DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

CHECKLIST FOR SUBMISSION OF APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS
PART 1 REQUIREMENT (ADMINISTRATIVE DATA & PRODUCT INFORMATION)

Application No:	**L O A - P / / S**
Product Name:	
Name of Applicant:	

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.	Processing fee of B$200.00		
4.	Company Registration Certificate		
5.	**Section 2** - **Letter of authorisation from the product owner / manufacturer**		
6.	**Section 3 – Certifications**		
	***6.1 For contract manufacturing*:**		
	6.1.1 Copy of licence of pharmaceutical industries and contract manufacturer endorsed by the Brunei Darussalam Embassy / Notary Public		
	6.1.2 Copy of contract manufacturing agreement endorsed by the Brunei Darussalam Embassy / Notary Public		
	6.1.3 Original copy of GMP certificate of contract manufacturer		
	6.2 For manufacturing "under licence":		
	6.2.1 Copy of licence of pharmaceutical industries endorsed by the Brunei Darussalam Embassy / Notary Public.		
	6.2.2 Original copy of GMP certificate of the manufacturer		
	6.2.3 Copy of "under-licence" agreement endorsed by the Brunei Darussalam Embassy / Notary Public		
	6.3 For locally manufactured products (excluding the above):		
	6.3.1 Copy of licence of pharmaceutical industries		
	6.3.2 Original copy of GMP certificate of the manufacturer		
	6.4 For imported products		
	6.4.1 Copy of Licence of pharmaceutical industries; importers and wholesalers		
	6.4.2 Original copy of certificate of pharmaceutical product issued by the competent authority in the country of origin. Certificate is not more than 2 years from the date of issue		
	6.4.3 Copy of GMP certificate of the manufacturer endorsed by the Brunei Darussalam Embassy/Notary Public or site master file of the manufacturer (unless previously submitted within the last 2 years and if GMP certificate cannot be produced) [Optional]		
7.	**Section 4 – Product Labelling**		
	7.1 Unit carton		
	7.2 Inner label		
	7.3 Blister / strips		
8.	**Section 5 – Product Information**		
	8.1 Proposed Package Insert for generic products.		
	8.2 Proposed Summary of Product Characteristics (SPC) for generic products (*optional*), new chemical entity and biotechnology products		
	8.3 Patient Information Leaflet (PIL) for over-the counter products		
	8.4 Approved Summary of Product Characteristic / package insert / PIL from at least three benchmark regulatory agencies (*if applicable*) recognised by DPS including the regulatory agency of the Country of Origin.		
9.	Application documents arranged in proper order, clearly indicated and filed		
10.	Additional documents required by DRU from the applicant:		