DEPARTMENT OF PHARMACEUTICAL SERVICES MINISTRY OF HEALTH BRUNEI DARUSSALAM

CHECKLIST FOR SUBMISSION OF APPLICATION FOR AN IMPORT PERMIT OF A MEDICINAL PRODUCT ON CONSIGNMENT BASIS

| For Official Use only | | |
|-------------------------------|--|--|
| Application No.: | | |
| Date of Application Received: | | |

| To be filled in by Applicant | | | |
|---------------------------------|--|--|--|
| Name of Applicant & Company | | | |
| | | | |
| | | | |
| Name of Product to be Imported: | | | |

| D | Documentations / Items Required for Submission of Application for An Import Permit of A Medicinal Product on Consignment Basis | | | | |
|-----|---|-----------|-----|--|--|
| No. | Items | Applicant | DRS | | |
| 1. | Application Form for An Import Permit of A Medicinal Product on Consignment Basis. | | | | |
| 2. | A copy of the Business Registration Certificate for Company; OR | | | | |
| | Certificate of Incorporation for Private Ltd Company & Memorandum and Articles of Association. | | | | |
| 3. | Copy of Poisons Licence (if applicable). | | | | |
| 4. | Copy of Import Permit for Psychotropic Drugs; OR Copy of Import Permit for Narcotic Drugs (<i>if applicable</i>). | | | | |
| 5. | Statement from the exporter that the company is a registered pharmaceutical dealer in the exporting country. | | | | |
| 6. | Documentary evidence to show that the product is registered in the exporting country. | | | | |
| 7. | Certificate of Analysis of the product to be imported from the manufacturer or from an approved local testing laboratory; OR | | | | |
| | Documentation on Good Distribution Practice compliance throughout the supply chain from the source of manufacture to importation. | | | | |
| 8. | An undertaking from the applicant that it will be responsible for the quality, safety and efficacy of the product. | | | | |
| 9. | A copy of the invoice from the exporter, indicating <i>the batch number</i> and <i>expiry date</i> of the product to be imported. | | | | |
| 10. | The sample of the proposed product (sufficient for use in assessing the product conformity and as retention sample for future reference) and its packaging and labeling materials including inserts, brochures, etc. | | | | |