MEDICINES ACT
(CHAPTER 176, SECTION 74)

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) REGULATIONS

ARRANGEMENT OF REGULATIONS

[30th June 1987]

Citation

1. These Regulations may be cited as the Medicines (Licensing, Standard Provisions and Fees) Regulations.

Definition

2. In these Regulations, "Chinese proprietary medicine" shall have the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6).

Standard provisions for licences

3.—(1) Subject to paragraph (2), the standard provisions for licences (including provisional licences) to be granted under Part II of the Act 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.

(2) The standard provisions for import licences to be granted under Part II of the Act in respect of Chinese proprietary medicines shall be as follows:

(*a*) those provisions set out in the Second Schedule except paragraphs 8, 9(2) and 11;

(*b*) the provision that the holder of the licence shall seek the prior approval of the licensing authority to deal with any medicinal product under his licence, and he shall, within such time as the licensing authority may specify, provide such information and documents as may be required by the licensing authority;

(*c*) the provision that the holder of the licence shall not import, sell or supply any medicinal product to which the licence relates unless —

(i) the approval of the licensing authority to deal with that medicinal product under his licence continues to be valid at the time of the import, sale or supply, as the case may be, of the medicinal product; and

(ii) he complies with any written law applicable to the import, sale or supply, as the case may be, of the medicinal product; and

(*d*) the provision that the holder of the licence shall not sell or supply any medicinal product to which the licence relates unless and until he has submitted to the licensing authority the following documents within 2 months of the import of the consignment of the medicinal product —

(i) a declaration of the absence of any poison as defined in the Poisons Act (Cap. 234) and any synthetic active substance in the medicinal product;

(ii) test results on the content of Arsenic, Copper, Lead and Mercury in the medicinal product;

(iii) where the medicinal product is for oral consumption, test results on the content of Escherichia coli, Salmonella, Staphylococcus aureus, *the total yeast and mould count, and *the total aerobic microbial count per gram or millilitre of the medicinal product (*not necessary if the medicinal product contains any active substance which is derived from plants, animals or a combination thereof and which has been produced by fermentation processes);

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(iv) where the medicinal product is for external application, test results on the content of Pseudomonas aeruginosa, Staphylococcus aureus, *the total yeast and mould count, and *the total aerobic microbial count per gram or millilitre of the medicinal product (*not necessary if the medicinal product contains any active substance which is derived from plants, animals or a combination thereof and which has been produced by fermentation processes); and

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(v) such other documents and test results as may be required by the licensing authority.

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(3) The standard provisions for wholesale dealer's licences to be granted under Part II of the Act in respect of Chinese proprietary medicines shall be those provisions set out in the Third Schedule except that paragraph 6 thereof shall read as if the words "or by the holder of the product licence" in the second line have been deleted.

(4) The standard provisions for manufacturer's licences to be granted under Part II of the Act in respect of Chinese proprietary medicines shall be —

(*a*) those provisions set out in the Fourth Schedule, except for paragraph 4(*b*) thereof and except that —

(i) paragraph 4(*a*) thereof shall read as if the words "under the relevant product licences" at the end thereof have been deleted; and

(ii) paragraph 12 thereof shall read as if the words ", except so far as the conditions of the relevant medicinal product licence may otherwise provide," in the third and fourth lines have been deleted;

[S 309/2001 wef 01/09/2001]

(*b*) the provision that the holder of the licence shall seek the prior approval of the licensing authority to deal with any medicinal product under his licence, and he shall, within such time as the licensing authority may specify, provide such information and documents as may be required by the licensing authority;

(*c*) the provision that the holder of the licence shall not manufacture, assemble, sell or supply any medicinal product to which the licence relates unless —

(i) the approval of the licensing authority to deal with that medicinal product under his licence continues to be valid at the time of the manufacture, assembly, sale or supply, as the case may be, of the medicinal product; and

(ii) he complies with any written law applicable to the manufacture, assembly, sale or supply, as the case may be, of the medicinal product; and

(*d*) the provision that the holder of the licence shall inform the licensing authority of any decision to cease the manufacture or assembly of the medicinal product to which the licence relates and shall state the reason for that decision.

Grant of licences

4.—(1) Every product licence, wholesale dealer's licence and manufacturer's licence granted shall be for a period of one year or such shorter period as specified in that licence.

(2) Every import licence granted to any person authorised by the holder of a product licence shall be for a period of one year or such shorter period as specified in the licence.

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

(4) Notwithstanding paragraphs (2) and (3), every import licence granted in respect of Chinese proprietary medicines shall be for a period of one year or such shorter period as specified in the licence.

[S 416/2005 wef 01/07/2005]

Fees

5.—(1) The fees in respect of applications for, and the grant of, licences and certificates and for any variation or 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

5A. Where for the purpose of dealing with an application for the grant or variation 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.

[S 641/2002 wef 20/12/2002]

Declaration, notice and prescribed periods under section 12A of Act

5B.—(1) The declaration under section 12A(2) of the Act shall be in the form set out in Part I of the Sixth Schedule.

(2) The notice under section 12A(3)(*a*) of the Act shall be in the form set out in Part II of the Sixth Schedule.

(3) The period under section 12A(5) of the Act shall be 45 days from the date that notice is served on the proprietor of the patent concerned.

(4) The period under section 12A(6)(*b*) of the Act shall be 30 months from the date the application for the order or declaration referred to in section 12A(5)(*a*) of the Act is made.

Offences

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

FIRST SCHEDULE

Regulation 3(1)(*a*)

STANDARD PROVISIONS FOR PRODUCT LICENCE

1. The holder of the licence shall forthwith report to the licensing 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 licensing 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

FIRST SCHEDULE — *continued*

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 licensing 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 licensing 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 licensing 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 licensing authority, who may take copies thereof and, if the licensing authority so directs, the holder of the licence shall furnish the licensing 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 licensing authority records in such form as the licensing 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 licensing 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 (Cap. 234) shall also be kept in such form as the licensing authority may require.

6. When the holder of the licence has been informed by the licensing 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 licensing

FIRST SCHEDULE — *continued*

authority and withdraw the defective products from the market immediately if the licensing authority requests him to do so.

7. The holder of the licence shall notify the licensing 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 licensing 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 licensing 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 licensing authority and shall submit samples if so requested by the licensing authority.

SECOND SCHEDULE

Regulation 3(1)(*b*)

STANDARD PROVISIONS FOR IMPORT LICENCE

1. The holder of the licence shall forthwith report to the licensing 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 licensing authority and shall submit samples if so requested by the licensing authority.

3. The holder of the licence shall forthwith inform the licensing 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 licensing 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

SECOND SCHEDULE — *continued*

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 licensing authority and withdraw the defective medicinal product from the market immediately if the licensing 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 licensing authority records in such form as the licensing authority may require.

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

(3) The holder of the licence shall permit a person authorised by the licensing 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 (Cap. 234) shall also be kept in such form as the licensing authority may require.

6. The holder of the licence shall inform the licensing 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 licensing 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 licensing authority, who may take copies thereof and, if the licensing authority so directs, the holder of the licence shall furnish the licensing 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 licensing 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 licensing 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 licensing authority within 7 days of that consignment has been imported.

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

SECOND SCHEDULE — *continued*

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 3(1)(*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 licensing authority.

2. The holder of the licence shall provide such information as may be requested by the licensing 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 licensing 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 licensing 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 licensing authority records in such form as the licensing authority may require.

(2) The records shall not be destroyed without the consent of the licensing 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 licensing 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 (Cap. 234) shall also be kept in such form as the licensing authority may require.

THIRD SCHEDULE — *continued*

6. Where the holder of the licence has been informed by the licensing 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 Act 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 licensing authority and withdraw the defective medicinal product from the market immediately if the licensing authority requests him to do so.

7. The holder of the licence shall return the original copy of the licence to the licensing 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 3(1)(*d*)

STANDARD PROVISIONS FOR MANUFACTURER'S LICENCE

1. The holder of the licence shall forthwith report to the licensing 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 licensing 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

FOURTH SCHEDULE — *continued*

(*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.

[S 309/2001 wef 01/09/2001]

5. 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.

5A. Where the holder of the licence does not carry out the tests referred to in paragraph 5 himself, he shall engage a testing laboratory that is approved by the licensing authority to carry out the tests.

[S 309/2001 wef 01/09/2001]

6. The holder of the licence shall provide such information, as may be requested by the licensing authority for the purposes of the Act, 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 licensing authority, the holder of the licence shall forthwith notify the licensing authority in writing of any changes in the particulars.

8.—(1) The holder of the licence shall inform the licensing 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 licensing 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 licensing 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 licensing authority may require such that the records will be easily

FOURTH SCHEDULE — *continued*

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 for a period of 2 years from the date when the manufacture or assembly of the relevant batch occurred without the consent of the licensing authority.

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 licensing 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 licensing authority and withdraw the defective medicinal product from the market immediately if the licensing 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 licensing authority.

13. The holder of the licence shall inform the licensing 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 licensing authority, who may take copies thereof and, if the licensing authority so directs, the holder of the licence shall furnish the licensing 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 licensing 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 5(1)

FEES FOR LICENCES AND CERTIFICATES

PART I

WESTERN MEDICINES

1. PRODUCT LICENCE

(1) Application for a licence for —

(*a*) an innovator product (i.e. containing any new chemical or biological entity, new combination, new dosage form or new route of administration) which has not yet been approved by any WHO-defined competent drug regulatory agency and which is required by the licensing authority to undergo full evaluation, in respect of —	
(i) the initial screening#	$2,750
(ii) the evaluation*	$82,500
(*b*) an innovator product (i.e. containing any new chemical or biological entity, new combination, new dosage form or new route of administration) which has been approved by at least one WHO-defined competent drug regulatory agency and which is allowed by the licensing authority to undergo abridged evaluation, in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$11,000
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,500
(*c*) an innovator product (i.e. containing any new chemical or biological entity, new combination, new dosage form or new route of administration) which has been	

FIFTH SCHEDULE — *continued*

approved by any reference drug regulatory agency specified by the licensing authority and which is allowed by the licensing authority to undergo verification evaluation, in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$16,500
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,500
(*d*) a generic drug product (i.e. essentially similar to another medicinal product which is currently registered with the licensing authority) which has been approved by at least one WHO-defined competent drug regulatory agency and which is allowed by the licensing authority to undergo abridged evaluation in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$3,850
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$2,200
(*e*) a generic drug product (i.e. essentially similar to another medicinal product which is currently registered with the licensing authority) which has been approved by any reference drug regulatory agency specified by the licensing authority and which is allowed by the licensing authority to undergo verification evaluation under the "Special Scheme for Registration of Generic Medicinal Products from India" established pursuant to Chapter 5 of the India-Singapore	

FIFTH SCHEDULE — *continued*

Comprehensive Economic Cooperation Agreement, in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$10,000
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,000
(*f*) a generic drug product (i.e. essentially similar to another medicinal product which is currently registered with the licensing authority) which has been approved by any reference drug regulatory agency specified by the licensing authority and which is allowed by the licensing authority to undergo verification evaluation, in respect of —	
(i) the initial screening#	$550
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$10,000
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$5,000
(2) Licence for —	
(*a*) the first year	No charge
(*b*) each subsequent year	$300
(3) Application to amend a licence —	
(*a*) to make a major variation to the product specifications (i.e. changes relating to indications, dosage recommendations, patient groups or clinical trial information), where the application is required to undergo full evaluation by the licensing authority, in respect of —	

FIFTH SCHEDULE — *continued*

(i) the initial screening#	$2,500
(ii) the evaluation*	$51,000
(*b*) to make a major variation to the product specifications (i.e. changes relating to indications, dosage recommendations, patient groups or clinical trial information), where the application can be reviewed by the licensing authority through abridged evaluation, in respect of —	
(i) the initial screening#	$500
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$5,500
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$2,750
(*c*) to make a major variation to the product specifications (i.e. changes relating to indications, dosage recommendations, patient groups or clinical trial information), where the application can be reviewed by the licensing authority through verification evaluation, in respect of —	
(i) the initial screening#	$500
(ii) the evaluation* for a single-strength product or the first product in a series of products of different strengths	$8,250
(iii) the evaluation* for each subsequent product in a series of products of different strengths	$2,750
(*d*) to make any other variations to the product specifications of a product#	$550

2. IMPORT LICENCE

(1) Application for a licence for —

(*a*) importation authorised by product licence holder	$500

FIFTH SCHEDULE — *continued*

(*b*) importation not authorised by product licence holder — per consignment imported	$250
(2) Licence for —	
(*a*) importation authorised by product licence holder for —	
(i) the first year	No charge
(ii) each subsequent year	$500
(*b*) importation not authorised by product licence holder — per consignment imported	No charge
(3) Application to amend a licence —	
(*a*) with site inspection	$300
(*b*) without site inspection	$50

3. WHOLESALE DEALER'S LICENCE

(1) Application for a licence	$500
(2) Licence for —	
(*a*) the first year	No charge
(*b*) each subsequent year	$500
(3) Application to amend a licence —	
(*a*) with site inspection	$300
(*b*) without site inspection	$50

4. MANUFACTURER'S LICENCE

(1) Application for a licence for —	
(*a*) manufacture of external preparations	$1,500
(*b*) manufacture of oral preparations	$1,500
(*c*) manufacture of contact lens solutions	$1,500
(*d*) manufacture of external and oral preparations	$2,000

FIFTH SCHEDULE — *continued*

(*e*) manufacture of sterile preparations or other types of dosage forms, or dosage form combinations other than the above	$3,000
(*f*) primary assembly	$1,000
(*g*) secondary assembly	$600
(2) Licence for —	
(*a*) the first year	No charge
(*b*) each subsequent year for —	
(i) a manufacturer of external preparations	$1,500
(ii) a manufacturer of oral preparations	$1,500
(iii) a manufacturer of contact lens solutions	$1,500
(iv) a manufacturer of external and oral preparations	$2,000
(v) a manufacturer of sterile preparations or other types of dosage forms, or dosage form combinations other than the above	$3,000
(vi) a primary assembler	$1,000
(vii) a secondary assembler	$600
(3) Application to amend a licence —	
(*a*) with site inspection (for manufacturer)	$1,000
(*b*) with site inspection (for assembler)	$500
(*c*) without site inspection	$50

5. CERTIFICATES AND DOCUMENTS (NON-MANDATORY)	
(1) a Certificate to Export a Medicinal Product	$100
(2) a Confirmation of Authorisation to Import Psychotropic Substances	$100

FIFTH SCHEDULE — *continued*

(3) a Confirmation of Authorisation to Import Restricted Substances	$100
(4) a Statement of Licensing Status of a Medicinal Product	$100

PART II

CHINESE PROPRIETARY MEDICINES

1. IMPORT LICENCE

(1) Application for a licence	$500
(2) Licence for —	
(*a*) the first year	No charge
(*b*) each subsequent year	$500
(3) Application to amend a licence —	
(*a*) with site inspection	$300
(*b*) without site inspection	$50

2. WHOLESALE DEALER'S LICENCE

(1) Application for a licence	$500
(2) Licence for —	
(*a*) the first year	No charge
(*b*) each subsequent year	$500
(3) Application to amend a licence —	
(*a*) with site inspection	$300
(*b*) without site inspection	$50

3. MANUFACTURER'S LICENCE

(1) Application for a licence for —	
(*a*) manufacture of external preparations	$1,500
(*b*) manufacture of oral preparations	$1,500
(*c*) manufacture of external and oral preparations	$2,000

FIFTH SCHEDULE — *continued*

(*d*) primary assembly	$1,000
(*e*) secondary assembly	$600
(2) Licence for —	
(*a*) the first year	No charge
(*b*) each subsequent year for —	
(i) a manufacturer of external preparations	$1,500
(ii) a manufacturer of oral preparations	$1,500
(iii) a manufacturer of external and oral preparations	$2,000
(iv) a primary assembler	$1,000
(v) a secondary assembler	$600
(3) Application to amend a licence —	
(*a*) with site inspection (for manufacturer)	$1,000
(*b*) with site inspection (for assembler)	$500
(*c*) without site inspection	$50

4. CERTIFICATES (NON-MANDATORY)	
(1) a Certificate to Export a Chinese Proprietary Medicine	$100.

* Fees are payable upon acceptance of application.

Fees are payable upon submission of application.

SIXTH SCHEDULE

Regulation 5B(1)

PART I

SIXTH SCHEDULE — *continued*

REPUBLIC OF SINGAPORE

HEALTH SCIENCES AUTHORITY

MEDICINES ACT
(CHAPTER 176)

DECLARATION ON PATENT RELATED INFORMATION FOR APPLICATION FOR PRODUCT LICENCE

Application No (for HSA use only):

SECTION 1: APPLICANT PARTICULARS

Name

Address

SECTION 2: PRODUCT PARTICULARS

Proprietary Name

Active Substance(s) and Strength

Dosage Form

SECTION 3: APPLICATION CATEGORY

Application Category *(check one box)**

☐ Category A1 (Proceed to Section 4)
Refers to an application where no patent is in force in respect of the medicinal product to which the application relates.

☐ Category A2 (Proceed to Section 5)
Refers to an application where a patent is in force in respect of the medicinal product to which the application relates; and the applicant is either the proprietor of the patent or, if the applicant is not the proprietor of the patent, the proprietor has consented to or acquiesced in the grant of the product licence.

SIXTH SCHEDULE — *continued*

☐ Category A3 (Proceed to Section 6)
Refers to an application where a patent is in force in respect of the medicinal product to which the application relates, the applicant is not the proprietor of the patent, the proprietor has not consented to nor acquiesced in the grant of the product licence; and the applicant is requesting for grant of product licence after the expiry of the patent. Such an application may not be made earlier than 18 months before the expiry of the patent.

☐ Category B (Proceed to Section 7)
Refers to an application where a patent is in force in respect of the medicinal product to which the application relates, the applicant is not the proprietor of the patent, the proprietor has not consented to nor acquiesced in the grant of the product licence; and in the opinion and to the best belief of the applicant, the patent is invalid or will not be infringed by the doing of the act for which the licence is sought.

SECTION 4: INFORMATION FOR CATEGORY A1 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

there is no patent under the Patents Act (Cap. 221) in force in respect of the product stated in Section 2 on the date of this declaration.

SECTION 5: INFORMATION FOR CATEGORY A2 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that — ***(check one box)***

☐ a patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. I am the proprietor of the patent. The Singapore Patent No. for the patent is _____.

☐ a patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. I am not the proprietor of the patent but the proprietor has consented to or acquiesced in the grant of the product licence for the product stated in Section 2 to me. The name and address of the proprietor of the patent or his authorised agent are _____. The Singapore Patent No. for the patent is _____.

*For categories A2, A3 and B, please submit a separate declaration for each patent that is in force in respect of the medicinal product.

SIXTH SCHEDULE — *continued*

SECTION 6: INFORMATION FOR CATEGORY A3 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

a patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. I am not the proprietor of the patent and the proprietor has not consented to nor acquiesced in the grant of the product licence for the product stated in Section 2 to me. I am requesting for the grant of the product licence after the expiry of the patent. I am making the application not earlier than 18 months before the expiry of the patent.

The name and address of the proprietor of the patent or his authorised agent are _____. The Singapore Patent No. for the patent is _____.

The patent will expire on _____, which is _____ months from the date of my product licence application.

SECTION 7: INFORMATION FOR CATEGORY B APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

a patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration. I am not the proprietor of the patent and the proprietor has not consented to nor acquiesced in the grant of the product licence for the product stated in Section 2 to me. In my opinion and to my best belief, the patent *(check one box)* —

☐ is invalid; or

☐ will not be infringed by the doing of the act for which the licence is sought.

The name and address of the proprietor of the patent or his authorised agent are _____.

The Singapore Patent No. for the patent is _____.

The patent will expire on _____.

SIXTH SCHEDULE — *continued*

SECTION 8: DECLARATION
I am duly authorised by the applicant to make this declaration on behalf of the applicant, and enclose herewith evidence of such authorisation†. I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that all information furnished in this form is true. I am aware that a false declaration is an offence under the Medicines Act (Cap. 176). I further undertake to notify the Health Sciences Authority of any change in the information furnished in this form. Name: Designation: Signature and Date: Applicant's Stamp:

†Please enclose appropriate evidence of authorisation. Delete this statement if applicant is a natural person making the application personally.

SIXTH SCHEDULE — *continued*

Regulation 38 (2)

PART II

MEDICINES ACT
(CHAPTER 176)

NOTICE TO PROPRIETOR OF PATENT

Date:

Name and Address of Proprietor of Patent:

Dear Sir

Notice pursuant to section 12A (3) (*a*) of the Medicines Act

Pursuant to section 12A (3) (*a*) of the Medicines Act and a requirement of the Health Sciences Authority (HSA), I hereby give you notice that the following application for a product licence has been made to the HSA.

Application Number Assigned by HSA:

Product Name:

Active Substance(s) and Strength:

Dosage Form:

Date of Product Licence Application Filing:

Patent Number and Expiry Date of the relevant Patent:

*2. In my opinion and to the best of my belief, the above-mentioned patent is invalid/will not be infringed by the doing of the act for which the licence is sought‡. The basis of my opinion is
(state factual and legal basis of applicant's opinion).

*3. Unless an application is made, within 45 days from the date this Notice is served on you, for a court order restraining the act for which the licence is applied for or a declaration by a court or the Registrar of Patents that —

(*a*) the patent is valid†; or

(*b*) the patent will be infringed by the doing of that act,

the HSA may proceed to grant the licence.

*Delete where inapplicable.

†Delete if applicant has declared that in his opinion and to the best of his belief the patent will not be infringed by the doing of the act for which the licence is sought.

‡Delete whichever is inapplicable.

[Name and signature of applicant or his authorised agent]

Copy to:

Centre for Drug Administration,
Health Sciences Authority.

[Acknowledgment and date of receipt by proprietor of patent]

[G.N. Nos. S 174/87; S 345/87; S 277/92; S 99/96; S 387/97; S 496/98; S 587/99]

LEGISLATIVE HISTORY

MEDICINES (LICENSING, STANDARD PROVISIONS AND FEES) REGULATIONS (CHAPTER 176, RG 6)

This Legislative History is provided for the convenience of users of the Medicines (Licensing, Standard Provisions and Fees) Regulations. It is not part of these Regulations.

1. **G. N. No. S 174/1987 — Medicines (Licensing, Standard Provisions and Fees) Regulations 1987**

   Date of commencement : 30 June 1987

2. **G. N. No. S 345/1987 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1987**

   Date of commencement : 24 December 1987

3. **1990 Revised Edition — Medicines (Licensing, Standard Provisions and Fees) Regulations**

   Date of operation : 25 March 1992

4. **G. N. No. S 277/1992 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1992**

   Date of commencement : 1 July 1992

5. **G. N. No. S 99/1996 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1996**

   Date of commencement : 1 April 1996

6. **G. N. No. S 387/1997 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1997**

   Date of commencement : 1 October 1997

7. **G. N. No. S 496/1998 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1998**

   Date of commencement : 1 September 1999

8. **G. N. No. S 587/1999 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1999**

   Date of commencement : 1 January 2000

9. **2000 Revised Edition — Medicines (Licensing, Standard Provisions and Fees) Regulations**

   Date of operation : 31 January 2000

10. G. N. No. S 309/2001 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2001

Date of commencement : 1 September 2001

11. G. N. No. S 641/2002 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2002

Date of commencement : 20 December 2002

12. G. N. No. S 621/2003 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2003

Date of commencement : 1 January 2004

13. G. N. No. S 384/2004 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2004

Date of commencement : 1 July 2004

14. G. N. No. S 416/2005 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2005

Date of commencement : 1 July 2005

15. G. N. No. S 499/2005 — Medicines (Licensing, Standard Provisions and Fees) (Amendment No. 2) Regulations 2005

Date of commencement : 1 August 2005

16. G. N. No. S 558/2005 — Medicines (Licensing, Standard Provisions and Fees) (Amendment No. 3) Regulations 2005

Date of commencement : 1 September 2005

17. G. N. No. S 681/2005 — Medicines (Licensing, Standard Provisions and Fees) (Amendment No. 4) Regulations 2005

Date of commencement : 1 November 2005

18. G. N. No. S 821/2005 — Medicines (Licensing, Standard Provisions and Fees) (Amendment No. 5) Regulations 2005

Date of commencement : 1 January 2006

19. G. N. No. S 648/2006 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2006

Date of commencement : 1 December 2006

20. G. N. No. S 28/2007 — Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2007

Date of commencement : 1 February 2007