



DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

MEDICINES ORDER, 2007
MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) REGULATIONS, 2010

APPLICATION FORM FOR IMPORT LICENCE AND WHOLESALER'S LICENCE
FOR MEDICINAL PRODUCTS

SECTION 1: INSTRUCTIONS

- 1) Please fill out this application form in CAPITAL LETTERS.
- 2) Please tick (✓) the appropriate boxes or write "N/A" for any item that is not applicable to your application.
- 3) The applicant must be the Import License holder.
- 4) When the symbol * appears, please strikethrough the wording that is not applicable.
- 5) The complete application form with the relevant fee should be submitted to the **Compliance and Licensing Section, 1st Floor, Department of Pharmaceutical Services, Kg Madaras, Mukim Gadong 'A', Brunei Darussalam.**
- 6) Payment of fees can either be made in the forms of cash or cheque only. Fees paid are non-refundable. Please note that payments can only be made from **Monday to Thursday, 8am to 11.30am** (8am to 10.30am for Ramadhan month) during government working days.

Fees:

- | | | |
|------------------------------------------------|---|-------|
| a) Application for Import Licence | - | \$50 |
| b) Application for Wholesaler's Licence | - | \$100 |
| c) Renewal of Import Licence | - | \$50 |
| d) Renewal of Wholesaler's Licence | - | \$100 |

Note: Only complete application forms (one original and one photocopy) submitted with confirmed payment will be processed.

SECTION 2: CHECKLIST FOR SUPPORTING DOCUMENTS

- 1) This checklist is to be filled in by the applicant.
- 2) The application form should be submitted with the list of supporting documents.
- 3) Please tick (✓) the appropriate boxes if the documents are attached.
- 4) For New Application, please proceed to **Section 2(A)** whereas Application for Licence Renewal, please proceed to **Section 2(B)**.

List of Supporting Documents

A) NEW APPLICATION	<input type="checkbox"/>	<i>For official use only</i>
1) A copy of applicant's Identity Card issued in Brunei Darussalam.	<input type="checkbox"/>	<input type="checkbox"/>
2) A copy of Business Certificate of Registration (Sections 16 & 17); or Certificate of Incorporation and Memorandum of Article & Association.	<input type="checkbox"/>	<input type="checkbox"/>
3) Layout plan of the storage area.	<input type="checkbox"/>	<input type="checkbox"/>
4) List of registered medicinal products (<i>arranged alphabetically in hard and soft copies</i>).	<input type="checkbox"/>	<input type="checkbox"/>
5) Copy of each of the Product Licences. <i>(Note: These will be returned to the applicant <u>after completion</u> of the screening process.)</i>	<input type="checkbox"/>	<input type="checkbox"/>
6) Authorisation letter issued by the <u>Product Licence holder</u> if its company is not the product licence holder.	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>

Additional documents required from applicant:

B) APPLICATION FOR LICENCE RENEWAL		<input type="checkbox"/>	For official use only
1) A copy of <u>previous</u> *Import/Wholesaler's licence.		<input type="checkbox"/>	<input type="checkbox"/>
2) A copy of applicant's Identity Card issued in Brunei Darussalam.		<input type="checkbox"/>	<input type="checkbox"/>
3) Layout plan of the storage area (<i>only required if there was any change made to previous layout plan</i>).		<input type="checkbox"/>	<input type="checkbox"/>
4) List of registered medicinal products (<i>arranged alphabetically in hard and soft copies</i>).		<input type="checkbox"/>	<input type="checkbox"/>
5) Copy of each of the Product Licences (<i>only required for additional medicinal products</i>). (<i>Note: These will be returned to the applicant <u>after completion</u> of the screening process.</i>)		<input type="checkbox"/>	<input type="checkbox"/>
6) Authorisation letter issued by the <u>Product Licence holder</u> if its company is not the product licence holder .		<input type="checkbox"/>	<input type="checkbox"/>
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 .		<input type="checkbox"/>	<input type="checkbox"/>

Additional documents required from applicant:

SECTION 3: DETAILS OF APPLICATION

Type of Licence	<input type="checkbox"/> Import Licence	<input type="checkbox"/> Wholesaler's Licence
Details of previous licence (if applicable)	Licence No. :	
	Validity Period :	

SECTION 4: DETAILS OF COMPANY

Name of Company		
Company Registration No.		
Business Address		
Store Address (if different from above)		
Correspondence Address (if different from above)		
Telephone	Fax	Official E-mail

Details of Two Responsible Persons (contactable 24 hours)

Title	<input type="checkbox"/> Dr <input type="checkbox"/> Mr <input type="checkbox"/> Mrs <input type="checkbox"/> Ms <input type="checkbox"/> Miss	Gender	<input type="checkbox"/> Dr <input type="checkbox"/> Mr <input type="checkbox"/> Mrs <input type="checkbox"/> Ms <input type="checkbox"/> Miss
Name		Name	
I.C. No. (Colour)		I.C. No. (Colour)	
Designation		Designation	
Telephone (Office)		Telephone (Office)	
Handphone		Handphone	

SECTION 5: DETAILS OF APPLICANT (IMPORT LICENSE AND/OR WHOLESALER'S LICENSE HOLDER)				
Title	<input type="checkbox"/> Dr <input type="checkbox"/> Mr <input type="checkbox"/> Mrs <input type="checkbox"/> Ms <input type="checkbox"/> Miss			
Name				
I.C. No. (Colour)	<input type="checkbox"/> Yellow <input type="checkbox"/> Red <input type="checkbox"/> Green			
Designation				
Telephone (Office)		Handphone		Official E-mail
SECTION 6: DECLARATION OF APPLICANT				
<p>I hereby declare that</p> <p>i) I, as the license holder understand and undertake to comply with all the provisions of the Medicines Order 2007 and its related Regulations, Poisons Act 1956 and Misuse of Drugs Regulations.</p> <p>ii) All particulars and attachments given in/with this application form are true.</p> <p>iii) There have been no changes to the information and attachments provided previously (<i>only applicable for licence renewal application</i>).</p> <p>I undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam of any change in the particulars submitted in/with this application form.</p>				
Name of Applicant		Signature		Date
SECTION 7: CERTIFICATION BY COMPANY				
<p>I hereby declare that</p> <p>i) The applicant is an *employee/owner of the above-mentioned company.</p> <p>ii) The *Import/Wholesaler's licence applied is only for the purpose of business of the above-mentioned company.</p> <p>iii) All of the information provided is true and complete.</p> <p>iv) The applicant is the licence holder.</p> <p>I understand that a wilfully false statement is an offence under the Medicines Order 2007 and that all documents submitted for evaluation are not returnable.</p>				
Name of *Company Owner / Manager / Director		Signature		Date & Company Stamp

