowchart;	
	b. A description of the manufacturing process;	
	c. A description of the source and quality of starting materials;	
	d. A description of in-process testing (e.g. quality controls {identity, assay, purity, impurities profile}); and	
	e. Tentative lot-release specifications [descriptions of identity, purity, sterility (e.g. sterilization process, release sterility and endotoxin testing, if applicable), stability, general safety and potency)	
3.1.4	Summary of pre-clinical data of the proposed vaccine that support a clinical study, including:	
	a. Safety studies; and	
	b. Activity studies (e.g. immunogenicity studies, neutralization assays, and investigations in animal protection models) (*linkage of pharmacological and/or toxicological batches to trial batches)*	
3.1.5	Summary of the proposed Phase I study protocol to include:	
	a. Description of study subjects;	
	b. Inclusion / exclusion criteria;	
	c. Statistical considerations; and	
	d. Safety monitoring	
	(Do not include information on study sites, Investigator's CVs, insurance, and informed consent procedures)	
3.1.6	List of questions or issues for discussion e.g.:	
	a. Formulation issues	
	b. Toxicology study design	
	c. Use of a novel excipient	
	d. Adequacy of in-process or lot release tests	
	e. Phase I trial design, and	
	f. Proposed label indication	
3.2	**Pre-Phase II** [Limited to 40 A4 pages]	
3.2.1	Description of product, including scientific rationale and chemical /biochemistry characterization	
3.2.2	Description of the manufacturing facility (*including status of facility e.g. certified for GMP; ISO 9001, etc.)*	
3.2.3	Summary of the manufacturing process including:	

Item		✓
	a. A flowchart	
	b. A description of the manufacturing process	
	c. A description of the source and quality of starting materials	
	d. A description of in-process testing, and	
	e. Tentative lot-release specifications (descriptions of identity, purity, sterility, stability, general safety and potency)	
3.2.4	Summary of pre-clinical data of the proposed vaccine that support a clinical study, including:	
	a. Safety studies; and	
	b. Activity studies (e.g. immunogenicity studies, neutralization assays, and investigations in animal protection models)	
3.2.5	Summary of the proposed Phase II study protocol including:	
	a. Design	
	b. Description of study subjects	
	c. Inclusion / exclusion criteria	
	d. Statistical consideration	
	e. Efficacy endpoints and correlates of protection, and	
	f. Safety monitoring	
	(Do not include information on study sites, Investigator's CVs, insurance, and informed consent procedures)	
3.2.6	List of questions or issues for discussion e.g.:	
	a. Formulation issues	
	b. Toxicology study design	
	c. Use of a novel adjuvant	
	d. Adequacy of in-process or lot release tests	
	e. Phase II trial design	
	f. Target population in South Africa	
	g. Measures of efficacy and safety	
	h. Proposed label indication, and	
	i. Package inserts	
3.3	**Pre-Phase III** (Limited to 50 A4 pages)	
3.3.1	Description of product, including scientific rationale and chemical /biochemistry characterization	
3.3.2	Description of the manufacturing facility *(including status of facility e.g. certified for GMP; ISO 9001)*	
3.3.3	Summary of the manufacturing process including:	
	a. A flowchart	
	b. A description of the manufacturing process	
	c. A description of the source and quality of starting materials	

Item		✓
	d. A description of in-process testing	
	e. Tentative lot-release specifications (descriptions of identity, purity, sterility, stability, general safety and potency).	
3.3.4	Summary of pre-clinical data of the proposed vaccine that support a clinical study, including:	
	a. Safety studies; and	
	b. Activity studies (e.g. immunogenicity studies, neutralization assays, and investigations in animal protection models)	
3.3.5	Detailed description of Phase I safety data and Phase II safety and efficacy data	
3.3.6	Previous human data relevant to the product (or similar products), if available, including relevant immunogenicity of efficacy data as appropriate	
3.3.7	Summary of the proposed Phase III study protocol to include:	
	a. Design	
	b. Description of study subjects	
	c. Inclusion / exclusion criteria	
	d. Statistical considerations	
	e. Efficacy endpoints and correlates of protection, and	
	f. Safety Monitoring	
	(Do not include information on study sites, investigators CVs, insurance, informed consent procedures)	
3.3.8	Summary of data on the product that support its clinical application in human subjects	
3.3.9	List of questions or issues for discussion e.g.:	
	a. Formulation issues	
	b. Trial design	
	c. Measures of efficacy and safety	
	d. Target population in South Africa, and	
	e. Proposed package inserts	

UPDATE HISTORY

Date	Reason for update	Version & publication
June 2014	First version approved for implementation	Version 1, March 2015
March 2015	Date of implementation	