No. S 68

MEDICINES ORDER, 2007
(S 79/07)

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

ARRANGEMENT OF REGULATIONS

Regulation

MEDICINES ORDER, 2007
(S 79/07)

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In exercise of the power conferred by section 81(1) of the Medicines Order 2007, the Minister of Health, with the approval of His Majesty the Sultan and Yang Di-Pertuan, hereby makes the following Regulations —

Citation and commencement.

1. These Regulations may be cited as the Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010 and shall commence on the 1st. July, 2010.

Standard provisions for licences.

2. The standard provisions for licences (including provisional licences) to be granted under Part III of the Order shall be the following —

(a) for product licences, those provisions set out in the First Schedule;

(b) for import licences, those provisions set out in the Second Schedule;

(c) for wholesale dealer's licences, those provisions set out in the Third Schedule; and

(d) for manufacturer's licences, those provisions set out in the Fourth Schedule.

Grant of licences.

3. Every import licence granted to any person not authorised by the holder of a product licence shall be on a per consignment basis.

Fees.

4. (1) The fees in respect of applications for, and the grant of, licences and certificates and for any amendment thereof shall be as specified in the Fifth Schedule.

(2) No refund shall be made in respect of any fee paid under these Regulations.

Cost of evaluation.

5. Where for the purpose of dealing with an application for the grant or amendment of a product licence the Authority conducts any assessment or evaluation of any medicinal product, the cost of the assessment or evaluation shall, unless otherwise required by the Authority, be borne by the person making the application.

Offences.

6. A holder of a licence who contravenes or fails to comply with any standard provision applicable to his licence is guilty of an offence and liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

FIRST SCHEDULE (regulation 2(a))

STANDARD PROVISIONS FOR PRODUCT LICENCE

1. The holder of the licence shall forthwith report to the Authority any change in his name and address and in any address at which there is carried on a business to which the licence relates.

2. (1) The holder of the licence shall forthwith inform the Authority of any material change that has been made or that he proposes to make in the particulars contained in his application, in relation to any medicinal product to which the licence relates, that is to say —

(a) in the specification of the medicinal product;

(b) in the specification of any of the constituents of the medicinal product;

(c) in the composition of the medicinal product, or of any of the constituents of the medicinal product;

(d) in the methods of manufacture or assembly of the medicinal product, or of any of the constituents of the medicinal product;

(e) in the methods and procedures described in the application for ensuring compliance with the specifications relating to the medicinal product;

(f) in the arrangements described in the application for storage of the medicinal product;

(g) in the indications for use of the medicinal product; and

(h) in the contents of any label affixed to or displayed on the container or package of the medicinal product or in the contents of any leaflet relating to the medicinal product enclosed in the container or package of the medicinal product.

(2) The holder of the licence shall forthwith inform the Authority of any change to a material extent in the licence that he proposes to make.

3. The holder of the licence shall forthwith inform the Authority of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with, his application for a product licence for the purpose of being taken into account in assessing the safety, quality or efficacy of any medicinal product to which the licence relates.

4. The holder of the licence shall inform the Authority within 7 days upon receipt of any report of which he is aware of adverse effects in one or more human beings or animals associated in that report resulting from the use of any medicinal product to which the licence relates, which shall be open to inspection by a person authorised by the Authority, who may take copies thereof and, if the Authority so directs, the holder of the licence shall furnish the Authority with a copy of any such report of which he has a record or of which he is or subsequently becomes aware.

5. (1) The holder of the licence shall —

(a) keep readily available for inspection by a person authorised by the Authority records in such form as the Authority may require; and

(b) permit the person authorised to take copies of or to make extracts from such records.

(2) The records shall not be destroyed without the consent of the Authority for a period of 2 years from the date when the importation, sale, supply or exportation of the relevant batch of the medicinal product was authorised by or on behalf of the holder of the licence.

(3) 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 (Chapter 114) shall also be kept in such form as the Authority may require.

6. When the holder of the licence has been informed by the Authority that any batch of any medicinal product to which the licence relates has been found to be harmful or unsafe or not to conform as regards strength, quality or purity with the specification of that medicinal product, the holder of the licence shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority and withdraw the defective products from the market immediately if the Authority requests him to do so.

7. The holder of the licence shall notify the Authority forthwith of any decision to withdraw from sale, supply or exportation any medicinal product to which the licence relates, and shall state the reason for that decision.

8. The holder of the licence shall state the licence number designated by the Authority on the label and package accompanying the product.

9. The holder of the licence shall 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.

10. The holder of the licence shall not use the licence for advertising purposes.

11. The holder of the licence shall undertake to arrange such tests as may be required by the Authority and shall submit samples if so requested by the Authority.

SECOND SCHEDULE (regulation 2(*b*))

STANDARD PROVISIONS FOR IMPORT LICENCE

1. The holder of the licence shall forthwith report to the Authority any change in his name and address and in any address at which there is carried on a business to which the licence relates.

2. The holder of the licence shall undertake to arrange such tests as may be required by the Authority and shall submit samples if so requested by the Authority.

3. The holder of the licence shall forthwith inform the Authority of any material change that has been made in the particulars contained in his application, in relation to any medicinal product to which the licence relates, that is to say —

(*a*) in the specification of the medicinal product;

(b) in the specification of any of the constituents of the medicinal product;

(c) in the composition of the medicinal products, or of any of the constituents of the medicinal product; or

(d) in the manufacture of the medicinal product.

4. When the holder of the licence has been informed by the Authority that any batch of any medicinal product to which the licence relates has been found to be harmful or unsafe or not to conform as regards strength, quality or purity with the specification of that medicinal product, the holder of the licence shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority and withdraw the defective medicinal product from the market immediately if the Authority requests him to do so.

5. (1) The holder of the licence shall keep readily available for inspection by a person authorised by the Authority records in such form as the Authority may require.

(2) The records shall not be destroyed without the consent of the Authority for a period of 2 years from the date of importation, sale, supply or exportation of the medicinal product.

(3) The holder of the licence shall permit a person authorised by the Authority to take copies of or to make extracts from such records.

(4) 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 (Chapter 114) shall also be kept in such form as the Authority may require.

6. The holder of the licence shall inform the Authority of any decision to withdraw the importation, sale or supply of the medicinal product to which the licence relates, and shall state the reason for that decision.

7. The holder of the licence shall inform the Authority within 7 days upon receipt of any report of which he is aware of adverse effects in one or more human beings or animals associated in that report resulting from the use of any medicinal product to which the licence relates, which shall be open to inspection by a person authorised by the Authority, who may take copies thereof and, if the Authority so directs, the holder of the licence shall furnish the Authority with a copy of any such report of which he has a record or of which he is or subsequently becomes aware.

8. The holder of the licence on a per consignment basis shall state the licence number designated by the Authority on the label and package accompanying the product.

9. (1) The holder of the licence shall 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.

(2) The holder of the licence on a per consignment basis shall return the licence to the Authority within 7 days of that consignment has been imported.

10. The holder of the licence shall not use the licence for advertising purposes.

11. The validity of the import licence, in respect of each medicinal product which the importer is dealing in, shall be subject to the continued validity of the corresponding product licence.

THIRD SCHEDULE (regulation 2(c))

STANDARD PROVISIONS FOR WHOLESALE DEALER'S LICENCE

1. The holder of the licence shall 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 and he shall not use for such purposes premises other than those specified in the licence or which may be approved from time to time by the Authority.

2. The holder of the licence shall provide such information as may be requested by the Authority concerning the type and quality of any medicinal product which he handles, stores or distributes.

3. The holder of the licence shall inform the Authority of any proposed structural alteration to, or discontinuance of use of, any premises to which the licence relates or any premises which are approved from time to time by the relevant Authority.

4. The holder of the licence shall keep in his business premises such documents relating to his transactions by way of the sale of medicinal products to which the licence relates as will facilitate the withdrawal or recall from sale or exportation of such products.

5. (1) The holder of the licence shall keep readily available for inspection by a person authorised by the Authority records in such form as the Authority may require.

(2) The records shall not be destroyed without the consent of the Authority for a period of 2 years from the date of receipt, sale, supply or exportation of the medicinal product.

(3) The holder of the licence shall permit the person authorised by the Authority to take copies of or to make extracts from such records.

(4) 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 (Chapter 114) shall also be kept in such form as the Authority may require.

6. Where the holder of the licence has been informed by the Authority or by the holder of the product licence that any batch of any medicinal product to which the wholesale dealer's licence relates has been found to be harmful or unsafe or not to conform as regards strength, quality or purity with the specification of that product or with the provisions of the Order or any regulations made thereunder that are applicable to the medicinal product, the holder of the licence shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority and withdraw the defective medicinal product from the market immediately if the Authority requests him to do so.

7. The holder of the licence shall 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.

8. The holder of the licence shall not use the licence for advertising purposes.

FOURTH SCHEDULE (regulation 2*(d)*)

STANDARD PROVISIONS FOR MANUFACTURER'S LICENCE

1. The holder of the licence shall forthwith report to the Authority any change in his name and address and in any address at which there is carried on a business to which the licence relates.

2. The holder of the licence shall provide and maintain such staff, premises, equipment and plant as are necessary for the carrying out in accordance with his licence and the relevant product licences of such stages of the manufacture and assembly of the medicinal products as are undertaken by him, and he shall not carry out any such manufacture or assembly except at the premises specified in his licence.

3. The holder of the licence shall 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 and he shall not use for such purposes premises other than those specified in his licence or which may be approved from time to time by the Authority.

4. The holder of the licence shall —

(a) conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products are of the correct identities and conform with the standards of strength, quality and purity applicable to them under the relevant product licences; and

(b) comply with the Pharmaceutical Inspection Convention/ Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products, as revised or amended from time to time.

5. (1) The holder of the licence shall carry out or cause to be carried out tests on the strength, quality or purity of the medicinal products to ensure that the standard of the medicinal products that he manufactures under his manufacturer's licence is complied with.

(2) Where the holder of the licence does not carry out the tests referred to in sub-paragraph (1) himself, he shall engage a testing laboratory that is approved by the Authority to carry out the tests.

6. The holder of the licence shall provide such information, as may be requested by the Authority for the purposes of the Order, in respect of the products currently being manufactured or assembled under his licence and of the operations being carried out in relation to such manufacture or assembly.

7. Where the manufacturer's licence relates to the assembly of a medicinal product and that medicinal product is not manufactured by the holder of the licence, and where the particulars as to the name and address of the manufacturer of, or of the person who imports, that medicinal product had been given by the holder of the licence to the Authority, the holder of the licence shall forthwith notify the Authority in writing of any changes in the particulars.

8. (1) The holder of the licence shall inform the Authority before making any material alteration to the premises or plant used under his licence, or in the operations for which they are used.

(2) The holder of the licence shall inform the Authority of any change that he proposes to make in any personnel named in his application form as respectively —

(a) responsible for supervising the production operations; or

(b) responsible for quality control of the medicinal products being manufactured or assembled.

9. (1) The holder of the licence shall keep readily available for inspection by a person authorised by the Authority durable records of the details of manufacture and assembly of each batch of every medicinal product being manufactured or assembled under his licence and of the tests carried out thereon, in such form as the Authority may require such that the records will be easily identifiable from the number of the batch as shown on each container in which the medicinal product is sold, supplied or exported.

(2) The holder of the licence shall permit the person authorised to take copies of or to make extracts from the records.

(3) Such records shall not be destroyed without the consent of the Authority for a period of 2 years from the date when the manufacture or assembly of the relevant batch occurred.

10. The holder of the licence shall keep such records as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal product to which the licence relates.

11. Where the holder of the licence has been informed by the Authority or where he has reason to suspect that any batch of any medicinal product to which his licence relates has been found to be harmful or unsafe or not to conform as regards strength, quality or purity with the specification of the relevant medicinal product, the holder of the licence shall, if so directed, withhold such batch from sale, supply or exportation, for such a period as may be specified by the Authority and withdraw the defective medicinal product from the market immediately if the Authority requests him to do so.

12. The holder of the licence shall ensure that any tests for determining conformity with the standards and specifications applying to any particular medicinal product used in the manufacture shall, except so far as the conditions of the relevant medicinal product licence may otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the Authority.

13. The holder of the licence shall inform the Authority within 7 days upon receipt of any report of which he is aware of any adverse effect in one or more human beings or animals associated in that report resulting from the use of any medicinal product to which the licence relates, which shall be open to inspection by any person authorised by the Authority, who may take copies thereof and, if the Authority so directs, the holder of the licence shall furnish the Authority with a copy of any such report of which he has a record or of which he subsequently becomes aware.

14. The holder of the licence shall 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.

15. The holder of the licence shall not use the licence for advertising purposes.

FIFTH SCHEDULE (regulation 4(1))

FEES FOR LICENCES AND CERTIFICATES

1. PRODUCT LICENCE	
(1) Processing fees (including screening and evaluation)	$200
(2) Product Licence —	
(a) the first year	No charge
(b) each subsequent year	$50
(3) Application to amend a licence —	
(a) major amendment	$150
(b) minor amendment	$50
2. IMPORT LICENCE	
(1) Application for a licence —	
(a) importation authorised by product licence holder	$50
(b) importation not authorised by product licence holder for —	$50/product/
per consignment imported	Consignment
(2) Licence for —	
(a) importation authorised by product licence holder for —	
(i) the first year	No charge
(ii) each subsequent year	$50

(b) importation not authorised by the product licence holder —	No charge
per consignment imported	
(3) Application to amend a licence —	
(a) with site inspection	$35
(b) without site inspection	$25

3. WHOLESALE DEALER'S LICENCE

(1) Application for a licence —	
(a) the first year	$100
(b) each subsequent year	$100
(2) Application to amend a licence —	
(a) with site inspection	$35
(b) without site inspection	$25

4. MANUFACTURER'S LICENCE

(1) Application for a licence for —	
(a) manufacture of external or oral preparations	$500
(b) manufacture of external and oral preparations	$1,000
(c) primary assembly	$350
(d) secondary assembly	$250
(2) Licence for —	
(a) the first year	No charge
(b) each subsequent year for —	
(i) a manufacturer of external or oral preparations	$500
(ii) a manufacturer of external and oral preparations	$1,000
(iii) a primary assembler	$350
(iv) a secondary assembler	$250

(3)	Application to amend a licence —	
	(a) with site inspection (for manufacturer)	$100
	(b) with site inspection (for assembler)	$50
	(c) without site inspection	$25

5. CERTIFICATES AND DOCUMENTS

(1)	a Certificate to Export a Medicinal Product	$50
(2)	a Statement of Licensing Status of a Medicinal Product	$25.

Made this 15th. day of Rejab, 1431 Hijriah corresponding to the 28th. day of June, 2010.

PEHIN ORANG KAYA JOHAN PAHLAWAN DATO SERI SETIA AWANG HAJI ADANAN BIN BEGAWAN PEHIN SIRAJA KHATIB DATO SERI SETIA AWANG HAJI MOHD. YUSOF
Minister of Health,
Brunei Darussalam.