DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
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CHECKLIST FOR SUBMISSION OF APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS PART IV REQUIREMENTS (CLINICAL 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.:**	

Section	**Document**	**APPLICANT** APPLICATION TYPE							**DRU**	**DRU Remarks**
				MaV			**MiV**	**GP**		
		NCE	**BIOTECH**	**RT**	**S/P**	**IND**				
A	**Table of Contents**	☐	☐	☐	☐	☐				
B	**Clinical Overview**	☐	☐	☐	☐	☐				
	1. Product Development Rationale	☐	☐	☐	☐	☐				
	2. Overview of Biopharmaceutics	☐	☐	☐	☐	☐				
	3. Overview of Clinical Pharmacology	☐	☐	☐	☐	☐				
	4. Overview of Efficacy	☐	☐	☐	☐	☐				
	5. Overview of Safety	☐	☐	☐	☐	☐				
	6. Benefits and Risks Conclusions	☐	☐	☐	☐	☐				
C	**Clinical Summary**	☐	☐	☐	☐	☐				
	C1. Summary of Biopharmaceutic Studies and Associated Analytical Methods	☐	☐	☐	☐	☐				
	1.1 Background and Overview	☐	☐	☐	☐	☐				
	1.2 Summary of Results of Individual Studies	☐	☐	☐	☐	☐				
	1.3 Comparison and Analyses of Results Across Studies	☐	☐	☐	☐	☐				
	Appendix 1	☐	☐	☐	☐	☐				

Section	Document	APPLICANT							DRU	DRU Remarks
		APPLICATION TYPE								
		NCE	BIOTECH	MaV			MiV	GP		
				RT	S/P	IND				
	C2. Summary of Clinical Pharmacology Studies	☐	☐	☐	☐	☐				
	2.1 Background and Overview	☐	☐	☐	☐	☐				
	2.2 Summary of Results of Individual Studies	☐	☐	☐	☐	☐				
	2.3 Comparison and Analyses of Results Across Studies	☐	☐	☐	☐	☐				
	2.4 Special Studies	☐	☐	☐	☐	☐				
	Appendix 2	☐	☐	☐	☐	☐				
	C3. Summary of Clinical Efficacy	☐	☐	☐	☐	☐				
	3.1 Background and Overview of Clinical Efficacy	☐	☐	☐	☐	☐				
	3.2 Summary of Results of Individual Studies	☐	☐	☐	☐	☐				
	3.3 Comparison and Analyses of Results Across Studies	☐	☐	☐	☐	☐				
	3.4 Analysis of Clinical Information Relevant to Dosing Recommendations	☐	☐	☐	☐	☐				
	3.5 Persistence of Efficacy and/or Tolerance Effects	☐	☐	☐	☐	☐				
	Appendix 3	☐	☐	☐	☐	☐				
	C4. Summary of Clinical Safety	☐	☐	☐	☐	☐				
	4.1 Exposure to the Drug	☐	☐	☐	☐	☐				
	4.2 Adverse Events	☐	☐	☐	☐	☐				
	4.3 Clinical Laboratory Evaluations	☐	☐	☐	☐	☐				
	4.4 Vital Signs, Physical Findings, and Other Observations Related to Safety	☐	☐	☐	☐	☐				
	4.5 Safety in Special Groups and Situations	☐	☐	☐	☐	☐				
	4.6 Post-marketing Data	☐	☐	☐	☐	☐				
	Appendix 4	☐	☐	☐	☐	☐				

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		APPLICATION TYPE								
		NCE	BIOTECH	MaV RT	MaV S/P	MaV IND	MiV	GP		
	C5. Synopses of Individual Studies	☐	☐	☐	☐	☐				
D	**Tabular Listing of All Clinical Studies**	☐	☐	☐	☐	☐				
E	**Clinical Study Reports (if applicable)**	☐	☐	☐	☐	☐				
	E1. Reports of Biopharmaceutic Studies	☐	☐	☐	☐	☐				
	1.1 Bioavailability (BA) Study Reports	☐	☐	☐	☐	☐				
	1.2 Comparative BA or Bioequivalence (BE) Study Reports	☐	☐	☐	☐	☐				
	1.3 *In vitro-In vivo* Correlation Study Reports	☐	☐	☐	☐	☐				
	1.4 Reports of Bioanalytical and Analytical Methods for Human Studies	☐	☐	☐	☐	☐				
	E2. Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials	☐	☐	☐	☐	☐				
	2.1 Plasma Protein Binding Study Reports	☐	☐	☐	☐	☐				
	2.2 Reports of Hepatic Metabolism and Drug Interaction Studies	☐	☐	☐	☐	☐				
	2.3 Reports of Studies Using Other Human Biomaterials	☐	☐	☐	☐	☐				
	E3. Reports of Human Pharmacokinetic (PK) Studies	☐	☐	☐	☐	☐				
	3.1 Healthy Subject PK and Initial Tolerability Study Reports	☐	☐	☐	☐	☐				
	3.2 Patient PK and Initial Tolerability Study Reports	☐	☐	☐	☐	☐				
	3.3 Population PK Study Reports	☐	☐	☐	☐	☐				
	E4. Reports of Human Pharmacodynamic (PD) Studies	☐	☐	☐	☐	☐				
	4.1 Healthy Subject PD and PK/PD Study Reports	☐	☐	☐	☐	☐				
	4.2 Patient PD and PK/PD Study Reports	☐	☐	☐	☐	☐				

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	E5. Reports of Efficacy and Safety Studies	☐	☐	☐	☐	☐				
	5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication	☐	☐	☐	☐	☐				
	5.2 Study Reports of Uncontrolled Clinical Studies	☐	☐	☐	☐	☐				
	5.3 Reports of Analyses of Data from More Than One Study, Including Any Formal Integrated Analyses, Meta-analyses, and Bridging Analyses	☐	☐	☐	☐	☐				
	5.4 Other Clinical Study Reports	☐	☐	☐	☐	☐				
	E6. Reports of Post-Marketing Experience	☐	☐	☐	☐	☐				
	E7. Case Report Forms and Individual Patient Listing	☐	☐	☐	☐	☐				
F	**List of Key Literature References**	☐	☐	☐	☐	☐				

Legends:

NCE - New Chemical Entity
Biotech - Biotechnological Products
MaV - Major Variation *(Pharmaceutical product that have undergone variation affecting one or more of the following aspects : the route of administration, strength and posology, indications.*
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 aspects : route of administration, strength and posology, indications and active ingredient(s).*
GP - Generic Products