DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

CHECKLIST FOR SUBMISSION OF APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS
PART 1: ADMINISTRATIVE DATA & PRODUCT INFORMATION

Application Reference No. :

Product Name :

Name of Company :

No.	Items	Applicant	DRU
1.	Letter of Intent		
2.	**Section 1** - **Application Form (Form No: BDMCA/DPS/01)**		
	2.1 Form signed by applicant		
3.	Company Registration Certificate		
4.	**Section 2** - **Letter of Authorisation**		
	4.1 Original Copy of Letter of Authorisation from Product Owner to Applicant		
	4.2 Copy of Letter of Authorisation from Product Owner to Manufacturer(s) of Finished Product including Repacker and Batch Releaser and Copy of Letter of Acceptance from the Manufacturer(s) of Finished Product including Repacker and Batch Releaser, if applicable		
5.	**Section 3** – **Certifications**		
	5.1 For Locally Manufactured Products:		
	5.1.1 Copy of Licence of Pharmaceutical Industries		
	5.1.2 Copy of GMP Certificate of the Manufacturer of Active Pharmaceutical Ingredient(s)		
	5.1.3 Copy of GMP Certificate of the Manufacturer of Finished Product		
	5.2 For Imported Products		
	5.2.1 Copy of Licence of Pharmaceutical Industries; Importers and Wholesalers		
	5.2.2 Pharmacists Certificate of Registration and Pharmacist Annual Practicing Certificate, if applicable		
	5.2.3 Original copy of Certificate of Pharmaceutical Product (CPP) issued by the Competent Authority in the Country of Origin. Certificate is not more than 2 years from the date of issue		
	5.2.4 Copy of GMP Certificate of the Manufacturer of Active Pharmaceutical Ingredient(s)		
	5.2.5 Copy of GMP Certificate of the Manufacturer(s) of Finished Product including Repacker and Batch Releaser, if applicable.		
6.	**Section 4** – **Product Labelling**		
	6.1 Unit Carton		
	6.2 Inner Label		
	6.3 Blister Label		
7.	**Section 5** – **Product Information**		
	7.1 Proposed Package Insert for Generic Products.		
	7.2 Proposed Summary of Product Characteristics (SmPC) for Generic Products (*optional*), New Chemical Entity (NCE) and Biotechnological Products		
	7.3 Patient Information Leaflet (PIL) for Over-The Counter Products		
	7.4 Approved SmPC / Package Insert / PIL from at least 3 benchmark regulatory agencies (*if applicable*) including the regulatory agency of the Country of Origin.		
8.	Application documents arranged in proper order, clearly indicated and filed		
9.	Additional documents required by DRU from the applicant:		