DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

CHECKLIST FOR SUBMISSION OF APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS
PART III REQUIREMENTS (NONCLINICAL DOCUMENT)

The table below provides as a checklist of information required for the application of registration of medicinal products for the various product classifications.

Product Name:		**Reference No.:**

Part III: Document	**APPLICANT Application Type**							**DRU**	**DRU Remarks**
			MaV			**MiV**	**GP**		
	NCE	**BIOTECH**	**RT**	**S/P**	**IND**				
Section A. Table of Content	☐	☐	☐	☐	☐				
Section B. Nonclinical Overview	☐	☐							
1. General Aspect	☐	☐							
2. Content and structural format	☐	☐							
Section C. Nonclinical Summary (Written and Tabulated)	☐	☐							
1. **Nonclinical Written Summaries**	☐	☐							
1.1 Introduction	☐	☐							
1.2 General Presentation Issues	☐	☐							
2. **Nonclinical Written and Tabulated Summaries**	☐	☐							
2.1 Pharmacology									
2.1.1 Written summary	☐	☐							
2.1.1.1 Primary Pharmacodynamics	☐	☐							
2.1.1.2 Secondary Pharmacodynamics	☐	☐							
2.1.1.3 Safety Pharmacology	☐	☐							
2.1.1.4 Pharmacodynamics Drug Interactions	☐	☐							
2.1.1.5 Tabulated Summary	☐	☐							

Part III: Document	APPLICANT Application Type							DRU	DRU Remarks
			MaV			MiV	GP		
	NCE	BIOTECH	RT	S/P	IND				
2.2 Pharmacokinetics									
2.2.1 Written summary	☐	☐							
2.2.1.1 Absorption	☐	*☐	*☐	*☐					
2.2.1.2 Distribution	☐	*☐	*☐	*☐					
2.2.1.3 Metabolism	☐	*☐	*☐	*☐					
2.2.1.4 Excretion	☐	*☐	*☐	*☐					
2.2.1.5 Pharmacokinetics Drug Interactions (non-clinical)	☐								
2.2.1.6 Other Pharmacokinetic Studies	☐		*☐						
2.2.2 Tabulated Summary	☐	☐							
2.3 Toxicology									
2.3.1 Written Summary	☐	☐							
2.3.1.1 Single dose toxicity	☐	☐							
2.3.1.2 Repeat dose toxicity	☐	☐							
2.3.1.3 Genotoxicity	☐								
2.3.1.4 Carcinogenicity	☐	**☐							
2.3.1.5 Reproductive and developmental toxicity	☐	☐							
2.3.1.5.1 Fertility and early embryonic development	☐	☐							
2.3.1.5.2 Embryo-fetal development	☐	☐							
2.3.1.5.3 Pre-natal and post-natal development	☐	☐							
2.3.1.6 Local tolerance	**☐	**☐	**☐	**☐	**☐				
2.3.1.7 Other toxicity studies, if available	**☐	**☐	**☐	**☐	**☐				
2.3.2 Tabulated Summary	☐	☐							

Part III: Document	APPLICANT Application Type							DRU	DRU Remarks
			MaV			MiV	GP		
	NCE	BIOTECH	RT	S/P	IND				
Section D. Nonclinical Study Report (As requested)									
1. **Table of Content**	☐	☐							
2. **Study Reports**									
2.1 Pharmacology									
2.1.1 Primary Pharmacodynamics	☐	☐							
2.1.2 Secondary Pharmacodynamics	☐	☐							
2.1.3 Safety Pharmacology	☐	☐							
2.1.4 Pharmacodynamic Drug Interactions	☐	☐							
2.2 Pharmacokinetics									
2.2.1 Analytical Methods and Validation Reports	☐	*☐							
2.2.2 Absorption	☐	*☐	*☐	*☐					
2.2.3 Distribution	☐	*☐	*☐	*☐					
2.2.4 Metabolism	☐	*☐	*☐	*☐					
2.2.5 Excretion	☐	*☐	*☐	*☐					
2.2.6 Pharmacokinetics Drug Interaction (non-clinical)	☐	*☐							
2.2.7 Other Pharmacokinetic Studies	☐	*☐	*☐						
2.3 Toxicology									
2.3.1 Single dose toxicity	☐	☐							
2.3.2 Repeat dose toxicity	☐	☐							
2.3.3 Genotoxicity	☐								
2.3.3.1 *In vitro*	☐								
2.3.3.2 *In vivo*	☐								
2.3.4 Carcinogenicity	☐	*☐							
2.3.4.1 Long-term studies	☐	*☐							
2.3.4.2 Short-or medium-term studies	☐	*☐							
2.3.4.3 Other studies	☐	*☐							

Part III: Document	APPLICANT Application Type							DRU	DRU Remarks
			MaV			MiV	GP		
	NCE	BIOTECH	RT	S/P	IND				
2.3.5 Reproductive and developmental toxicity	☐	☐							
2.3.5.1 Fertility and early embryonic development	☐	☐							
2.3.5.2 Embryo-fetal development	☐	☐							
2.3.5.3 Pre-natal and post-natal development	☐	☐							
2.3.5.4 Studies in which the offspring are dosed and/or further evaluated	☐	☐							
2.3.6 Local tolerance	*☐	*☐	*☐	*☐	*☐				
2.3.7 Other Toxicity Studies, if available	*☐	*☐	*☐	*☐	*☐				
2.3.7.1 Antigenicity									
2.3.7.2 Immunotoxicity									
2.3.7.3 Dependence									
2.3.7.4 Metabolites									
2.3.7.5 Impurities									
2.3.7.6 Other									
Section E. List of Key Literature References	☐	☐	*☐	*☐	*☐				

NCE - New chemical entity
Biotech - Biotechnology-derived product
MaV - Major variation *(Pharmaceutical product that have undergone variation affecting one or more of the following : the route of administration, strength and posology, indications. The submission of additional data is required and necessary to establish the quality, safety and efficacy of the new formulation resulting from the variation)*
RT - Route of administration
S / P - Strength and Posology
IND - Indication
MiV - Minor Variation *(Pharmaceutical product that have undergone variation affecting one or more of the following : route of administration, strength and posology, indications or active ingredient/s. The submission of additional data is required and necessary to establish the quality of the new formulation resulting from the variation)*
GP - Generic product
*☐ - Where applicable, i.e. change of route of administration due to change in formulation
**☐ - Generally inappropriate for biotechnology-derived products, however, product-specific assessment of carcinogenic potential may be needed depending upon duration of clinical dosing, patient population and /or biological activity of the product (eg. Growth factors, immunosuppressive agents, etc