1) INTRODUCTION

1.1) All medicinal products manufactured, sold, supplied or imported into Brunei Darussalam are regulated under the **Medicines Order, 2007**.

1.2) Under the Medicines Order, there are five licences that may be issued by the Brunei Darussalam Medicines Control Authority including Import Licence and Wholesaler's Licence.

1.3) The **Import Licence** and **Wholesaler's Licence** are required with respect to the importation, storage and supply of medicinal products in Brunei Darussalam.

1.4) **IMPORT LICENCE**

1.4.1) An **Import Licence** is required for the importation of medicinal products into Brunei Darussalam with the exception of medicinal products imported for the following purposes:

a) Personal use as part of his personal luggage (with a quantity not exceeding one month's use by one person);

b) A public officer importing any medicinal product in the course of his duty;
c) Any person, who in accordance with the written consent of the Authority, bringing any medicinal product into Brunei in transit;
d) Research in a school of pharmacy or a research or training institution;
e) Treatment of any person suffering from a life-threatening illness.

1.4.2) There are **two types** of Import Licence as shown below:

	TYPES OF IMPORT LICENCE	REMARKS
1)	**Licence for Importation Authorised by Product Licence Holder**	This licence can also be applied for by the product licence holder itself.
2)	**Licence for Importation Not Authorised by Product Licence Holder Per Consignment Imported**	Please refer to separate 'Guide to Application for An Import Permit of a Medicinal Product on Consignment Basis' and 'Guide to Application for Importation of Unregistered Medicinal Products'.

1.4.3) The Import Licence will authorise the licensee to import, store and sell by wholesale or supply registered medicinal products from premises specified in the licence.

Note: *Responsibilities of an Import Licence holder are described in* ***Appendix 1****.*

1.5) **WHOLESALER'S LICENCE**

1.5.1) A **Wholesaler's Licence** is required by a company to sell by wholesale or supply registered medicinal products from its business premises. This licence is however not

required if a company already holds an *Import Licence* for the medicinal products that it wishes to sell or supply.

1.5.2) The Wholesaler's Licence will authorise the licensee to sell by wholesale or supply registered medicinal products from premises specified in the licence.

***Note:** Responsibilities of a Wholesaler's Licence holder are described in **Appendix 2**.*

2) SCOPE

This guideline is intended to provide assistance in the submission of application for an Import Licence and a Wholesaler's Licence for medicinal products.

3) APPLICATION PROCEDURES FOR IMPORT / WHOLESALER'S LICENCE

3.1) There are **three types** of application that can be made with respect to an **Import Licence** and a **Wholesaler's Licence**:

a) **New** licence
b) **Renewal** of licence
c) **Amendment** of existing licence

3.2) **NEW IMPORT / WHOLESALER'S LICENCE**

3.2.1) *WHO CAN APPLY*

Any company registered under the Registry of Companies and Business Names in Brunei Darussalam is eligible to apply. The company should authorise a responsible person *(e.g. Director, Manager, Pharmacist* or *Sales Manager)* who is based in Brunei Darussalam to apply for the licence.

PREREQUISITE:

New applicant must first sit for a test arranged by the Pharmacy Enforcement Section if any medicinal product to be imported contains a poison listed in the Poisons List of the Poisons Act.

3.2.2) *WHEN TO APPLY*

At least **3 months** before the registered medicinal product is to be imported.

3.2.3) *HOW TO APPLY*

i) Applicant will need to fill out and submit the *Application Form for Import Licence and Wholesaler's Licence for Medicinal Products* along with its supporting documents as listed below:

NO.	SUPPORTING DOCUMENTS
1)	A copy of applicant's **Identity Card** issued in Brunei Darussalam.
2)	A copy of **Business Certificate of Registration** (Sections 16 & 17); or **Certificate of Incorporation and Memorandum of Article & Association**.
3)	Layout plan of the **storage area**.
4)	List of **registered medicinal products** (arranged alphabetically in hard and soft copies). *(**Note:** This list shall contain the Product Name; Pack size; Name & Country of Manufacturer; Product Licence Number and Validity Period.)*
5)	Copy of each of the **Product Licences**. *(**Note:** These will be returned to the applicant <u>after completion</u> of the screening process.)*
NO.	**SUPPORTING DOCUMENTS**
6)	**Authorisation letter** issued by the <u>Product Licence holder</u> if its **company is not the product licence holder**.
7)	**Authorisation letter** issued by the <u>company</u> authorising the applicant to apply for the licence on its behalf, if **applicant is not the company owner**.

ii) **One photocopy** of the <u>application form</u> and <u>supporting documents</u> *(only for items no. 1 – 3 above)* are required to be submitted with the original form and the complete set of supporting documents.

3.3) **RENEWAL**

3.3.1) *WHO CAN APPLY*

A company with an **existing** Import Licence or Wholesaler's Licence may apply for renewal of its licence.

3.3.2) *WHEN TO APPLY*

At least **3 months** before the licence is due to expire.

3.3.3) *HOW TO APPLY*

Applicant will need to fill out and submit the *Application Form for Import Licence and Wholesaler's Licence for Medicinal Products* along with its supporting documents as listed below:

NO.	SUPPORTING DOCUMENTS
1)	A copy of previous **Import Licence**.
2)	A copy of applicant's **Identity Card** issued in Brunei Darussalam.
4)	Layout plan of the **storage area** *(only required if there was any change made to the previous layout plan)*.
5)	List of **registered medicinal products** (arranged alphabetically in hard and soft copies). *(**Note:** This list shall contain the Product Name; Pack size; Name & Country of Manufacturer; Product Licence Number and Validity Period. Any new product entry must be typed in **bold** letters.)*
6)	Copy of each of the **Product Licences** *(only required for additional medicinal products)*. *(**Note:** These will be returned to the applicant <u>after completion</u> of the screening process.)*
7)	**Authorisation letter** (original copy) issued by the <u>Product Licence holder</u> if its **company is not the product licence holder**.
8)	**Authorisation letter** (original copy) issued by the <u>company</u> authorising the applicant to apply for the licence on its behalf, if **applicant is not the company owner**.

3.4) **AMENDMENT**

3.4.1) *WHO CAN APPLY*

A company with an **existing** Import Licence or Wholesaler's Licence may apply for an amendment to any particulars contained in its licence including to the *List of Registered Medicinal Products for Import Licence* or *Wholesaler's Licence*.

3.4.2) *TYPES OF AMENDMENT AND SUPPORTING DOCUMENTS REQUIRED*

	No.	Types of Amendment	Supporting Documents	Remarks
1) Company Details	1.1)	**Business Address**	□ Copy of Business Certificate of Registration (Sections 16 and 17)	-
	1.2)	**Company Name**	□ Copy of Business Certificate of Registration (Sections 16 and 17)	-
	1.3)	**Company Owner**	□ Copy of Business Certificate of Registration (Sections 16 and 17)	-
	1.4)	**Responsible Person**	□ Nil	-

	1.5)	**Store Address / Layout Plan / Floor Area**	□ Layout plan of the new Storage Area.	**Inspection required**
2) List of Registered Medicinal Products for Import	2.1)	**Addition of Registered Medicinal Product**	• Copy of Product Licence. • Authorisation letter issued by the Product Licence holder if its company is not the product licence holder.	-
	2.2)	**Deletion of Registered Medicinal Product**	□ Nil	-
	2.3)	**Product Licence**	□ Copy of new Product Licence and/or Letter of Approval for Variations to a Registered Medicinal Product.	-
	2.4)	**Product Licence Holder**	• Copy of new Product Licence. • Authorisation letter issued by the new Product Licence holder if its company is not the new product licence holder.	-

Note: *A change in company responsible for importing the medicinal products to another company that has no existing Import Licence or Wholesaler's Licence will require submission of a* ***new application*** *by the latter company.*

3.4.3) *WHEN TO APPLY*

	No.	Types of Amendment	Time Frame
1) Company Details	1.1)	**Business Address**	Within **7 working days** from the issue date of the new business **Certificate of Registration**.
	1.2)	**Company Name**	
	1.3)	**Company Owner**	
	1.4)	**Responsible Person**	At least **7 working days** before the change is due to take effect.
	1.5)	**Store Address / Layout Plan / Floor Area**	During its **proposal period**. ***Note:*** *Current or new store address/storage area is* ***not allowed*** *to be changed or used respectively, until it has been inspected and approved by the Authority.*
	2.1)	**Addition of Registered Medicinal Product**	Every **2 months**.

2) List of Registered Medicinal Products for Import	2.2)	**Deletion of Registered Medicinal Product**	**Immediately** or within **7 working days** from intended deletion date.
	2.3)	**Product Licence**	Within **7 working days** from the issue date of the new **Product Licence**.
	2.4)	**Product Licence Holder**	

3.4.4) *HOW TO APPLY*

The company will need to fill out and submit the **Application Form for Amendment to an Import Licence and Wholesaler's Licence for Medicinal Products** to the Drug Administration Section.

4) FEES

4.1.1)	Application for Import Licence	**$50**	*(Payable upon submission of application)*
4.1.2)	Application for Wholesaler's Licence	**$100**	*(Payable upon submission of application)*
4.1.3)	Renewal of Import Licence	**$50**	*(Payable upon collection of licence)*
4.1.4)	Renewal of Wholesaler's Licence	**$100**	*(Payable upon collection of licence)*

4.1.5) Amendment Fee

- With site inspection **$35**
- Without site inspection **$25**

(Payable upon collection of licence)

Note: *Payments can either be made in the forms of* ***cash*** *or* ***cheque*** *only and are* ***non-refundable****. Payments by cheque shall be made payable to "Kerajaan Brunei" or "Government of Brunei".*

5) CRITERIA FOR LICENCE APPROVAL

5.1) Applicant complies to all relevant provisions under the *Medicines Order, 2007* and its related *Regulations*, *Poisons Act 1956*, *Misuse of Drugs Regulations* and as well as to all terms and conditions imposed by the Authority.

5.2) Complete application form and supporting documents are submitted.

5.3) Premises inspected comply with inspection requirements.

6) VALIDITY OF LICENCE

The validity of an Import Licence and a Wholesaler's Licence is **one year**.

Note: *Approval for importation of a medicinal product is subject to the validity of its Product Licence.*

7) HOW TO OBTAIN APPLICATION FORMS

The **Application Form for Import Licence and Wholesaler's Licence for Medicinal Products** can be obtained from the:

a) **Compliance & Licensing Section**
First Floor,
Department of Pharmaceutical Services Building,
Spg: 433, Kg Madaras
Rimba Highway Mukim Gadong 'A'
Brunei Darussalam
Tel: 2393298 (Extension: **208**) **Fax: 2393291**

8) SUBMISSION OF APPLICATIONS

All applications either for a new, to renew or amend an Import Licence or Wholesaler's Licence, the respective supporting documents and fee (if applicable) must be submitted to:

Compliance & Licensing Section
First Floor,
Department of Pharmaceutical Services Building,
Spg: 433, Kg Madaras
Rimba Highway Mukim Gadong 'A'
Brunei Darussalam
Tel: 2393298 (Extension: **208**) **Fax: 2393291**

Submission of applications can be made on **working hours (Monday to Thursday, Saturday**). Please take note that payment can be made on **Monday to Thursday only from 8am to 11.30am** (8am to 10.30am for Ramadhan month) during government working days**.**

9) ENQUIRIES

For more information or enquiries regarding your licence application, please contact the **Compliance & Licensing Section**, Department of Pharmaceutical Services on **2393298** (ext: **208**).

Appendix 1

RESPONSIBILITIES OF AN IMPORT LICENCE HOLDER

An **Import Licence holder** must comply to the following requirements as per stipulated in *Regulation 2(b) of the Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010* of the *Medicines Order, 2007*:

1) To report to the Authority of any change in his name and any address (business, store or correspondence) to which the licence relates.

2) To undertake to arrange tests and submit samples as may be required or requested by the Authority at the licence holder's own expenses.

3) To inform the Authority of any change in material or particulars contained in his application with respect to any medicinal product to which the licence relates *i.e.* in terms of the:

    a) Specification of the medicinal product;
    b) Specification of any of the constituents of the medicinal product;
    c) Composition of the medicinal products, or any of the constituents of the medicinal product; or d) Manufacture of the medicinal product.

4) To withhold from sale, supply or exportation any batch of medicinal product that has been found to be harmful, unsafe or not to conform with the product specifications as regards strength, quality or purity, and to withdraw the defective medicinal product from the market immediately, if so directed by the Authority.

5) To keep records of importation, sale, supply or exportation of medicinal product readily available for inspection by a person authorised by the Authority and to allow the authorised person to take copies or make extracts from such records, which must be kept for 2 years from the date of transaction.

6) To inform the Authority of any decision to withdraw the importation, sale or supply of the medicinal product to which the licence relates and to state its reason.

7) To inform the Authority within 7 days upon receipt of any report concerning adverse effects in one or more human beings or animals resulting from the use of any medicinal product to which the licence relates.

8) To return the original copy of the licence to the Authority within 7 days of the date on which the licence has been suspended or revoked.

9) To not use the licence for advertising purposes.

Note:

Please refer to the *Second Schedule (regulation 2 (b))* of the *Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010* of the Medicines Order, 2007 for further details.

Appendix 2

RESPONSIBILITIES OF A WHOLESALER'S LICENCE HOLDER

A **Wholesaler's Licence holder** must comply to the following requirements as per stipulated in *Regulation 2(c) of the Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010* of the *Medicines Order, 2007*:

1) To provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products which he handles, stores or distributes under his licence, as are necessary to avoid deterioration of the medicinal products.

2) To not use other premises or sites for the handling, storage and distribution of the medicinal products except those specified in the licence.

3) To keep documents pertaining to the transactions of medicinal products related to his licence, in his business premises.

4) To keep records of importation, sale, supply or exportation of medicinal product readily available for inspection by a person authorised by the Authority and to allow the authorised person to take copies or make extracts from such records, which must be kept for 2 years from the date of transaction.

5) To keep records for the supply of commercial samples of medicinal products containing any item which is listed in the Poisons List in the Schedule to the Poisons Act.

6) To withhold from sale, supply or exportation any batch of medicinal product that has been found to be harmful, unsafe or not to conform with the product specifications as regards strength, quality or purity, and to withdraw the defective medicinal product from the market immediately, if so directed by the Authority.

7) To not use the licence for advertising purposes.

8) To return the original copy of the licence to the Authority within 7 days of the date on which the licence has been suspended or revoked.

Note:

Please refer to the *Second Schedule (regulation 2 (c))* of the *Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010* of the *Medicines Order,* 2007 for further details.