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## The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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(Published by Authority)

### PART I: SECTION (I) — GENERAL

#### Government Notifications

COSMETICS, DEVICES AND DRUGS ACT, No. 27 OF 1980

REGULATIONS made by the Minister of Health, under section 38 of the Cosmetics, Devices and Drugs Act, No. 27 of 1980, as amended by Act, No. 38 of 1984 and approved by Parliament.

Colombo, 14. 11.1985.

DR. RANJITH ATAPATTU,  
Minister of Health.

#### Regulations.

1. These regulations may be cited as the Cosmetics Regulations No. 38 of 1984 and shall come into operation on 1st January 1986, (hereinafter referred to as "the date of operation").

2. For the purposes of these regulations every cosmetic under the Cosmetics, Devices and Drugs Act, No. 27 of 1980, as amended by Act, No. 38 of 1984 (hereinafter referred to as "the Act") shall be called "a registered cosmetic."

#### PART I

#### REGISTRATION OF COSMETICS.

3. On or after the expiry of a period of three months from the date of operation the Cosmetics, Devices and Drugs Authority, (hereinafter referred to as "the Authority") shall prepare a register of every registered cosmetic and shall enter or cause to be entered therein the following particulars relating to such registered cosmetic :

- (a) the name of the cosmetic ;
- (b) the name of the manufacturer ;
- (c) the country of manufacture ;
- (d) the registration number assigned to it ;
- (e) the name and address of the holder of the certificate of registration ;
- (f) whether he is an importer or manufacturer ; and
- (g) the number of the licence issued to him.

4. (1) Every person desirous of registering a cosmetic with the Authority shall make an application in that behalf to the Authority.

- (2) A separate application shall be made in respect of each cosmetic intended to be registered.
- (3) Every applicant for registration of any cosmetic shall along with his application, furnish to the Authority all such information as may be required and specified in Form A of Schedule I hereto for the purpose of enabling the Authority to dispose of such application.
- (4) Every application made by an importer for a certificate of registration of a cosmetic shall be substantially in form B of Schedule I hereto.
- (5) Every application made by a manufacturer for a certificate of registration of a cosmetic shall be substantially in Form C of Schedule I hereto.
- (6) The fee payable in respect of a certificate of registration of a cosmetic shall be as specified in Schedule II hereto.
5. (1) On receipt of an application for a certificate of registration of a cosmetic the Authority shall forward such application to the Sub-Committee on Cosmetics of the Cosmetics, Devices and Drugs Technical Advisory Committee for advice and report.
- (2) Having considered the report of the Sub Committee on Cosmetics, if the Authority is satisfied that if a certificate of registration is granted, the conditions of such certificate of registration will be observed, the Authority shall, on payment of the specified fee, register or cause to be registered such cosmetic and issue a certificate of registration substantially in Form A of Schedule III hereto in respect of that cosmetic.
6. (1) The certificate of registration of a cosmetic shall, unless it is earlier suspended or cancelled, be valid for a period of five years from the date of issue of such certificate.
- (2) Every application for renewal of the certificate of registration of a cosmetic shall be substantially in form B of Schedule III hereto.
- (3) Where an application for a renewal of a certificate of registration is made six months before the date of expiry of the period of validity of the current certificate of registration, such certificate of registration shall be deemed to continue in force until an order is made in respect of the application for its renewal.
7. The holder of a certificate of registration of a cosmetic shall forthwith inform or notify the Authority of—
- any material changes that have been made or that are proposed to be made in the particulars maintained in or furnished in connection with his application, in relation to any cosmetic to which the certificate of registration relates ;
  - any information by him that casts doubt on the continued validity of the data which was submitted with, or in connection with the application for the registration of the cosmetic, for the purpose of assessing the safety, quality or efficacy of the cosmetic ;<sup>1</sup>
  - any decision to withdraw the cosmetic from the register and shall state the reason for such decision ;  
and
  - any decision to terminate his activities as an importer or manufacturer of the said cosmetic.
8. (1) If the holder of the certificate of registration of a cosmetic fails to comply with any of the conditions of the registration of such cosmetic, the Authority may, after giving such holder of the certificate of registration of such cosmetic an opportunity to show cause why such an order should not be made, remove the name of the cosmetic from the register of cosmetics by an order in writing and state the reasons therefor.
- (2) Any person aggrieved by the order for such removal of the name of the cosmetic from the register of cosmetics may, within three months from the date of such order, appeal to the Authority against such order.
- (3) The Authority shall, on the advice of the Sub Committee on Cosmetics remove the name of a cosmetic from the register of cosmetics and inform the holder of the certificate of registration of that cosmetic of the reasons therefor.

PART II

LICENSING OF IMPORTERS OF COSMETICS

9. On or after the expiry of a period of three months from the date of operation no person shall import a registered cosmetic except under authority of a licence issued under regulation II. Every person to whom a licence is issued under regulation II shall hereinafter be referred to as a "licensed importer of cosmetics."

10. (1) Every person desirous of obtaining a licence to import any registered cosmetic shall make a separate application to the Authority in respect of each such cosmetic which he intends to import. Every such application shall be substantially in Form A of Schedule IV hereto.

(2) Every applicant for a licence to import a registered cosmetic shall furnish to the Authority all such information as may be required for the purpose of enabling the Authority to dispose of such application.

(3) The fee payable in respect of a licence to import a registered cosmetic shall be as specified in Schedule II hereto.

11. (1) On receipt of an application for a licence to import a registered cosmetic shall, on being satisfied, the conditions of the licence will be observed if the licence is issued, issue such licence to the applicant.

(2) Every licence issued by the Authority under this regulation shall be substantially in Form B of Schedule IV hereto.

(3) The fee payable in respect of a licence to import a registered cosmetic shall be as specified in Schedule II hereto.

CONDITIONS OF A LICENCE TO IMPORT A COSMETIC

12. Every licence issued under regulation II shall contain the following conditions :

- (a) the licenced importer of cosmetics shall allow any officer authorised by the Authority to enter with or without notice, any premises where the imported cosmetic is stored, for the purpose of inspecting and if necessary taking samples for test, examination or analysis.
- (b) the licensed importer of cosmetics shall furnish to the Authority such samples as the Authority may consider adequate from every batch of each cosmetic imported under a licence, for test, examination or analysis. The licensed importer of cosmetics shall, if so required, furnish full particulars of the quality control tests carried out by the manufacturer of that particular batch of cosmetics
- (c) the licensed importer of cosmetics shall, on being informed by the Authority that any part of any batch of the cosmetics imported has been found by the Authority not to be in conformity with the standard specified by the Authority, withdraw the batch from sale ;
- (d) the licensed importer of cosmetics shall maintain a record of all particulars of import, sale and supply of any cosmetic by him and such records shall be open to inspection by any officer authorised in that behalf by the Authority.

13. (1) The licence to import a cosmetic shall unless it is earlier suspended or cancelled be valid for a period of one year from the date of issue of such licence.

(2) Where an application for renewal of such licence is made three months before the expiry of the period of validity of the current licence, such licence shall be deemed to continue in force until an order is made in respect of such application.

14. (1) If the licensed importer of cosmetics fails to comply with any of the conditions of the licence to import such cosmetics the Authority may, after giving such licensed importer of cosmetics an opportunity to show cause why such an order should not be made, by an order in writing stating the reasons therefor, suspend such licence for such period as the Authority thinks fit, or cancel it either in respect of all or some of the cosmetics to which it relates.

(2) Any person who is aggrieved by an order made under paragraph (1) suspending or cancelling his licence may, within three months from the date of such order, make an appeal to the Authority against such order.

15. No person shall import except for the purpose of test, examination, analysis or clinical trial, any cosmetic under the same name or under any other name if the manufacture, sale or distribution of such cosmetic is prohibited in the country of manufacture.

16. Every licensed importer of cosmetics shall exhibit the licence issued to him under regulation 11 in a conspicuous place in the premises at which he sells, stores or distributes the cosmetics imported under that licence.

17. The Authority shall keep a register of all licensed importers of cosmetics and shall enter or cause to be entered therein the following particulars relating to each such licensed importer of cosmetic :

- (a) the name of the licensed importer of cosmetics ;
- (b) the address of the premises in respect of which the licence has been issued ;
- (c) the date of issue of the licence ; and
- (d) the number and date of the certificate of registration if any issued to him under the Business Names Ordinance (Chapter 149).

The name of the licensed importer of cosmetics shall be published in the Gazette.

18. (1) Every licensed importer of cosmetics shall forthwith inform the Authority in writing of any circumstances or event which may occur which affects the accuracy of any particulars stated by such licensed importer of cosmetics in the application for a licence to import cosmetics and shall at the same time forward his licence to the Authority.

(2) Upon the receipt of any information furnished by a licensed importer of cosmetics under paragraph (1) the Authority may make or cause to be made such appropriate alterations in the register and in the licence of that importer as may be necessary and shall return the licence to the licensed importer of cosmetics.

19. The Authority may revoke any licence to import a cosmetic issued under regulation 11, if the authority is satisfied that the licensed importer of cosmetics has acted in contravention of any regulation contained in this part or any other regulation pertaining to importation and distribution of cosmetics made under the Act.

### PART III

#### LICENCE TO MANUFACTURE COSMETICS.

20. On or after the expiry of a period of three months from the date of operation no person shall manufacture any cosmetic except under the authority of a licence issued under regulation 24. Every person to whom a licence is issued under regulation 24, shall hereinafter be referred to as a "licensed manufacturer of cosmetics".

21. No cosmetic other than any registered cosmetic referred to in regulation 2, shall be manufactured in Sri Lanka.

22. Every person desirous of obtaining a licence to manufacture any registered cosmetic shall make a separate application to the Authority in respect of each cosmetic he intends to manufacture. Every such application shall be in Form C of Schedule IV hereto.

23. Every applicant for a licence to manufacture a registered cosmetic shall furnish to the Authority all such information as may be required for the purpose of enabling the Authority to dispose of such application.

24. (1) The Authority shall, on receipt of an application for a licence to manufacture a registered cosmetic cause the premises where such manufacture is to be carried out to be inspected and on being satisfied that such premises are suitable for the manufacture of cosmetics and that all the conditions for issuing a licence for the manufacture of cosmetics have been complied with, issue a licence to the applicant.

(2) The fee payable in respect of such licence shall be as specified in Schedule II hereto.

(3) Any manufacturer of cosmetics who has been given approval to manufacture cosmetics before the coming into operation of the Act may continue with the manufacture of a cosmetic in respect of which he has already obtained approval pending the issue of a licence in accordance with the regulations contained in this Part.

#### CONDITIONS OF A LICENCE TO MANUFACTURE COSMETICS.

25. Every applicant for a licence to manufacture cosmetics shall comply with the following conditions :—

- (a) the licensed manufacturer of cosmetics shall provide and maintain such staff, premises and plant as are considered by the Authority to be necessary for the manufacture of cosmetics undertaken by such licensed manufacturer, and he shall not carry out any such manufacture except at the premises specified in his licence ;

- (b) the licensed manufacturer of cosmetics shall provide and maintain such staff, premises, equipment and facilities for the handling and storage of such materials and cosmetics as are considered necessary by the Authority to avoid deterioration and he shall not use for such purposes, premises other than those specified in the licence or premises which may be approved from time to time by the Authority ;
- (c) the licensed manufacturer of cosmetics shall carry out all manufacture of cosmetics in such a way as to ensure that the cosmetics conform to the standards applicable to them as specified by the Authority ;
- (d) the licensed manufacturer of cosmetics shall provide such information as may be required by the Authority in respect of the cosmetics currently being manufactured and of the operations being carried out in relation to such manufacture ;
- (e) the licensed manufacturer of cosmetics shall inform the Authority before making any material alterations in the premises, plant or machinery used under his licence, or in the operations for which they are used, and he shall inform the Authority of any change he intends to take in any personnel named in the licence as :--
  - (i) responsible for supervising the production operations ; or
  - (ii) responsible for quality control of the products manufactured ;
- (f) the licensed manufacturer of cosmetics shall keep readily available for inspection by the Authority or by any person authorised by the Authority, the records of details of manufacture of each batch of every cosmetic which is being manufactured under the authority of such licence, and the tests carried out in respect of thereof, in such form that the records will be easily identifiable from the number of the batch as shown on each container in which the cosmetics are sold, supplied or exported and the licensed manufacturer of cosmetics shall allow the person authorised to take copies or make extracts from such records. Such records shall not be destroyed for a period of five years from the date of manufacture of the relevant batch, without the consent of the Authority ;
- (g) the licensed manufacturer of cosmetics shall keep such documents which will facilitate the withdrawal or recall from sale, supply or exportation of any cosmetic to which the licence relates ;
- (h) the licensed manufacturer of cosmetics shall allow the Authority or any officer authorised by the Authority to enter with or without notice any premises where the manufacture of any cosmetic is carried out under the licence or any premises where the raw materials and other substances used in the manufacture are stored or where the manufactured cosmetic is stored, sold or supplied, for the purpose of inspecting and if necessary taking samples for test, examination, analysis or clinical trial ;
- (i) where the licensed manufacturer of cosmetics has been informed by the Authority that any batch of any cosmetic in respect of which the licence is issued has been found not to be in conformity with the specifications as regards strength, quality or purity of the relevant cosmetic, or with the provisions of the Act or of any regulation made thereunder, that are applicable to cosmetics, such licensed manufacturer of cosmetics 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 ;
- (j) the licensed manufacturer of cosmetics shall comply with such further requirements if any, applicable to licensed manufacturers of cosmetics as may be specified in any regulations made under the Act.

26. Every licence issued by the Authority under regulation 24 shall be in Form D of Schedule IV hereto and be valid only for the premises in respect of which it is issued.

27. The fee payable in respect of a licence issued under regulation 24 shall be as specified in Schedule II hereto.

28.(1) The licence to manufacture a registered cosmetic shall, unless it is earlier suspended or cancelled be valid for a period of one year from the date of issue of such licence.

(2) Where the application for renewal of such licence is made three months before the expiry of the period of validity of the current licence, such licence shall be deemed to continue in force until an order is made in respect of the application for renewal.

(3) Any application for renewal of such licence shall be substantially in Form C of Schedule IV hereto.

29.(1) If the licensed manufacturer of cosmetics fails to comply with any of the conditions of a licence to manufacture a registered cosmetic, the Authority may, after giving the licensed manufacturer an opportunity to show cause why such an order should not be made, by an order in writing stating the reasons therefor, suspend the licence for such period as the Authority thinks fit, or cancel it, either in respect of all or some of the cosmetics to which it relates.

(2) Any person who is aggrieved by an order made under paragraph (1) suspending or cancelling his licence may, within three months of the date of such order, make an appeal to the Authority against such order.

30. Every licensed manufacturer of cosmetics shall exhibit the licence issued to him in a conspicuous place in the premises at which he manufactures the cosmetics.

31. The Authority shall keep a register of every licensed manufacturer of cosmetics and shall enter or cause to be entered therein the following particulars relating to each such licensed manufacturer :

- (a) the name of such licensed manufacturer ;
- (b) the address of the premises at which he is authorised to manufacture the cosmetic in respect of which the licence has been issued ;
- (c) the number of the licence ;
- (d) the date of issue of the licence ; and
- (e) the number and date of the certificate of registration if any, issued to him under the Business Names Ordinance (Chapter 149).

32. (1) Every licensed manufacturer of cosmetics shall forthwith inform the Authority in writing of any circumstances or events which affects the accuracy of any particulars stated by such licensed manufacturer in the application for a licence to manufacture cosmetics and shall together with such information, furnish to the Authority his licence.

(2) Upon the receipt of any information furnished by a licensed manufacturer of cosmetics under paragraph (1) the Authority may make or cause to be made such appropriate alterations in the register and in the licence of that licensed manufacturer as may be necessary and shall return the licence to the licensed manufacturer.

33. The Authority may revoke any licence issued under regulation 24, to manufacture cosmetics, if he is satisfied that the licensed manufacturer of cosmetics has acted in contravention of any regulations contained in this Part or any other regulation made under the Act pertaining to the manufacture of cosmetics.

#### PART IV

##### CONDITIONS FOR SALE OF COSMETICS (RETAIL AND WHOLESALE)

34. On or after the date of expiry of a period of three months from the date of operation no person shall sell any cosmetics other than a cosmetic registered with the Authority.

35. Every person who is engaged in selling any registered cosmetic (by retail or wholesale) hereinafter referred to as "the dealer" shall comply with the following conditions :—

- (a) the dealer shall allow any officer authorized by the Authority in that behalf to enter with or without notice, any premises where retail or wholesale trade of cosmetics is being carried out for the purpose of inspecting and taking samples of the cosmetics for test, examination, analysis or clinical trial ;
- (b) the dealer shall, on request and on payment, of the relevant fee furnish to the Authority from any batch of each cosmetic, such sample as the Authority may consider necessary for any test, examination, analysis or clinical trial ;
- (c) if the Authority so directs, the dealer shall not sell or offer for sale any batch of a cosmetic in respect of which samples are furnished under paragraph (b) until a certificate authorizing the sale of that batch of the cosmetic has been issued to him, by or on behalf of the Authority ;

(d) the dealer shall, on being informed by the Authority that any part of any batch of a cosmetic has been found by the Authority not to be in conformity with the standard specified in regard to quality and purity of the cosmetic and on being directed to do so, withdraw the remainder of that batch from sale, and, so far as is practicable in the particular circumstances of the case recall the issues already made from that batch.

#### PART V

#### DESTRUCTION

36. Any cosmetic which fails to conform to the standards required or the storage life of which has expired shall be destroyed. The destruction shall be carried out under the supervision of an officer authorised by the Authority.

#### PART VI

#### LABELLING

37. The containers of all cosmetics imported, manufactured, processed or packed locally or sold or exposed for sale shall have labels bearing the following information clearly indicating :—

- (a) the brand name,
- (b) the weight or volume of contents,
- (c) warnings or precautions that may be necessary,
- (d) the date of manufacture,
- (e) the batch or lot number assigned by the manufacturer, and ;
- (f) the name and address of the manufacturer.

#### PART VII

#### ADVERTISING OF COSMETICS

38. On or after the date of expiry of a period of three months from the date of operation no person shall advertise any cosmetic in contravention of the provisions of the Act or any regulation made thereunder.

39. No person shall advertise any cosmetic which is not registered with the Authority.

40. No person shall import into Sri Lanka—

- (a) advertising material of any cosmetic which is not registered with the Authority ;
- (b) advertising material of any cosmetic registered in Sri Lanka in contravention of the provisions of the Act or regulations made there under.

41. No person shall make any false or exaggerated claim for any cosmetic or misuse research results or quotations from scientific literature to support such claim.

42. The Authority may after giving the advertiser an opportunity of being heard, prohibit the publication of any advertisement which is in contravention of the provisions of the Act or regulations made thereunder.

Form A.

Regulation 4 (3)

#### SCHEDULE I

#### INFORMATION REQUIRED FOR REGISTRATION OF A COSMETIC

1. Name of applicant :.....
2. Address :.....
3. Status of applicant :  
Manufacturer :.....  
Importer :.....
4. Name and Address of Manufacturer :.....

5. Name of the Cosmetic :
    - (1) Brand name (if any) :.....
    - (2) Official or approved name :.....
  6. Type of Cosmetic : e.g. : Hair Lotion, Face Powder, Toilet Soap :.....
  7. Formulation and Package size : e.g. : Powder, Cream, Lotion, etc. :.....
  8. Composition :
 

The ingredients should be listed by their chemical name and should include their exact quantities.
  9. A certificate from the health authorities of the country in which the cosmetic is produced, confirming that the cosmetic is in use there and the period of use and if not, reasons for not marketing it in the country of manufacture.
  10. Certificate of analysis and full information concerning analytical assessment and other control methods to ensure strength, quality and stability.
  11. List of countries in which the cosmetic is approved or registered for sale.
  12. Fully packed sample of the cosmetic in the form that will be offered for sale should also be sent.
  13. A sample of the label (s) used in the containers and package insert (if any) should be supplied.
  14. All data should be submitted in English, in a *hard* file cover, in duplicate.
- Applications made without these requirements will not be accepted.*

SCHEDULE I

Form B

Regulation 4 (4)

APPLICATION FORM FOR CERTIFICATE OF REGISTRATION OF A COSMETIC BY AN IMPORTER.  
 (to be filled in triplicate by applicant)

I/We .....of ..... hereby apply for registration of the cosmetic namely..... details of which are enclosed herewith.

Signature :.....

Date :.....

Address :.....

Designation of applicant :.....

FOR OFFICIAL USE ONLY.

Application No. :.....

Decision : Registered/Not registered.

Dated :.....

Registration No. :.....

Dated :.....

Fees Paid :.....

Dated :.....

Date :.....

Receipt :.....

Authority.

SCHEDULE I

Form C

Regulation 4 (5)

APPLICATION FORM FOR CERTIFICATE OF REGISTRATION OF A COSMETIC BY A MANUFACTURER  
 (To be filled in triplicate by Applicant)

I/We ..... of ..... hereby apply for registration of the cosmetic and formulation for manufacture namely ..... details of which are enclosed herewith.

Signature :.....

Date :.....

Address :.....

Designation of applicant :.....



FOR OFFICIAL USE ONLY

Application No. : ..... Dated : .....  
 Decision : Registered/Not registered Dated : .....  
 Registration No. : ..... Dated : .....  
 Fees paid : ..... Receipt No. : .....

Date : ..... Authority

Regulations 4(6), 10(3), 11(3), 24(2), 27

SCHEDULE II

FEES

1. *Certificate of Registration.*—The fee for the Certificate of Registration shall be as follows :—  
 (a) rupees five hundred for registration of a cosmetic.  
 (b) rupees two hundred and fifty for the renewal of registration of a cosmetic.

Provided that the application, or the renewal of registration is made six months before the expiry of the validity of the Certificate of Registration.

(c) A fee of rupees fifty shall be made for a duplicate copy of the Certificate of Registration if the original is damaged or lost and such copy of the certificate shall bear the words "Duplicate Copy".

2. *Licence to Import Cosmetics.*—Fee for a licence to import a registered cosmetic is Rs. 1,000/- (Thousand.)
3. *Licence to Manufacture Cosmetics.*—The fee for a licence to manufacture a cosmetic is Rs. 1,000/- (Thousand.)

Form A

Regulation 5(2)

SCHEDULE III

CERTIFICATE OF REGISTRATION

The following cosmetic is hereby registered under the Cosmetics, Devices and Drugs Act, No.27 of 1980 :—

Name of cosmetic : .....  
 Type of cosmetic : .....  
 Name of manufacturer : .....  
 Country of manufacture : .....  
 Name of importer : .....  
 Registration No. : .....  
 Date of registration : .....  
 Type of registration : .....  
 Full registration : .....  
 Provisional registration : ..... Period : .....

Schedule :

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled.  
 Provisional registration shall be valid for the period stipulated.

Date of issue : .....

Authority.

Form B

Regulation 6(3)

SCHEDULE III

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF A COSMETIC.

I/We ..... of ..... hereby apply for renewal of registration of the cosmetic for import/manufacture.

Registration No. : .....

Expiry date of last registration : .....

Signature : .....

Address : .....

Date : .....

Designation of applicant : .....

Form A

Regulation 10(1)

SCHEDULE IV

APPLICATION FOR LICENCE TO IMPORT A REGISTERED COSMETIC.

I/We ..... hereby apply for the import of a cosmetic registered by the Authority.

Signature : .....

Address : .....

Date : .....

Designation of applicant : .....

Form B

Regulation 11(2)

SCHEDULE IV

LICENCE TO IMPORT A REGISTERED COSMETIC

Licence number :

M/s. .... of ..... is/are hereby licenced to import into Sri Lanka during the period for which this licence is in force the cosmetic specified below manufactured by .....

This licence is subject to the conditions prescribed in regulation 12 of the Cosmetics Regulations made under the Cosmetics, Devices and Drugs Act No. 27 of 1980 as amended by Act No.38 of 1984 and shall be in force for one year from the date of issue unless it is earlier suspended or cancelled.

Name of cosmetic to which this licence is applicable.

1. ....
2. ....
3. ....

Date of issue : .....

.....  
Authority.

Form C

Regulation 22

SCHEDULE IV

APPLICATION FOR ISSUE/RENEWAL OF A LICENCE TO MANUFACTURE A COSMETIC BY WAY OF BAISO.

MANUFACTURE/SEMI-BASIS MANUFACTURE/FORMULATION/REPACKING

I/We, ..... of ..... hereby apply, for an issue/renewal of a licence to manufacture by way of ..... on premises situated at .....

Name of Cosmetic : .....

Details of the firm required to be registered are given in the enclosed form.

Signature :.....

Address :.....

Date :.....

Designation of Applicant :.....

Form D

Regulation 26

SCHEDULE IV

LICENCE TO MANUFACTURE A COSMETIC

License Number :

M/s. .... of ..... is/are hereby licenced to manufacture the cosmetic specified below at the premises situated at .....

This licence is subject to the conditions prescribed in regulation 25 of the Cosmetics Regulations made under the Cosmetics, Devices and Drugs Act No. 27 of 1980 as amended by Act No. 38 of 1984 and shall be in force for one year from the date of issue unless it is earlier suspended or cancelled.

Name of cosmetic to which this licence is applicable.

1. ....
2. ....
3. ....

Date of issue :.....

.....  
Authority.

COSMETICS, DEVICES AND DRUGS ACT, No. 27 OF 1980

REGULATIONS made by the Minister of Health, under section 38 of the Cosmetics, Devices and Drugs Act, No. 27 of 1980, as amended by Act No. 38 of 1984 and approved by Parliament.

DR. RANJITH ATAPATTU,

Minister of Health.

Colombo, 14.11.1985.

Regulations

1. These regulations may be cited as the Devices Regulations, No. 38 of 1984 and shall come into operation on (hereinafter referred to as "the date of operation") 01.01.1986.

2. For the purposes of these regulations every device registered under the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act No. 38 of 1984 (hereinafter referred to as "the Act") shall be called "a registered device".

PART I

REGISTRATION OF DEVICES

3. On or after the expiry of a period of three months from the date of operation, the Cosmetics, Devices and Drugs Authority, (hereinafter referred to as "the Authority") shall prepare a register of every registered device and shall enter or cause to be entered therein the following particulars relating to such registered device :

- (a) the name of the device;
- (b) the name of the manufacturer;
- (c) the country of manufacture;
- (d) the registration number assigned to it;

- (e) the name and address of the holder of the certificate of registration and whether he is an importer or manufacturer ; and
- (f) the number of the licence issued to him.

4. (1) Every person desirous of registering a device with the Authority shall make an application in that behalf to the Authority.

(2) A separate application shall be made in respect of each device intended to be registered.

(3) Every applicant for registration of a device shall along with his application furnish to the Authority all such information as may be required and specified in Form A of Schedule I hereto for the purpose of enabling the Authority to dispose of such application.

(4) Every application made by an importer for a Certificate of Registration of a device shall be substantially in Form B of Schedule I hereto.

(5) Every application made by a manufacturer for a Certificate of Registration of a device shall be substantially in Form C of Schedule I hereto.

(6) The fee payable in respect of a Certificate of Registration of a device shall be as specified in Schedule II hereto.

5. (1) On receipt of an application for a Certificate of Registration of a device the Authority shall forward such application to the Sub-Committee on Devices of the Cosmetics devices and Drugs Technical Advisory Committee for advice and report.

(2) Having considered the report of the Sub-Committee on Devices, if the Authority is satisfied that if a Certificate of Registration is granted the conditions of such certificate of registration will be observed, the Authority shall, on payment of the specified fee, register or cause to be registered such device and issue a Certificate of Registration in Form A of Schedule III hereto in respect of that device.

6. (1) The Certificate of Registration of a device shall, unless it is earlier suspended or cancelled, be valid for a period of five years from the date of issue of such certificate.

(2) Where an application for a renewal of a Certificate of Registration is made six months before the date of expiry of the period of validity of the current Certificate of Registration, such Certificate of Registration shall, be deemed to continue in force until an order is made in respect of the application for its renewal.

(3) Every application for renewal of a registration of a device shall be substantially in Form B of Schedule III hereto.

7. The holder of a Certificate of Registration of a device shall forthwith inform or notify the Authority of

(a) any material changes that have been made or that are proposed to be made in the particulars<sup>s</sup> contained in or furnished in connection with his application, in relation to any device to which the certificate of registration relates ;

(b) any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with the application for the registration of the device, for the purpose of assessing the safety, quality, or efficacy of the device ;

(c) any decision to withdraw the device from the register and shall state the reasons for such decision ; and

(d) any decision to terminate his activities as an importer or manufacturer of the said device.

8. (1) If the holder of a Certificate of Registration of a device fails to comply with any of the conditions of registration of such device, the Authority may, after giving such holder of the Certificate of Registration of such device an opportunity to show cause why such an order should not be made, remove the name of the device from the register of devices, by an order in writing and state the reasons therefor.

(2) Any person aggrieved by the order for such removal of the name of the device from the register of devices, may, within three months from the date of such order, appeal to the Authority against such order.

(3) The Authority shall, on the advice of the Sub-Committee on Devices remove the name of a device from the register of devices and inform the holder of the Certificate of Registration of the device of the reasons therefor.

PART II

LICENSING OF IMPORTERS OF DEVICES

9. On or after the expiry of a period of three months from the date of operation, no person shall import a registered device except under the authority of a licence issued under regulation II. Every person to whom a licence is issued under regulation II shall hereinafter be referred to as a "licensed importer of devices."

10. (1) Every person desirous of obtaining a licence to import any registered device shall make a separate application to the Authority in respect of each such device which he intends to import. Every such application shall be substantially in Form A of of Schedule IV hereto.

(2) Every applicant for a licence to import any registered device shall furnish to the Authority all such information as may be required for the purpose of enabling the Authority to dispose of such application.

11. (1) On receipt of an application for a licence to import a registered device under regulation 10, the Authority shall, on being satisfied that the conditions of the licence will be satisfied if the licence is issued, issue such licence to the applicant.

(2) Every licence issued by the Authority under this regulation shall be substantially in Form B of Schedule IV hereto.

(3) The fee payable in respect of a licence to import a registered device shall be as specified in Schedule II hereto.

CONDITIONS OF LICENCE TO IMPORT DEVICES

12. Every licence issued under regulation 11 to import a device shall contain the following conditions :

- (a) the licensed importer of devices shall allow any officer authorised in that behalf by the Authority, to enter with or without notice any premises where the imported device is stored for the purpose of inspecting and if necessary taking samples for test, examination, analysis or clinical trial ;
- (b) the licensed importer of devices shall furnish to the Authority such samples as the Authority may consider adequate from every batch of each device imported under a licence, for test, examination, analysis or clinical trial ;
- (c) the licensed importer of devices shall on being informed by the Authority that any part of any batch of the device imported has been found by the Authority not to be in conformity with the standard specified by the Authority, withdraw the batch from sale ;
- (d) the licensed importer of devices shall maintain a record of all particulars of import, sale and supply of such device by him and such record shall be open for inspection by any officer authorised in that behalf by the Authority.

13. (1) The licence to import a device shall unless it is earlier suspended or cancelled be valid for a period of one year from the date of issue of such licence.

(2) Where the application for renewal of such licence is made three months before the expiry of the period of validity of the current licence, such licence shall be deemed to continue in force until an order is made in respect of such application.

14. (1) If the licensed importer of devices fails to comply with any of the conditions of a licence to import devices the Authority may, after giving such licensed importer of devices an opportunity to show cause why such an order should not be made, by an order in writing stating the reasons therefor, suspend such licence for such period as the Authority thinks fit, or cancel it, either in respect of all or some of the devices to which it relates.

(2) Any person who is aggrieved by the order made under paragraph (1) suspending or cancelling his licence may, within three months from the date of such order, make an appeal to the Authority.

15 No person shall import except for the purpose of test, examination, analysis or clinical trial, any device under the same name or under any other name if the manufacture, sale or distribution of such device is prohibited in the country of manufacture.

16. Every licensed importer of devices shall exhibit the licence issued to him under regulation 11 in a conspicuous place in the premises at which he sells, stores or distributes the devices imported under that licence.

17. The Authority shall keep a register of all licensed importers of devices and shall enter or cause to be entered therein the following particulars relating to each such licensed importer of devices :

- (a) the name of such licensed importer of devices ;
- (b) the address of the premises in respect of which the licence has been issued ;
- (c) the date of issue of the licence ; and
- (d) the number and date of the certificate of registration, if any, issued to him under the Business Names Ordinance (Chapter 149). The name of the licensed importer of devices shall be published in the Gazette.

18. (1) Every licensed importer of devices shall forthwith inform the Authority in writing of any circumstances or event which may occur which affects the accuracy of any particulars stated by such licensed importer of devices in the application for a licence to import devices and shall at the same time forward his licence to the Authority.

(2) Upon the receipt of any information furnished by a licensed importer of devices under paragraph (1), the Authority may make or cause to be made such appropriate alterations in the register and in the licence of that importer as may be necessary and shall return the licence to the licensed importer of devices.

19. The Authority may revoke any licence to import a device issued under regulation 11 if the Authority is satisfied that the licensed importer of devices has acted in contravention of any regulation contained in this Part or any other regulation made under the Act pertaining to importation and distribution of devices.

#### IMPORT OF DEVICES FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS OR CLINICAL TRIAL

20. Every applicant for a licence to import devices for test, examination, distribution as samples, analysis or clinical trial shall comply with the following conditions :

- (a) he shall make a separate application to the Authority in respect of each such device as he intends to import.
- (b) Every such application shall be substantially in Form C of Schedule IV hereto.

21. (1) On receipt of an application for a licence to import any device for test, examination, distribution as samples, analysis or clinical trial, the Authority shall, on being satisfied that the conditions of the licence will be observed if such licence is issued, issue such licence to the applicant ;

- (2) Every licence issued by the Authority under this regulation shall be in form D of Schedule IV hereto ;
- (3) The licence fee shall be as specified in Schedule II hereto.

#### IMPORT OF DEVICES FOR PERSONAL USE

22 (1) Any device imported for personal use by any person shall be intended for the exclusive personal use of that person.

- (2) Any device imported for personal use, may be allowed to be imported subject to the following conditions :
  - (a) that the Authority is satisfied on an application made to such Authority by any person in Form E of Schedule IV hereto that the device is for bona fide personal use ;
  - (b) that a licence has been issued in respect of the said device in Form F of Schedule IV hereto.

### PART III

#### LICENCE TO MANUFACTURE DEVICES

23. On or after the expiry of a period of three months from the date of operation no person shall manufacture any device except under the authority of a licence issued under regulation 27. Every person to whom a licence is issued under regulation 27 shall hereinafter be referred to as a " licensed manufacturer of devices ".

24. No device other than a registered device referred to in regulation 2 shall be manufactured in Sri Lanka.
25. Every person desirous of obtaining a licence to manufacture any registered device shall make a separate application to the Authority in respect of each device he intends to manufacture. Every such application shall be in Form G of Schedule IV hereto.
26. Every applicant for a licence to manufacture a registered device shall furnish to the Authority all such information as may be required for the purpose of enabling the Authority to dispose of such application.
27. (1) The Authority shall, upon receipt of an application for a licence to manufacture any registered device cause the premises where such manufacture is to be carried out to be inspected and on being satisfied that such premises are suitable for the manufacture of devices and that all the conditions for issuing a licence for the manufacture of devices have been complied with, issue a licence to the applicant.
- (2) The fee payable in respect of such licence shall be as specified in Schedule II hereto.

#### CONDITIONS OF A LICENCE TO MANUFACTURE DEVICES

28. Every applicant for a licence to manufacture a device shall comply with the following conditions:—
- (a) the licensed manufacturer of devices shall provide and maintain such staff, premises and plant as are considered by the Authority, to be necessary for the manufacture of devices undertaken by him and he shall not carry out any such manufacture except at the premises specified in his licence ;
- (b) the licensed manufacturer of devices shall provide and maintain such staff, premises, equipment and facilities for the handling and storage of the raw materials and devices as are considered necessary to avoid deterioration and he shall not use for such purposes premises other than those specified in the licence or premises which may be approved from time to time by the Authority ;
- (c) the licensed manufacturer of devices shall carry out all manufacture of devices in such a way as to ensure that the devices conform to the standards applicable to them as specified by the Authority ;
- (d) the licensed manufacturer of devices shall provide such information as may be required by the Authority in respect of the devices currently being manufactured and of the operations being carried out in relation to such manufacture ;
- (e) the licensed manufacturer of devices shall inform the Authority before making any material alterations in the premises, plant or machinery used under his licence, or in the operations for which they are used, and he shall inform the Authority of any change he proposes to make in any personnel named in the licence as—
- (i) responsible for supervising the production operations or ;
- (ii) responsible for quality control of the products manufactured ;
- (f) the licensed manufacturer of devices shall keep readily available for inspection by the Authority or by any person authorized by the Authority, the records of details of manufacture of each batch of every device which is being manufactured under the authority of such licence, and the tests carried out in respect thereof, in such form that the records will be easily identifiable from the number of the batch as shown on each container in which the device is sold, supplied or exported. The licensed manufacturer of devices shall allow the person authorised to take copies or make extracts from such records. Such records shall not be destroyed for a period of five years from the date of manufacture of the relevant batch without the consent of the Authority ;
- (g) the licensed manufacturer of devices shall keep such documents which will facilitate the withdrawal or recall from sale, supply or exportation of any device to which the licence relates ;
- (h) the licensed manufacturer of devices shall allow the Authority or any officer authorised by the Authority to enter with or without notice, any premises where the manufacture of any device under the licence is carried out or any premises where the raw materials and other substances used in its manufacture are stored or where the manufactured device is stored, sold or supplied for the purpose of inspecting and if necessary taking samples for test, examination, analysis or clinical trial ;

- (i) where the licensed manufacturer of devices has been informed by the Authority that any batch of of any device in respect of which the licence is issued has been found not to be in conformity with the specifications as regards the quality of the relevant device, or with the provisions of the Act or of any regulations made thereunder, that are applicable to devices, he 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 ;
- (j) the licensed manufacturer of devices, shall comply with such further requirements if any, applicable to licensed manufacturers of devices as may be specified in any regulations made under the Act.

29. Every licence issued by the Authority under regulation 27 shall be in Form H of Schedule IV hereto and be valid only for the premises in respect of which it is issued.

30. The fee payable in respect of a licence issued under regulation 27 shall be as specified in Schedule II hereto.

31.(1) The licence to manufacture a registered device shall, unless it is earlier suspended or cancelled, be valid for a period of one year from the date of issue of such licence.

(2) Where the application for a renewal of such licence is made three months before the expiry of the period of validity of the current licence such licence shall be deemed to continue in force until an order is made in respect of the application for renewal.

(3) Any application for renewal of such licence shall be substantially in Form G of Schedule IV hereto.

32. (1) If the licensed manufacturer of devices fails to comply with any of the conditions of a licence to manufacture a registered device, the Authority may, after giving such licensed manufacturer an opportunity to show cause why such an order should not be made, by an order in writing stating the reasons therefor, suspend the licence for such period as he thinks fit or cancel it, either in respect of all or some of the devices to which it relates.

(2) Any person who is aggrieved by the order made under paragraph (1) suspending or cancelling his licence may, within three months of the date of such order make an appeal to the Authority, against such order.

33. Every licensed manufacturer of devices shall exhibit the licence issued to him under regulation 27, in a conspicuous place in the premises at which he manufactures the device.

34. The Authority shall keep a register of all licensed manufacturers and shall enter or cause to be entered therein the following particulars relating to each such licensed manufacturer :—

- (a) the name of such licensed manufacturer ;
- (b) the address of the premises at which he is authorised to manufacture the devices in respect of which the licence has been issued ;
- (c) the number of the licence ;
- (d) the date of issue of the licence ; and
- (e) the number and the date of the Certificate of Registration, if any, issued to him under the Business Names Ordinance (Chapter 149).

35. (1) Every licensed manufacturer of device shall forthwith inform the Authority in writing of any circumstances or event which affect the accuracy of any particulars stated by such licensed manufacturer in the application for a licence to manufacture devices and shall, together with such information, furnish to the Authority his licence.

(2) Upon the receipt of any information furnished by a licensed manufacturer of devices under paragraph (1), the Authority may make or cause to be made such appropriate alterations in the register and in the licence of that manufacturer as may be necessary and shall return the licence to the licensed manufacturer.

36. The Authority may revoke any licence issued under regulation 27 to manufacture devices, if he is satisfied that the licensed manufacturer of devices has acted in contravention of any regulations contained in this Part or any other regulation made under the Act pertaining to the manufacture of devices.



#### PART IV

##### CONDITIONS OF SALE OF DEVICES (RETAIL AND WHOLESALE)

37. On or after the date of expiry of a period of three months from the date of operation no person shall sell any device other than a device registered with the Authority.

38. Every person who is engaged in selling any registered device (by retail or wholesale) hereinafter referred to as "the dealer" shall comply with the following conditions :—

- (a) the dealer shall allow any officer Authorised by the Authority in that behalf to enter with or without notice, any premises where retail or wholesale trade of devices is being carried out, for the purposes of inspecting and if necessary taking samples of the device for test, examination, analysis or clinical trial ;
- (b) the dealer shall, on request and on payment of the relevant fee furnish to the Authority from any batch of each device, such samples as the Authority may consider necessary for any test, examination, analysis or clinical trial ;
- (c) if the Authority so directs, the dealer shall not sell or offer for sale any batch of each device in respect of which samples are furnished under paragraph (b) until a certificate authorising the sale of that batch of the device, has been issued to him, by or on behalf of the Authority ;
- (d) the dealer shall, on being informed by the Authority that any part of any batch of a device has been found by the Authority not to be in conformity with the standard specified in regard to the quality of the device and on being directed to do so, withdraw the remainder of that batch from sale, and, so far as is practicable in the particular circumstances of the case, recall the issues already made from that batch.

#### PART V

##### DESTRUCTION

39. Any device which fails to conform to the standards required or the storage life of which has expired, shall be destroyed. The destruction shall be carried out under the supervision of an officer authorized by the Authority.

#### PART VI

##### LABELLING

40. The container of every device imported, manufactured, processed or packed locally or sold or exposed for sale shall have labels bearing the following information clearly indicating :--

- (a) the brand name ;
- (b) any special storage conditions that may be necessary ;
- (c) any warning and precautions that may be necessary ;
- (d) the date of manufacture ;
- (e) the date of expiry where applicable ;
- (f) the batch or lot number assigned by the manufacturer ;
- (g) the name and address of the manufacturer ; and
- (h) adequate directions for use of the device.

PART VII

ADVERTISING OF DEVICES.

41. On or after the date of expiry of a period of three months from the date of operation no person shall advertise any device in contravention of the provisions of the Act or regulations made thereunder.
42. No person shall advertise any device which is not registered with the Authority.
43. No person shall import into Sri Lanka—
  - (a) advertising material of any device which is not registered with the Authority ;
  - (b) advertising material of any device registered in Sri Lanka, in contravention of the provisions of the Act or regulations made thereunder.
44. No person shall send any advertising material about any device to the medical, dental, pharmaceutical<sup>1</sup> or allied professions, which is false, misleading or inconsistent with the particulars contained in the application originally submitted with the application for the registration of the device or particulars submitted subsequently.
45. No person shall make any false or exaggerated claim for any device or misuse research results or quotations from scientific literature to support such claim.
46. The Authority may, after giving the advertiser an opportunity of being heard, prohibit the publication of any advertisement which is in contravention of the provisions of the Act or regulations made thereunder.

Form : A

Regulation 4 (3)

SCHEDULE I

INFORMATION REQUIRED FOR REGISTRATION OF A DEVICE

1. Name of Applicant :.....
2. Address :.....
3. Status of applicant :.....
  - Manufacturer :.....
  - Importer :.....
4. Name of the device :.....
  - Brand name (if any) :.....
  - Official or approved name :.....
5. A certificate from the health authorities of the country in which it is produced, confirming that the device is in use there and the period of use and if not, reasons for not marketing it in the country of manufacture.
6. List of countries in which the device is approved or registered for sale.
7. Fully packed samples of the device in the form that will be offered for sale should also be sent to enable study of the product (if requested).
8. A sample of the lable (s) used on the containers should be supplied.
9. All data should be submitted in English, in a hard file cover, in duplicate.  
*Applications made without these requirements will not be accepted.*

Form : B

Regulation 4 (4)

SCHEDULE I

APPLICATION FORM FOR CERTIFICATE OF REGISTRATION OF A DEVICE BY AN IMPORTER

(To be Filled In Triplicate by Applicant)

I/We ..... of .....  
 ..... hereby apply for registration of the device namely,.....  
 .....details of which are enclosed herewith.

Signature : .....

Address : .....

Designation of Applicant : .....

Date : .....

*For Official use only*

Application No : .....

Dated : .....

Decision : Registered/Not registered

Dated : .....

Registration No : .....

Dated : .....

Fees Paid : .....

Receipt No : .....

Date : .....

Signature : .....

(Authority)

Form : C

Regulation 4 (5)

SCHEDULE I

APPLICATION FORM FOR CERTIFICATE OF REGISTRATION OF A DEVICE BY A MANUFACTURER

(To be Filled In Triplicate by Applicant)

I/We ..... of .....  
 ..... hereby apply for registration of the device and formulation for local  
 manufacture namely ..... details of which are enclosed herewith.

Signature : .....

Address : .....

Date : .....

Designation of Applicant : .....

*For Official use only*

Application No : .....

Dated : .....

Decision : Registered/Not registered

Dated : .....

Registration No : .....

Dated : .....

Fees paid : .....

Receipt No : .....

Date : .....

(Authority)

Regulation 4(6) 10 (3), 11(3), 21(3), 27(2), 30

SCHEDULE II

FEEs

1. *Certificate of Registration* .— The fee for the Certificate of Registration shall be as follows :—

- (a) rupees five hundred for registration of a device;
- (b) rupees two hundred and fifty for the renewal of registration of a device :

Provided that the application for the renewal of registration is made six months before the expiry of the validity of the Certificate of Registration.

- (c) a fee of rupees fifty shall be paid for a duplicate copy of the Certificate of Registration if the original is damaged or lost and such copy of the certificate shall bear the words "Duplicate Copy".

2. *Licence to Import a Device*.— The fee for a licence to import a registered device is Rs. 1,000.

3. *Licence to Manufacture a Device*.— The fee for a licence to manufacture a device is Rs. 1,000.

Form A

Regulation 5 (2)

SCHEDULE III

CERTIFICATE OF REGISTRATION

The following device is hereby registered under the Cosmetics, Devices and Drugs Act, No.27 of 1980. :—

- Name of device :.....
- Type of device :.....
- Name of manufacturer :.....
- Country of manufacture :.....
- Name of Importer :.....
- Registration No. :.....
- Date of Registration :.....
- Type of Registration :.....
  - Full Registration :.....
  - Provisional Registration :.....      Period :.....      Schedule :.....

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled.

Provisional registration shall be valid for the period stipulated.

Date of issue :——.

.....  
 Authority.

Form B

Regulation 6(3)

SCHEDULE III

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF A DEVICE

I/We,.....

..... of .....  
hereby apply for renewal of registration of the device for import/local manufacture.

Registration No. :.....

Expiry date of last Registration :.....

Signature :.....

Address :.....

Designation of Applicant :.....

Date :.....

Form A

Regulation 10(1)

SCHEDULE IV

APPLICATION FOR LICENCE TO IMPORT A REGISTERED DEVICE/s

I/We, ..... hereby  
apply for the import of a device/s registered by the Authority.

Signature :.....

Address :.....

Date :.....

Designation of applicant :.....

Form B

Regulation 11(2)

SCHEDULE IV

LICENCE TO IMPORT A REGISTERED DEVICE/s

Licence No. :.....

M/s ..... of ..... is/are hereby licensed to import into Sri Lanka during the period for which this licence is in force the device/s specified below, manufactured by .....

This licence is subject to the conditions prescribed in regulation 12 of the Devices Regulations made under the Cosmetics, Devices and Drugs Act, No.27 of 1980, as amended by Act No. 38 of 1984 and shall be in force for one year from the date of issue unless it is earlier suspended or cancelled.

Name of device/s to which this licence applies. —

1. ....
2. ....
3. ....

Date of issue :.....

Form C Regulation 20(b)

SCHEDULE IV

APPLICATION FOR IMPORT OF A DEVICE/S FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES,  
ANALYSIS OR CLINICAL TRIAL

I/We..... of ..... herby apply for a licence to import from M/s. .... of ..... the device/s specified below for the purpose of test ; examination, distribution as samples, analysis or clinical trial .

Name of device/s.—

1. ....
2. ....
3. ....

Signature : .....

Address :.....

Designation of applicant :.....

Date :.....

Form D Regulation 21 (2)

SCHEDULE IV

LICENCE TO IMPORT A DEVICE/S FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS  
OR CLINICAL TRIAL

Licence Number :.....

M/s. .... of ..... is/are hereby licensed to import from ..... the device/s specified below for the purpose of test, examination, distribution as samples, analysis or clinical trial.

This licence is subject to the conditions prescribed in regulation 20 of the Devices Regulations made under the Cosmetics, Devices and Drugs Act, No.27 of 1980 as amended by Act No. 38 of 1984.

The licence shall be valid for importation of one batch only and shall be valid for one year from the date of issue.

Name/s of device/s with quantities which may be imported :—

1. ....
2. ....
3. ....

Date of issue :... ..

.....  
Authority.

Form E Regulation 22 (2) (a)

SCHEDULE IV

APPLICATION FOR LICENCE TO IMPORT A DEVICE/S FOR PERSONAL USE

I, ..... of ..... hereby apply for a licence to import the device/s specified below solely for my personal use.

I attach a prescription from a registered medical practitioner in regard to the need for the said device.

Name of device/s and quantity :

Signature : .....

Address : .....

Date : .....

Form F

Regulation 22 (2) (b)

SCHEDULE IV

LICENCE TO IMPORT DEVICE/S FOR PERSONAL USE

Licence Number : .....

M/s. .... of ..... is hereby licensed to import the following device/s in the quantities specified.

*Device/s*

*Quantity*

This licence is subject to the conditions prescribed in paragraph (2) of regulation 22 of the Devices Regulations made under the Cosmetics, Devices and Drugs Act, No. 27 of 1980, as amended by Act No. 38 of 1984.

Date of Issue : .....

.....  
Authority.

Form: G

Regulation 25

SCHEDULE IV

APPLICATION FOR ISSUE/RENEWAL OF A LICENCE TO MANUFACTURE A DEVICE/S BY WAY OF  
BASIC MANUFACTURE/SEMI-BASIC MANUFACTURE/FORMULATION/REPACKING

I/We, ..... of ..... hereby apply for an issue/renewal of a licence to manufacture by way of ..... on premises situated at .....

Name of device/s :

Details of the firm requiring to be registered are given in the enclosed form.

Signature : .....

Address : .....

Date : .....

Designation of Applicant : .....

Form H

Regulation 29

SCHEDULE IV

LICENCE TO MANUFACTURE DEVICE/S

Licence Number : .....

M/s. .... of ..... is/are hereby licensed to manufacture the device/s specified below at the premises situated at .....

This licence is subject to the conditions prescribed in regulation 28 of the Devices Regulations, made under the Cosmetics, Devices and Drugs Act, No. 27 of 1980, as amended by Act No. 38 of 1984 and shall be in force for one year from the date of issue unless it is earlier suspended or cancelled.

Name/s of device/s to which this licence is applicable.—

1. ....
2. ....
3. ....

.....  
Authority.

.....  
Date of issue :

3252/2

COSMETICS, DEVICES AND DRUGS ACT, No. 27 OF 1980

REGULATIONS made by the Minister of Health, under section 38 of the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act, No. 38 of 1984 and approved by Parliament.

Colombo, 14.11.1985.

DR. RANJITH ATAPATTHU,  
Minister of Health.

REGULATIONS

1. These regulations may be cited as the Drugs Regulations, No. 38 of 1984 and shall come into operation on 01.01.1986. (hereinafter referred to as "the date of operation").

2. For the purposes of these regulations every drug registered under the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act, No. 38 of 1984. (hereinafter referred to as "the Act") shall be called "a registered drug."

3. (1) No licence is required under these regulations, to sell any registered drug, specified in Schedule I hereto and such drug shall be sold only in the original unopened containers or packs of the manufacturer and shall not contain any substance specified in Group B of Schedule II hereto and Schedule III hereto.

(2) No person shall, unless he is a holder of a licence issued in that behalf, sell without a prescription, any registered drug specified in Group A of Schedule II hereto.

(3) No person shall, unless he is a holder of a licence issued in that behalf, sell without a prescription, any registered drug that may be specified from time to time in Group B of Schedule II hereto.

(4) No person shall, unless he is a holder of a licence issued in that behalf, sell without a prescription, any registered drug specified in Schedule III hereto.

PART I

REGISTRATION OF DRUGS

4. On or after the date of expiry of a period of three months from the date of operation, the Cosmetics, Devices and Drugs Authority (hereinafter referred to as "the Authority") shall prepare a register of every registered drug and shall enter or cause to be entered therein the following particulars relating to such registered drug :

- (a) the approved official name and brand name of the drug ;
- (b) the name of the manufacturer ;
- (c) the country of manufacture ;
- (d) the registration number assigned to it ;
- (e) the name and address of the holder of the Certificate of Registration ;
- (f) whether he is an importer or manufacturer ; and
- (g) the number of the licence issued to him.

5. (1) Every person desirous of registering a drug with the Authority shall make an application in that behalf to the Authority.

(2) A separate application shall be made in respect of each drug intended to be registered.

(3) Every applicant for registration of any drug shall furnish along with his application to the Authority all such information as may be required as specified in Form A of Schedule IV hereto, for the purpose of enabling the Authority to dispose of such application.

(4) Every application made by an importer for a Certificate of Registration of a drug shall be substantially in Form B of Schedule IV hereto.

(5) Every application made by a manufacturer for a Certificate of Registration of a drug shall be substantially in Form C of Schedule IV hereto.

(6) The fee payable in respect of a Certificate of Registration shall be as specified in Schedule XI hereto.

6. (1) On receipt of an application for a Certificate of Registration of a drug the Authority shall forward such application to the Sub-Committee on Drugs of the Cosmetics devices and Drugs Technical Advisory Committee for advice and report.



(2) Having considered the report of the Sub-Committee on Drugs, if the Authority is satisfied that if a Certificate of Registration is granted the conditions of such Certificate of Registration will be observed, the Authority shall, on payment of the specified fee, register or cause to be registered such drug and issue a certificate of registration substantially in Form D of Schedule IV hereto, in respect of such drug.

(3) Every drug registered under paragraph (2) shall be assigned a number.

(4) The fee payable in respect of a Certificate of Registration of a drug shall be as specified in Schedule XI hereto.

(5) Where the Authority is not satisfied with the efficacy, safety or quality of a drug in respect of which an application for a Certificate of Registration is made, the Authority may reject such application and inform the applicant in writing of the reasons for such rejection.

(6) The rejection of any application for a Certificate of Registration of a drug shall not debar an applicant from submitting a fresh application if new data is available which meets the requirements for registration.

7. (1) The Certificate of Registration of a drug shall, unless it is earlier suspended or cancelled, be valid for a period of five years from the date of issue of such certificate.

(2) Where an application for a renewal of such Certificate of Registration is made six months before the date of expiry of the period of validity of the current Certificate of Registration, such certificate of registration shall, be deemed to continue in force until an order is made in respect of the application for its renewal.

(3) Every application for renewal of registration of a drug shall be substantially in Form E of Schedule IV hereto.

8. The holder of a Certificate of Registration of a drug shall forthwith inform or notify the Authority :—

(a) of any material changes that have been made or that are proposed to be made in the following particulars contained in or furnished in connection with his application, in relation to any drug to which the Certificate of Registration relates :—

(i) the specification of the drug ;

(ii) the specification of any of the constituents of the drug ;

(iii) the composition of the drug or any of the constituents of the drug ;

(iv) the methods of manufacture of the drug ;

(v) the methods and procedures described in the application for ensuring compliance with such specifications ; and

(vi) the arrangements described in the application for storage of the drug.

(b) of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with the application for the registration of the drug, for the purpose of assessing the safety, quality or efficacy of the drug ;

(c) of any decision to withdraw the drug from the register and shall state the reason for such decision ; and

(d) of any decision to terminate his activities as an importer or manufacturer of the said drug.

9. (1) If the holder of the Certificate of Registration of a drug fails to comply with any of the conditions of registration of such drug, the Authority may, after giving such holder of the Certificate of Registration of such drug an opportunity to show cause why such an order should not be made, remove the name of the drug from the register of drugs by an order in writing and state the reasons therefor.

(2) Any person aggrieved by the order for such removal of the name of the drug from the register of drugs may, within three months from the date of such order, appeal to the Authority against such order.

10. The Authority shall, on the advice of the Sub-Committee on Drugs remove the name of a drug from the register of drugs and inform the holder of the Certificate of Registration of such drug of the reasons therefor.

## PART II

### LICENSING OF IMPORTERS OF DRUGS

11. On or after the date of expiry of a period of three months from the date of operation no person shall import any registered drug except under the authority of a licence issued under regulation 14. Every person to whom a licence is issued under regulation 14 shall hereinafter be referred to as a "licensed importer of drugs".

12. (1) Every person desirous of obtaining a licence to import any registered drug shall make a separate application to the Authority in respect of each drug he intends to import. Every such application shall be substantially in Form A of Schedule V hereto.

(2) Every applicant for a licence to import any registered drug shall furnish to the Authority all such information as the Authority may require for the purpose of enabling the Authority to dispose of such application.

13. Every applicant for a licence to import a registered drug other than an applicant for a licence to import a drug for test examination, distribution as samples, analysis or clinical trial and an applicant for a drug for personal use shall be a registered pharmacist or any person authorised by him in that behalf, acting under the supervision of a registered pharmacist.

14.(1) The Authority shall, upon receipt of an application for a licence to import any registered drug, cause the premises where such drug is to be stored to be inspected, and on being satisfied that, such premises are suitable for the storage of drugs, and that all the conditions for issuing a licence for the importation of drugs have been complied with, issue a licence to the applicant.

(2) The Authority may, at his discretion refuse to issue a licence to.—

- (a) a minor ;
- (b) a mentally deficient person ;
- (c) a person addicted to narcotic drugs.

15. (1) Every licence issued by the Authority, to import a drug under regulation 14 shall be in Form B of Schedule V hereto, and be valid only in respect of the premises where such drugs are stored.

(2) The fee payable in respect of a licence to import a drug shall be as specified in Schedule XI hereto.

### CONDITIONS OF LICENCE TO IMPORT DRUGS

16. Every licence issued under regulation 14 to import a drug shall contain the following conditions :

- (a) the licensed importer of drugs shall allow any officer authorized in that behalf by the Authority, to enter with or without notice any premises where the imported drug is stored, for the purpose of inspecting and if necessary taking samples of such drug for test, examination or analysis ;
- (b) the licensed importer of drugs shall furnish to the Authority such samples as the Authority may consider adequate, from every batch of a drug imported under a licence, for test, examination or analysis. The licensed importer of drugs shall, if so required, furnish full particulars of the quality control tests carried out by the manufacturer of that particular batch of a drug ;
- (c) the licensed importer of drugs shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of any drug which he may import under his licence, as are necessary to avoid deterioration of such drug and shall not use for such purposes any premises other than the premises specified in the licence or premises which may be approved from time to time by the Authority ;
- (d) the licensed importer of drugs shall, on being informed by the Authority that any part of any batch of the drug imported has been found by the Authority to be not in conformity with the standards specified by the Authority, withdraw the batch from sale ;
- (e) the licensed importer of drugs shall maintain a record of all particulars of import, sale and supply of drugs by him and such record shall be open to the inspection of any officer authorized in that behalf by the Authority.

17. (1) The licence to import a drug shall, unless it is sooner suspended or cancelled, be valid for a period of one year from the date of issue of such licence.

(2) Where an application for renewal of such licence is made three months before the expiry of the period of validity of the current licence, such current licence shall be deemed to continue in force until an order is made in respect of the application for renewal.

18. (1) If the licensed importer of drugs fails to comply with any of the conditions of a licence to import drugs, the Authority may, after giving such licensed importer of drugs an opportunity to show cause why such an order should not be made, by an order in writing stating the reasons therefor, suspend such licence for such period as the Authority thinks fit or cancel it, either in respect of all or some of the drugs to which it relates.

(2) Any person who is aggrieved by the order made under paragraph (1), suspending or cancelling his licence may, within three months from the date of such order, make an appeal to the Authority against such order.

19. No person shall import any biological or other special drug specified in Group B of Schedule II hereto, after the date shown on the label, wrapper or container of such drug as the date until which the drug may be expected to retain potency not less than or to acquire toxicity greater than that which is permitted by the specified test.

20. Every licensed importer of drugs shall exhibit the licence issued to him under regulation 14 together with the original of the Certificate of Registration of the pharmacist issued by the Ceylon Medical Council in a conspicuous place in the premises at which he sells, stores or distributes the imported drugs.

21. The Authority shall keep a register of all licensed importers of drugs and shall enter or cause to be entered therein the following particulars relating to each licensed importer of drugs :—

- (a) the name of such licensed importer of drugs ;
- (b) the address of the premises in respect of which the licence has been issued ;
- (c) the date of issue of the licence issued under regulation 14 ; and
- (d) the number and date of the Certificate of Registration if issued to him under the Business Names Ordinance (Chap. 149). The name of the licensed importer of drugs shall be published in the Gazette.

22. (1) Every licensed importer of drugs shall forthwith inform the Authority in writing of any circumstances or event which may occur which affects the accuracy of any particulars stated by such licensed importer of drugs in the application for a licence to import drugs and shall at the same time forward his licence to the Authority.

(2) Upon the receipt of any information furnished by a licensed importer of drugs under paragraph (1), the Authority may make or cause to be made such appropriate alterations in the register and in the licence of that importer as may be necessary and shall return the licence to such licensed importer of drugs.

23. The Authority may revoke any licence issued under regulation 14 to import a drug if he is satisfied that the licensed importer of drugs has acted in contravention of any regulation contained in this Part or any other regulation made under the Act pertaining to importation and distribution of drugs.

#### IMPORT OF DRUGS FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS AND CLINICAL TRIAL

24. (1) Every person desirous of obtaining a licence to import small quantities of any drug for test, examination, distribution as samples or clinical trial, shall make a separate application to the Authority in respect of each drug he intends to import. Every such application shall be substantially in Form C of Schedule V hereto.

(2) No person shall import samples of any drug specified in Schedule III hereto.

(3) Every applicant for a licence to import any registered drug shall furnish to the Authority all such information as the Authority may require for the purpose of enabling the Authority to dispose of such application.

25. (1) On receipt of an application for a licence to import any drug under regulation 24, the Authority shall, on being satisfied that the conditions of the licence will be observed if such licence is issued, issue such licence to the applicant.

(2) Every licence issued under this regulation to import a drug, shall be substantially in Form D of Schedule V hereto, and shall be valid for one year from the date of issue.

(3) The fee payable in respect of a licence to import a drug for test, examination, distribution as samples, analysis or clinical trial shall be as specified in Schedule XI hereto.

CONDITIONS OF LICENCE TO IMPORT DRUGS FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS OR CLINICAL TRIAL

26. Every licence to import drugs issued under regulation 25 shall contain the following conditions :—

- (a) the holder of such licence shall use the drugs for distribution as samples, imported under the licence exclusively for the purposes of test, examination, analysis or clinical trial and shall carry on such test, examination, distribution as samples, analysis or clinical trial in the premises specified in the licence or in such other place as the Authority may from time to time authorise ;
- (b) the holder of the licence shall allow any officer authorized by the Authority in that behalf to enter with or without notice, any premises where such drugs are kept, for the purpose of inspecting the premises and investigating the manner in which the drugs are used and if necessary, taking samples thereof ;
- (c) the holder of the licence shall keep a record of, and shall report to the Authority on, the drugs imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer ;
- (d) the holder of the licence shall comply with any such further requirements if any, as are applicable to such holders of licences to import a drug for test, examination distribution as samples, analysis or clinical trial, as may be specified in any regulation made under the Act.

27. On receipt of an application for a licence to import any drug under regulation 25, the Authority shall, on being satisfied that the conditions of the licence will be observed if such licence is issued, issue such licence as specified in form D of Schedule V hereto.

28. (1) A licence issued under regulation 25 to import a drug, may be cancelled by the Authority for breach of any condition subject to which a licence was issued.

(2) The holder of a licence, whose licence has been cancelled under paragraph (1) may appeal to the Authority against such order.

IMPORT OF DRUGS FOR PERSONAL USE

29. (1) Any drug imported for personal use by any person shall be intended for the exclusive personal use of that person.

(2) The quantity of any single drug so imported shall not exceed one hundred average doses ;

Provided that the Authority may, if he deems necessary in the circumstances, permit the import of a larger quantity ;

Provided further that, any drug imported for personal use may be allowed to be imported subject to the following conditions :—

- (a) that the Authority is satisfied on an application made to the Authority by any person in Form E of Schedule V, that such drug is for personal use ;
- (b) that the quantity to be imported is reasonable in the opinion of the Authority and is covered by a prescription from a medical practitioner or a dental surgeon registered under the Medical Ordinance (Chapter 105) ;
- (c) that a licence has been issued by the Authority in Form F of Schedule V hereto, in respect of the said drug.

PART III

LICENCE TO MANUFACTURE DRUGS

30. (1) On or after the date of expiry of a period of three months from the date of operation, no person shall manufacture any drug except under the authority of a licence issued under regulation 32. Every person to whom a licence is granted under regulation 32 shall hereinafter be referred to as "a licensed manufacturer of drugs".

(2) No drug other than a registered drug referred to in regulation 2 shall be manufactured in Sri Lanka.

31. (1) Every person desirous of obtaining a licence to manufacture any registered drug shall make a separate application to the Authority in respect of each drug he intends to manufacture. Every such application shall be substantially in Form A of Schedule VI.

(2) Every applicant for a licence to manufacture a registered drug shall furnish to the Authority all such information as may be required for the purpose of enabling the Authority to dispose of such application.

32. (1) The Authority shall, upon receipt of an application for a licence to manufacture any registered drug, cause the premises where such drug is to be stored to be inspected, and on being satisfied that such premises are suitable for the storage of drugs, and that all the conditions for issuing a licence for the manufacture of drugs have been complied with, issue a licence to the applicant.

(2) The Authority may, at his discretion refuse to issue a licence to a :—

- (a) minor ;
- (b) mentally deficient person ; or
- (c) person addicted to narcotic drugs.

33. (1) Every licence to manufacture a drug issued by the Authority under regulation 32 shall—

- (a) be substantially in Form B of Schedule VI hereto ; and
- (b) be valid only in respect of the premises for which it is issued.

(2) The fee payable in respect of a licence to manufacture a drug shall be as specified in Schedule XI hereto.

#### CONDITIONS OF LICENCE TO MANUFACTURE DRUGS

34. Every licence to manufacture a drug issued under regulation 32 shall contain the following conditions:

- (a) the licensed manufacturer of drugs shall provide and maintain such staff, premises and plant as are considered by the Authority to be necessary for the manufacture of a drug undertaken by such licensed manufacturer and he shall not carry out such manufacture except at the premises specified in his licence ;
- (b) the licensed manufacturer of drugs shall provide and maintain such staff, premises, equipment and facilities for the handling and storage of the raw materials and drugs as are considered necessary by the Authority to avoid deterioration and he shall not use for such purposes premises other than those specified in the licence or premises which may be approved from time to time by the Authority.
- (c) the licensed manufacturer of drugs shall carry out all manufacture of such drug in such a way as to ensure that the drug conforms to the standards of strength, quality and purity applicable to them as specified by the Authority.
- (d) the licensed manufacturer of drugs shall provide such information as may be required by the Authority in respect of a drug currently being manufactured and of the operations being carried out in relation to such manufacture.
- (e) the licensed manufacturer of drugs shall inform the Authority before making any material alterations in the premises, plant or machinery used under his licence, or in the operations for which they are used and he shall inform the Authority of any change he intends to make of any personnel named in the licence as :
  - (i) responsible for supervising the production operations ; or
  - (ii) responsible for quality control of the products manufactured.
- (f) the licensed manufacturer of drugs shall keep readily available for inspection by the Authority or by any person authorised by the Authority, the records of the details of manufacture of each batch of every drug which is being manufactured under the authority of such licence, and the tests carried out in respect thereof, in such form that the records will be easily identifiable from the number of the batch as shown on each container in which the drug is sold, supplied or exported.

The licensed manufacturer of drugs shall allow the person authorised, to take copies or make extracts from such records. Such records shall not be destroyed for a period of five years from the date of manufacture of the relevant batch of drugs without the consent of the Authority.

- (g) the licensed manufacturer of drugs shall keep all documents which would facilitate the withdrawal or recall from sale, supply or exportation of any drug to which the licence relates.
- (h) the licensed manufacturer of drugs shall allow the Authority or any officer authorised by him, to enter with or without notice, any premises where the manufacture of any drug is carried out under a licence, or any premises where the raw materials and other substances used in its manufacture are stored, or where the manufactured drug is stored, supplied or sold, for the purpose of inspecting and if necessary, taking samples for test, examination or analysis or clinical trial.
- (i) where the licensed manufacturer of drugs has been informed by the Authority that any batch of any drug in respect of which the licence is issued has been found to be not in conformity with the specifications of the relevant drug as regards strength, quality, purity or with the provisions of the Act or of any regulation made thereunder. Such licensed manufacturer shall, if so directed withhold such batch from sale, supply or exportation so far as may be reasonable, practicable, for such period as may be specified by the Authority.
- (j) the licensed manufacturer of drugs shall comply with such further requirements if any, applicable to the licensed manufacturer of drugs as may be specified in any regulation made under the Act.

35. (1) The licence to manufacture any registered drug shall, unless earlier suspended or cancelled be valid for a period of one year from the date of issue of such licence.

(2) Where the application for a renewal of such licence is made three months before the expiry of the period of validity of the current licence, such licence shall be deemed to continue in force, until an order is made in respect of such application.

(3) Any application for renewal of such licence shall be substantially in Form A of Schedule VI hereto.

36. (1) If the licensed manufacturer of drugs fails to comply with any of the conditions of a licence to manufacture any registered drug, the Authority may, after giving him an opportunity to show cause why such an order should not be made by an order in writing stating the reasons therefor, suspend such licence for such period as he thinks fit or cancel it, either in respect of all or some of the drugs to which it relates.

(2) Any person who is aggrieved by an order under paragraph (1) suspending or cancelling his licence may within three months of the date of such order, make an appeal to the Authority.

37. Every licensed manufacturer of drugs shall exhibit the licence issued to him under regulation 32, in a conspicuous place in the premises at which he manufactures the drug.

38. The Authority shall keep a register of every licensed manufacturer of drugs, and shall enter or cause to be entered therein the following particulars relating to each such licensed manufacturer :—

- (a) the name of such licensed manufacturer ;
- (b) the address of the premises at which he is authorised to manufacture the drugs in respect of which the licence has been issued ;
- (c) the number of the licence ;
- (d) the date of issue of the licence ; and
- (e) the number and date of the Certificate of Registration if issued to him under the Business Names Ordinance (Chapter 149).

39. (1) Every licensed manufacturer of drugs shall forthwith inform the Authority in writing of any circumstances or event which may occur which affects the accuracy of any particulars stated by such licensed manufacturer in the application for a licence to manufacture drugs and shall, together with such information furnish his licence to the Authority.

(2) Upon the receipt of any information furnished by a licensed manufacturer of drugs under paragraph (1), the Authority may make or cause to be made such appropriate alterations as may be necessary in the register and in the licence of that manufacturer and shall return the licence to the licensed manufacturer.

40. The Authority may revoke any licence issued under regulation 32 to manufacture drugs, if he is satisfied that the licensed manufacturer of drugs has acted in contravention of any regulations contained in this Part or any other regulation made under the Act pertaining to the manufacture of drugs.

#### PART IV

##### LICENSING OF RETAIL DEALERS IN DRUGS

41. On or after the date of expiry of a period of three months from the date of operation, no person shall sell any registered drug other than a drug specified in Schedule I hereto, except under the authority of a licence issued under regulation 44. Every person to whom a licence is issued under regulation 44 to sell (by retail) any drug shall hereinafter be referred to as a "licensed retail dealer".

42. (1) Every person desirous of obtaining a licence to sell (by retail) any registered drug shall make a separate application in respect of each such drug to the Authority. Every such application shall be substantially in Form A of Schedule VII hereto.

(2) Every applicant for a licence to sell (by retail) any registered drug shall furnish to the Authority all such information as may be required for the purpose of enabling the Authority to dispose of such application.

43. Every applicant for a licence to sell drugs (by retail) shall comply with the following conditions:—

- (a) he shall be a registered pharmacist or a person employed by a registered pharmacist to transact business in the premises;
- (b) the premises in which the sale of drugs is to be carried out shall be adequate and equipped with proper storage facilities for preserving the properties of the drugs in respect of which the licence is issued and shall be in charge of a registered pharmacist;
- (c) where any drug is to be sold or stored by the same person for sale at more than one premises, a separate application shall be made and a separate licence shall be issued in respect of each such premises.

44. (1) The Authority shall upon receipt of an application for a licence to sell any drug (by retail) cause the premises in which such drug is to be sold to be inspected before issuing a licence to the applicant:

Provided, however, that the Authority may refuse to issue a licence to any person whose previous licence has been revoked under regulation 54.

(2) The Authority shall, on being satisfied that all the conditions for issuing a licence for the sale of drugs (by retail) have been complied with, issue a licence to the applicant.

(3) The Authority may refuse to issue a licence to—

- (a) a minor;
- (b) a mentally deficient person;
- (c) a person addicted to narcotic drugs.

45. (1) Every licence issued by the Authority under regulation 44 shall:—

- (a) be substantially in Form B of Schedule VII hereto; and
- (b) shall be valid only in respect of the premises for which it is issued.

(2) The fee payable in respect of a licence to sell drugs (by retail) shall be as specified in Schedule XI hereto.

##### CONDITIONS OF LICENCE TO SELL DRUGS (BY RETAIL)

46. Every licence to sell drugs (by retail) issued under regulation 44 shall contain the following conditions:

- (a) no licensed retail dealer shall expose or offer for sale or sell any drug bearing the State mark or any other mark indicating State property;
- (b) no drug specified in Schedule II hereto shall be sold after expiry of the date specified as the date of expiry on the label, wrapper or container of such drug;
- (c) the licensed retail dealer shall allow any officer authorised in that behalf by the Authority to enter with or without notice during business hours, any premises where drugs are sold (by retail) for the purpose of inspecting and taking samples of drugs for test, examination, analysis or clinical trial.

(d) the licensed retail dealer shall comply with such further requirements if any, applicable to any holder of a licence to sell (by retail) any such drug as may be specified in any regulation made under the Act.

47. (1) The licence for the sale of drugs (by retail) shall, unless it is sooner suspended or cancelled, be valid for a period of one year from the date of issue of such licence.

(2) Where the application for a renewal of such licence is made three months before the date of expiry of the period of validity of the current licence, such licence shall be deemed to continue in force until an order is made in respect of the application for such renewal.

(3) An application for renewal of such licence shall be substantially in Form C of Schedule VIII hereto.

48. (1) If the licensed retail dealer fails to comply with any of the conditions of the licence the Authority may, after giving him an opportunity to show cause why such order should not be made, by an order in writing stating the reasons therefor sent by registered post, suspend such licence for such period as the Authority thinks fit or cancel it either in respect of all or some of the drugs to which such licence relates.

(2) Any person who is aggrieved by an order made under paragraph (1) may, within three months from the date of such order, make an appeal to the Authority.

49. Every licensed retail dealer shall exhibit the licence issued to him under regulation 44, together with the original of the Certificate of Registration of the pharmacist issued by the Ceylon Medical Council, in conspicuous place in the premises at which he sells drugs.

50. The Authority shall keep a register of all licensed retail dealers and shall enter or cause to be entered therein the following particulars in respect of each such dealer :—

- (a) the name of the licensed dealer ;
- (b) the address of the premises at which he is authorised to sell drugs ;
- (c) the schedule of drugs in respect of which a licence has been issued ;
- (d) the date of issue of such licence ; and
- (e) the number and date of the Certificate of Registration, if any, issued to him under the Business Names Ordinance (Chapter 149).

51. (1) Every licensed retail dealer shall forthwith inform the Authority in writing of any circumstances or event which may affect the accuracy of any particulars stated by such licensed retail dealer in the application for a licence to sell drugs (by retail) and shall at the same time forward his licence to the Authority.

(2) Upon the receipt of any information furnished by a licensed retail dealer under paragraph (1), the Authority may make or cause to be made such appropriate alterations as may be necessary in the register of drugs and the licence of that dealer and shall return the licence to such licensed retail dealer.

52. Any licensed retail dealer who has under his control any shop or any other place of business shall sell any registered drug specified in Schedule II(B) and Schedule III only to the following persons :

- (a) a medical practitioner, dental surgeon or pharmacist registered under the Medical Ordinance (Chapter 105) ; or
- (b) a veterinary surgeon registered under the Veterinary Surgeons and Practitioners Act No. 46 of 1956, or
- (c) any person who produces a prescription from a registered medical practitioner, dental surgeon or veterinary surgeon.

53. A licensed retail dealer shall maintain a register of drugs specified in Group B of Schedule II hereto which may be sold only on prescription (by retail).

54. The Authority may revoke any licence to sell drugs if the Authority is satisfied that the licensed dealer has acted in contravention of any regulation contained in this Part or any other regulation pertaining to sale of drugs (by retail).



PART V

LICENSING OF WHOLESALE DEALERS IN DRUGS

55. On or after the date of expiry of a period of three months from the date of operation no person shall sell (by wholesale) any registered drug except under the authority of a licence issued in that behalf, under regulation 58. Every person to whom a licence is issued under regulation 58 to sell (by wholesale) any registered drug shall hereinafter be referred to as a "licensed wholesale dealer."

56. (1) Every person desirous of obtaining a licence to sell (by wholesale) any registered drug specified in Group A and Group B of Schedule II hereto, shall make a separate application to the Authority in respect of the drugs so specified. Every such application shall substantially be in Form A of Schedule VIII hereto.

(2) Every applicant for a licence to sell (by wholesale) any registered drug shall furnish to the Authority such information as may be required for the purpose of enabling him to dispose of such application.

57. Every applicant for a licence to sell drugs (by wholesale) shall comply with the following conditions :

- (a) he shall be a registered pharmacist or a person employed by a registered pharmacist to transact business in the premises ;
- (b) the premises in which the sale of drugs is to be carried out shall be adequate and equipped with proper storage facilities for preserving the properties of the drugs in respect of which the licence is issued and shall be in charge of a registered pharmacist ;
- (c) where any drug is to be sold or stored by the same person for sale at more than one premises, a separate application shall be made and a separate licence shall be issued in respect of each such premises.

58. (1) The Authority shall, upon receipt of an application for a licence to sell any drug (by wholesale) cause the premises where such sale is to be carried out, to be inspected before issuing a licence to the applicant :

Provided, however that, the Authority may refuse to issue a licence to any person whose previous licence was revoked under regulation 67.

(2) The Authority at his discretion may refuse to issue a licence to a—

- (a) minor ;
- (b) mentally deficient person ; or
- (c) person addicted to narcotic drugs.

(3) The Authority shall, on being satisfied that all the conditions for the issuing of a licence for the sale of drugs (by wholesale) have been complied with, issue a licence to the applicant.

59. (1) Every licence to sell any drug (by wholesale) issued by the Authority under regulation 58 shall be substantially in Form B of Schedule VIII hereto and be valid only in respect of the premises for which it is issued.

(2) The fee payable in respect of a licence to sell drugs (by wholesale) shall be as specified in Schedule XI hereto.

CONDITIONS OF LICENCE TO SELL DRUGS (BY WHOLESALE)

60. Every licence to sell drugs (by wholesale) issued under regulation 57 shall contain the following conditions:

- (a) no licensed wholesale dealer shall expose or offer for sale or sell any drug bearing the State mark or any mark indicating State property ;
- (b) the wholesale licensed dealer shall allow any officer authorised in that behalf by the Authority to enter with or without notice during business hours, any premises where drugs are sold (by wholesale) for the purpose of inspecting and taking samples for test, examination or analysis ;
- (c) the licensed wholesale dealer shall, on a request made in that behalf and on payment of the relevant fee, furnish to the Authority, from any batch of each drug a sample of such amount as the Authority may consider adequate for any test, examination or analysis to be made
- (d) if the Authority so directs, the wholesale dealer shall not sell or offer for sale, any batch of a drug in respect of which samples are furnished under paragraph (c) until a certificate authorising the sale of such drugs of that batch, has been issued to him, by or on behalf of the Authority ;

- (e) the wholesale licensed dealer shall, on being informed by the Authority that any part of any batch of a drug has been found by the Authority to be not in conformity with the specified standard of strength, quality and purity and on being directed to do so, withdraw the remainder of that batch from sale, and, so far as is practicable in the particular circumstances of the case, recall the issues already made from that batch ;
- (f) the licensed wholesale dealer shall maintain a record of all particulars of sale made by him and such records shall be open to inspection by any officer authorised by the Authority.

61. (1) The licence for the sale of drugs (by wholesale) shall, unless it is earlier suspended or cancelled, be valid for a period of one year from the date of issue of such licence.

(2) Where an application for a renewal of such licence is made three months before the date of expiry of the validity of the current licence, such licence shall, be deemed to continue in force until an order is made in respect of such application.

(3) An application for renewal of such licence shall be substantially in Form C of Schedule VIII hereto.

62. (1) If the licensed wholesale dealer fails to comply with any of the conditions of the licence for the sale of drugs (by wholesale) the Authority may, after giving him an opportunity to show cause why such an order should not be made, by an order in writing, stating the reasons therefor, suspend such licence for such period as the Authority thinks fit, or cancel it in respect of either all or some of the drugs to which such licence relates.

(2) Any person who is aggrieved by an order under paragraph (1) suspending or cancelling his licence may, within three months from the date of such order make an appeal to the Authority.

63. Every licensed wholesale dealer shall exhibit the licence issued to him under regulation 58 in a conspicuous place in the premises at which he sells drugs, together with the original of the Certificate of Registration of the pharmacist issued by the Ceylon Medical Council.

64. The Authority shall keep a register of every licensed wholesale dealer of drugs and shall enter or cause to be entered therein the following particulars relating to each such licensed wholesale dealer, namely :—

- (a) the name of such licensed wholesale dealer ;
- (b) the address of the premises at which he is authorised to sell the drugs specified in Schedule II hereto, and in respect of which a licence has been issued ;
- (c) the date of issue of the licence ; and
- (d) the number and date of the Certificate of Registration, if any, issued to him under the Business Names Ordinance (Chapter 149.)

65. (1) Every licensed wholesale dealer shall forthwith inform the Authority in writing of any circumstances or event which may occur which may affect the accuracy of any particulars stated by such licensed wholesale dealer in the application for a licence to sell drugs (by wholesale) and shall at the same time forward his licence to the Authority.

(2) Upon receipt of any information furnished by a licensed wholesale dealer under paragraph (1), the Authority may make or cause to be made such appropriate alterations in the register and in the licence of that dealer as may be necessary and shall return the licence to such licensed wholesale dealer.

66. Any licensed wholesale dealer who has under his control any shop, premises, vehicle or any other place of business used for dealing in drugs shall sell any registered drug specified in Schedule IIB only to the following persons :—

- (a) a medical practitioner, dental surgeon or pharmacist registered under the Medical Ordinance, (Chapter 105) ;
- (b) to a veterinary surgeon registered under the Veterinary Surgeons and Practitioners Act, No. 46 of 1956 ;
- (c) to a retail licensed dealer who holds a valid licence under the Act ; or
- (d) to a person authorised by the Authority.

67. The Authority may revoke any licence to sell any drug (by wholesale) if the Authority is satisfied that the licensed wholesale dealer has acted in contravention of any regulation contained in this Part or any other regulation made under the Act pertaining to exposing for sale, sale or distribution of any drugs (by wholesale).

#### PART VI

##### LICENCES FOR TRANSPORT OF DRUGS SPECIFIED IN SCHEDULES II AND III

68. (1) Where any licensed retail or wholesale dealer, importer or manufacturer of drugs under these regulations desires to transport any registered drugs specified in Schedules II and III hereto for the specific purpose of distribution through an agent to medical practitioners, dental surgeons or to veterinary surgeons or to a licensed retail or wholesale dealer, such licensed retail or wholesale dealer, importer or manufacturer shall obtain a licence for such agent from the Authority.

(2) Every such application shall be substantially in Form A of Schedule IX hereto.

69. (1) Every applicant for a licence to transport any registered drug specified in Schedules II and III hereto, shall furnish to the Authority all such information as the Authority may require for the purpose of enabling the Authority to dispose of such application.

(2) The Authority shall, on being satisfied that all the conditions for issuing a licence have been complied with, issue a licence to the applicant.

##### CONDITIONS OF LICENCE TO TRANSPORT DRUGS SPECIFIED IN SCHEDULES II AND III

70. Every licence to transport a drug specified in Schedules II & III shall contain the following conditions :—

- (a) the vehicle in which the drug is to be transported shall be adequately equipped with proper storage facilities to preserve the properties of the drug to be transported.
- (b) the agent of the licensed retail or wholesale dealer, importer or manufacturer shall be a competent person in the opinion of the Authority to supervise and control the distribution and preservation of the drug under his charge.

71. Every licence issued by the Authority under regulation 69 shall be substantially in Form B of Schedule IX hereto.

#### PART VII

##### DESTRUCTION

72. Any drug which fails to conform to the specified standards or the storage life of which has expired shall be destroyed. The destruction shall be carried out under the supervision of an officer, authorised by the Authority.

#### PART VIII

##### LABELLING

73. The container of every drug imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label bearing the following information clearly indicated thereon :

- (a) the approved name found in official pharmacopoeias or formularies. (The source should be stated in abbreviations ; e.g. B.P., U.S.P. etc.)
- (b) the brand name ;
- (c) list of the active ingredients showing :
  - (a) the amount of each present in each dosage unit (e.g. per 5 ml. etc.) ;
  - (b) a statement of the nett contents (e.g. number of dosage units, weight or volume) ;
- (d) any special storage conditions that may be necessary ;
- (e) warnings and precautions that may be necessary ;
- (f) the date of manufacture ;
- (g) the date of expiry where applicable ;

- (h) the batch or lot number assigned by the manufacturer ; and
- (i) the name and address of the manufacturer.

74. (1) The container of every drug, specified in Schedule II hereto shall be accompanied by a printed insert which shall contain all the particulars specified in Schedule X hereto.

(2) Where a prescription contains a drug which has to be prepared or has to be taken out of the original labelled container for dispensing, the licensed retail dealer shall dispense the drug in a suitable container labelled clearly with the following particulars :

- (a) name of the patient ;
- (b) name and quantity of the drug dispensed ;
- (c) the dose prescribed and directions for use ;
- (d) the name and address of the dispenser/chemist.

(3) Drugs for external application should be labelled—

“ FOR EXTERNAL USE ONLY ”.

#### PART IX

#### ADVERTISING OF DRUGS

75. On or after the date of expiry of a period of three months from the date of operation no person shall advertise any drug in contravention of the provisions of the Act or regulations made thereunder.

76. No person shall advertise any drug which is not registered with the Authority.

77. No person shall import into Sri Lanka :

- (a) any advertising material of any drug which is not registered with the Authority ;
- (b) any advertising material of any drug registered in Sri Lanka which is in contravention of the provisions of the Act or any regulation made thereunder.

78. No person shall send any advertising material about any drug to the Medical, Dental, Veterinary, Pharmaceutical and allied professions which is false, misleading or inconsistent with the particulars contained in the data sheet originally submitted with the application for the registration of the drug or particulars submitted subsequently.

79. (1) No person shall advertise any drug specified in Group B of Schedule II and Schedule III hereto except through professional journals and publications which are intended for circulation among the members of the Medical, Dental, Veterinary, Pharmaceutical and allied professions or in magazines for students of these professions.

(2) Any drug referred to in paragraph (1) may only be advertised through the media of the Press if it is merely intended to inform the public of its availability or its price.

80. No person shall make any false or exaggerated claim for any drug or misuse research results or quotations from scientific literature to support such claim.

81. No person shall advertise any drug to the public as a treatment, preventive or cure for any of the diseases, disorders or abnormal physical states set out in Schedule F of the Act.

82. Every advertisement of any drug shall contain the generic or official name of such drug. Where no official name is available as in some drug combinations, the official names of the important constituents shall be given.

83. The Authority may, after giving the advertiser an opportunity of being heard, prohibit the publication of any advertisement which is in contravention of the provisions of the Act or regulations made thereunder.

PART X

DISTRIBUTION OF DRUG SAMPLES

84. Samples of registered drugs specified in Schedule II may be distributed only to the registered medical practitioners or dental surgeons registered under the Medical Ordinance (Chapter 105), or veterinary surgeons registered under the Veterinary Surgeons and Practitioners Act, No. 46 of 1956. Such samples shall be labelled " Free medical samples. Not for sale ".

PART XI

PROCEDURE FOR TAKING OF SAMPLES FOR TEST, EXAMINATION, ANALYSIS OR CLINICAL TRIAL

85. An officer who obtains or takes a sample of any drug under Section 22(1)(a) of the Act, for test, examination, analysis or clinical trial shall, after procuring a suitable quantity according to his opinion, of the drug in question, notify the person from whom the samples were obtained of his intention to submit a sample thereof to an Approved Analyst for examination.

86. If in the opinion of the Authorised Officer, division of the procured quantity would not interfere with the test, examination, analysis or clinical trial—

- (a) he shall divide the sample into three parts ;
- (b) seal the three parts separately with his seal ;
- (c) permit the person or owner from whom the sample was procured to place his seal or thumb impression, if he so desires ;
- (d) deliver one part of the sample to the person or owner from whom the sample was procured ;
- (e) retain one part of the sample and if a label is present on the sample procured, retain the part that contains the label for producing it in court under Section 32(1) of the Act ; and
- (f) forward one part of the sample to the Approved Analyst with a description of such sample and an extract of the relevant portion of the label, for test, examination, analysis or clinical trial.

87. If in the opinion of the Authorised Officer, division of the procured quantity would interfere with the test, examination, analysis or clinical trial, he shall seal the entire quantity and permit the person or owner from whom the sample was obtained to place his seal or thumb impression if he desires to do so and forward the same to the Approved Analyst with a notification as to the method, for test, examination, analysis or clinical trial.

88. An Authorised Officer purchasing any quantity of a sample for test, examination, analysis or clinical trial, except in instances where the Authority has specifically authorised a purchase shall tender the cost of the sample to the person or owner from whom the sample was obtained.

89. (1) An Authorised Officer who obtains or takes a sample of vaccine or serum for test, examination analysis or clinical trial, under Section 22(1)(a) of the Act shall notify the person or owner from whom the sample was obtained of his intention to submit the sample to an Approved Analyst for test, examination, analysis or clinical trial.

(2) The Authorised Officer shall—

- (a) obtain and forward a single sample to the Approved Analyst ;
- (b) collect the sample under sterile conditions where the sample is collected from bulk or from an opened package ;
- (c) permit the person or owner of the vaccine or serum from whom the sample was obtained to place his seal or thumb impression, if he so desires, together with the seal of the Authorised Officer.
- (d) despatch the sample to reach the Approved Analyst under suitable storage during transport.

90. The Regulations made under the Food and Drugs Act (Chapter 216) are hereby rescinded.

## SCHEDULE I

Regulation 3(1)

Aspirin and soluble aspirin tablets	hydroxide mixture, Magnesium sulphate, Castor oil.
Paracetamol in tablet and liquid form	Fish liver oil and vitamins for oral use.
Analgesic balms/plasters	Preparations of iron and calcium for oral use.
Antacid preparations	Simple cough preparations and throat lozenges not
Antiseptics and disinfectants for household use	containing any antibiotics.
Compound effervescent salts for purgation. Magnesium	

## SCHEDULE II

Regulation 3(2)

## GROUP A

<i>Acne acid cream</i>	B G Phos
<i>Actal</i>	Bisacodyl
<i>Adexolin</i>	<i>Biunal Forte with vitamin C</i>
<i>Agarol</i>	<i>Bonate</i>
<i>Air Salonpas</i>	<i>Bonjela</i>
<i>Alka Seltzer</i>	<i>Calberon C capsules</i>
<i>Algipan</i>	<i>Calcilac</i>
<i>Almacarb</i>	Calcium gluconate, oral preparations
<i>Aloxiprin</i>	Calcium lactate
<i>Aludrox</i>	Calcium with vitamin D
Aluminium hydroxide and Dimethicone, oral pre- parations	<i>Calcium Sandoz syrup</i>
Aluminium hydroxide, oral preparations	<i>Caldeferrum</i>
<i>Adcolan</i>	<i>Calpol</i>
<i>Antistin Privine</i>	<i>Carbaryl lotion</i>
<i>Andrew's liver salt</i>	<i>Caripeptic liquid</i>
<i>Anusol</i>	<i>C-B's</i>
<i>Anussol HC</i>	<i>Cecon</i>
<i>Arobon</i>	<i>Celin</i>
<i>Ascabiol</i>	Cerationia seed powder
<i>Ascorbic acid</i>	<i>Cetapyrin</i>
<i>Asilone</i>	<i>Cetavlon</i>
Aspirin tablets	Cetrimide cream
<i>Arovit, oral preparations</i>	<i>Ce-Vi-Sol drops</i>
<i>Asmac</i>	Charcoal tablets
Aspirin and Codeine	<i>Chestorub</i>
Aspirin	Chlorhexidine
<i>Auralgicin</i>	Chlorhexidine and Cetrimide
<i>Avomine</i>	Chlorphenesin
<i>B—All Leo, oral preparations</i>	Choline salicylate compound gel
<i>Bayferron</i>	Cicatrin powder and cream
<i>Bc Grunovit</i>	<i>Clearasil</i>
<i>Becadex</i>	<i>Cobadex capsules</i>
<i>Becoforal C</i>	<i>Codis</i>
<i>Beconex</i>	<i>Codopyrin</i>
<i>Becosules</i>	Cod liver oil
<i>Becozyme Forte oral preparations</i>	<i>Collomack</i>
<i>Becozyme Forte with C oral preparations</i>	<i>Corex D</i>
<i>Becozyme tablets and syrup</i>	<i>Coskin</i>
<i>Beminal</i>	<i>Gosome</i>
<i>Benoral oral preparations</i>	Crotomiton cream
Benorylate, oral preparations	<i>Cytacon</i>
Benzalkonium and chlorbutol soaking solution	<i>Cytexin, oral preparation</i>
Benzyl benzoate application	<i>C-Vitam oral preparations</i>
<i>Berocca</i>	<i>C-Vitam Forte oral preparations</i>
<i>Betabion</i>	<i>Decavitamin capsules Dequadin</i>

<i>Dettol</i>	<i>Guardian liquid sweetener</i>
<i>Dextromethorphan syrup and tablets</i>	<i>Hacks original flavour tablets</i>
<i>Diethylamine salicylate cream</i>	<i>Hacks Menthol and Eucalyptus tablets</i>
<i>Digene</i>	<i>Haliborange</i>
<i>Dimethicone compound cream</i>	<i>Hexachlorophane</i>
<i>Dioclyle sodium sulfosuccinate</i>	<i>Hexavitamin tablets</i>
<i>Disprin</i>	<i>Hibitane</i>
<i>Drapolene</i>	<i>Hydrogen peroxide solution</i>
<i>Dulcolax</i>	<i>Iberol</i>
<i>Dumasules</i>	<i>Ipesandrine</i>
<i>Duofilm</i>	<i>Jadit</i>
<i>Durol</i>	<i>Kaolin compound poultice</i>
<i>Duwit Beco oral preparations</i>	<i>Kaolin and Pectin</i>
<i>Duwit C</i>	<i>Kaopez</i>
<i>Ephedrine nasal drops</i>	<i>Kaomagma plain suspension</i>
<i>Ephedrine oral preparations</i>	<i>Kaomagma with Pectin suspension</i>
<i>Ephedrine-Ipecac compound tablets</i>	<i>Khasinol syrup</i>
<i>Ephedrine compound tablets</i>	<i>Krushen salt</i>
<i>Ephynal</i>	<i>Kwell cream and lotion</i>
<i>Eskamel</i>	<i>Lactic acid compound lotion</i>
<i>Estone vitamin tablets</i>	<i>Listerin antiseptic</i>
<i>Ethine</i>	<i>Lorexane</i>
<i>Eurax</i>	<i>Lozene</i>
<i>Evion</i>	<i>Liquor Diastos</i>
<i>Famel</i>	<i>Lumagel tablets</i>
<i>Fergon</i>	<i>Maalox suspension</i>
<i>Fer-In-Sol</i>	<i>Maalox tablets</i>
<i>Ferradol</i>	<i>Magnesium hydroxide</i>
<i>Ferromyn</i>	<i>Magnesium sulphate</i>
<i>Ferromyn-B</i>	<i>Magnesium sulphate compound powder</i>
<i>Ferrous fumarate</i>	<i>Magnesium sulphate effervescent granules</i>
<i>Ferrous gluconate</i>	<i>Marvita</i>
<i>Ferrous sulphate</i>	<i>Meclozine</i>
<i>Fersamal</i>	<i>Menthol compound rub</i>
<i>Fersolate</i>	<i>Menthol compound spray</i>
<i>Fersovite</i>	<i>Metamucil</i>
<i>Fluorescein</i>	<i>Methylnicotinate compound cream</i>
<i>Fluorescite</i>	<i>Methylsalicylate compound ointment</i>
<i>Folic acid, oral preparations</i>	<i>Methylsalicylate compound spray</i>
<i>Folic acid and iron, oral preparations</i>	<i>Minadex</i>
<i>Folvron</i>	<i>Milton antiseptic</i>
<i>Fortibec</i>	<i>Multibay</i>
<i>Franol</i>	<i>Multibionta</i>
<i>Gamma benzene hexachloride preparations</i>	<i>Multi-Sanostol Syrup</i>
<i>Garlic capsules and pills</i>	<i>Multivitamin oral preparations</i>
<i>Gelusil plain</i>	<i>Multivitamin-mineral syrup</i>
<i>Gelusil MPS</i>	<i>Multivitamin-mineral tablets</i>
<i>Genatosan multivitamin plain tablets</i>	<i>Multivitaplex</i>
<i>Genatosan junior vitamin tablets</i>	<i>Multivitaplex Forte</i>
<i>Genasprin</i>	<i>Naphazoline compound eye drops</i>
<i>Glucose Powder</i>	<i>Natalins</i>
<i>Glycerin Suppositories (Adult size)</i>	<i>Natalins M</i>
<i>Glycerin Suppositories (Infant size)</i>	
<i>Gripe water</i>	
<i>Gripe mixture</i>	

Neopolazine	<i>Syl cream</i>
Neurogrunovit	<i>Tedral oral preparations</i>
New Hepavit syrup	<i>Tempa</i>
Noks	Tetrahydrozoline solution
Numotizine	<i>Theragran M tablets</i>
Nutrifil liquid	Thermogene medicated rub
Nutroferol Plus	Thimerosal cleaning solution
Nyal tooth-ache drops	<i>Tokuhon medicated spray</i>
Obron	<i>Tonos 7 syrup</i>
Ominibeta	<i>Toothex tincture</i>
Optrex eye lotion	<i>Transvasin</i>
Optrex eye drops	<i>Tympalgin</i>
Orheptal	<i>Ultraproct</i>
Oronine	<i>Uvistat</i>
Ossivite	<i>Valmelix syrup</i>
Ostocalcium	<i>Vasaka compound syrup</i>
Paladac	<i>Veganin</i>
Palaprin forte	<i>Vick's Formula 44</i>
Panadol	<i>Vick's inhaler</i>
Pantozyme	<i>Vick's medicated cough syrup</i>
Paracetamol	<i>Vick's Vaporub</i>
Phenylephrine nasal drops	<i>Vidaylin-M</i>
Phillips gripe medicine	<i>Vigoron tonic</i>
Phillips milk of magnesia	<i>Vitamin vitamin syrup</i>
Phisohex	Vitamin A and D oral preparations
Pholcodine cough linctus	Vitamin B complex tablets
Pluravit	Vitamin B complex with vitamin C oral preparations
Polybion, oral preparation	Vitamin B complex strong oral preparations
Polytar	Vitamin B complex and Iron syrup
Polyvinyl alcohol eye drops	Vitamin B <sub>6</sub> oral preparations
Polyvinyl alcohol wetting solution	Vitamin B <sub>12</sub> syrup
Simeco	Vitamin C oral preparations
Siopel cream	Vitamin E oral preparations
Sloan's liniment	<i>Vitanorm</i>
Sloan's massage	<i>Vitcee</i>
Sodium hypochloride	<i>Waterbury's compound</i>
Soluble Aspirin tablets	<i>Waterbury's vapour rub</i>
Strepsils	<i>Waterbury's vitamin tonic</i>
Sweeta	<i>Winlogeno</i>
Sweetex	<i>Woodward's gripe water</i>
	<i>Zactirin</i>

SCHEDULE II — GROUP B

Regulation 3(3)

Drugs that fall into this Schedule will be listed as and when they are forwarded to the 'Authority' for registration.

SCHEDULE III

Regulation 3(4)

Opium  
Coca plant  
Hemp plant

Any produce obtained from any of the phenanthrene alkaloid of opium or from the Ecgonine alkaloid of the coca leaf not being a product which was in use on or before the 13th day of July 1931, for medical or scientific purposes.

Any extract or tincture of the Hemp plant

Morphine and its salts

Cocaine (including synthetic cocaine) eagonin and their respective salts.

Any solution or dilution of morphine or cocaine or their salts in an inert substance whether liquids or solids containing any proportion of morphine or cocaine and any preparation, admixture, extract



or other substances (not being such a solution or dilution as aforesaid) containing not less than 1/5 percentum of morphine or 1/10 percentum of cocaine or eugomine Acetorphine.

Acetylmethadol	*Mescaline
Allylprodine	Metazocine
Alphacetylmethadol	Methadone
Alphameprodine	*Methadone-Intermediate (4-cyano-2 dimethyl amino-4-diphenylbutane)
Alphamethadol	*Methamphetamine
Alphaprodine	Methyl desorphine
Amphetamine	Methyldihydro morphine
Anileridine	*Methyl phenidate
Benzethidine	Metopon
Betacetylmethadol	Moramide-Intermediate (2-methyl-3-morpholino-1, 1-diphenylpropane carboxylic acid)
Betameprodine	Morpheridine
Betamethadol	Morphine
Betaprodine	Morphine-N-oxide
Bezitramide	Myrophine
Cannabis and Cannabis resin	Nicomorphine
Clonitazene	Noracymethadol
Cocaine (methyl ester of benzoylcegonine)	Norlevorphanol
Codeine (Methyl morphine)	Normethadone
Codoxime	Normorphine
Desomorphine	Norpipanone
Det	Oxycodone
Dexamphetamine	Oxymorphone
Dextromoramide	Paraloxyl
Diampromide	Pethidine
Diethylthiambutene	Pethidine-Intermediate-A (4-cyano-1-methyl-4-phenyl piperidine)
Difenoxin	Pethidine-Intermediate-B (4-phenylpiperidine-4-carboxylic acid ethyl ester)
Dimenoxadol	Pethidine-Intermediate-C (1-methyl-4-phenyl piperidine-4-carboxylic acid)
Limepheptano	Phenodoxone
Dimethylthiambutine	Phenampromide
Dioxaphetyl butyrate	Phenazocine
Diphenoxylate	*Phencyclidine
Dipipanone	*Phenmetrazine
DMHP	Phenomorphin
DET	Phenoperidine
Drotebanol	Pholcodine
Egonine, its esters and derivatives which are convertible to eegonine and cocaine	Piminodine
Ethyl methyl thiambutene	Piritramide
Etonitazene	Proheptazine
Etorphine	Properidine
Etozeridine	Psilocine
Fentanyl	Psilotsin
Furethidine	Psilocybine
Heroin (diacetyl morphine)	Racemethorphan
Hydrocodone	Recemoramide
Hydromorfinol	Racemorphan
Hydromorphone	*STP, DOM
Hydroxypethidine	Sufentanil
Isomethadone	Thebacon
Ketobemidone	Tilidine
Levomethorphan	Trimeperidine
Levomoramide	
Levophenacymorphan	
Levorphanol	
*(+) — Lysergide	

Form A

Regulation 5(3)

SCHEDULE IV

INFORMATION REQUIRED FOR REGISTRATION OF A DRUG

1. Name of applicant : .....
2. Address : .....
3. Status of applicant : .....

Manufacturer
--------------

  

Importer : .....
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4. Name of the drug : .....

  - (1) Brand Name (if any) : .....
  - (2) Official or approved name indicating the official body that has given this name. (whether B.P U.S.P. etc.)

5. Dosage form of the drug. e.g. tablet, syrup, injection :
6. *Composition.*—The ingredients should be listed by their official or approved names and should include their exact quantities as per unit dose or if it is not practicable as percentage of their total formulation.
7. Main pharmacological group to which the drug belongs : (e. g. diuretic etc.).
- \*8. A certificate from the health authorities of the country in which it is produced, confirming that the drug is in use there and the period of use and if not, reasons for not marketing it in the country of origin.
9. Certificate of analysis and full information concerning analytical assay and other control methods to ensure identity, strength, quality and stability.
- \*10. *Published reports of controlled clinical trials.*—establishing the therapeutic efficacy of the drug. (Un-controlled studies would be accepted only if controlled clinical trials are not necessary to prove efficacy). In the case of drug combinations, evidence must be provided to justify the inclusion of all the active constituents in the formulation.
- \*11. Summary of toxicity tests and tests for teratogenicity indicating the safety of the drug.
12. *Data sheet* giving the following information :
  - (a) *Pharmacology*—
    - Pharmacological actions
    - Mechanism of action (if known)
    - Relevant Pharmacokinetic data
  - (b) *Clinical Information*
    - Indications
    - Contraindications
    - Precautions
    - Warnings
    - Adverse effects
    - Drug interactions
    - Dosage regimen

Average dose and dose range for adults and children  
 Dosing interval  
 Average duration of treatment.  
 Dosage in special situations e.g. renal, hepatic and cardiac insufficiency.

Overdosage :  
 Brief clinical description of symptoms.  
 Treatment of overdosage

(c) *Pharmaceutical Information*—

Dosage forms and strengths of different dosage forms.  
 Storage conditions and shelf life (expiration date)  
 Package sizes  
 Description of product e.g. tablet size, colour, markings etc.

Name and address of manufacturer (if not given earlier).

\*13. List of countries in which the drug is approved or registered for sale.

\*14. Fully packed samples of the drug in the form that will be offered for sale should also be sent, to enable *analysis of the product*.

15. A sample of the label (s) used on the containers should be supplied.

16. All data should be submitted in English, in a *hard* file cover, in duplicate.

17. Information marked with an asterisk\* is not required in the case of drugs that have been already approved for import or local manufacture. In the case of drugs approved for import, the names should be in the Government gazettes published on July 18, 1980 and thereafter.

**APPLICATIONS MADE WITHOUT THESE REQUIREMENTS WILL NOT BE ACCEPTED**

Form B

Regulation 5(4)

**SCHEDULE IV**

**APPLICATION FORM FOR CERTIFICATE OF REGISTRATION OF A DRUG BY AN IMPORTER**

*(To be filled in triplicate by applicant)*

I/We ..... of ..... hereby  
 apply for registration of the drug namely ..... details  
 of which are enclosed herewith.

Signed :.....,  
 Address :.....,  
 Designation of applicant :.....

**For official Use only**

Application No. :.....

Dated :.....

Decision : Registered/Not registered.

Dated :.....

Registration No :.....

Dated :.....

Fees paid :.....

Receipt No :.....

Date :.....

Signature :.....  
 Authority

Form C Regulation 5(5)

SCHEDULE IV

APPLICATION FORM FOR CERTIFICATE OF REGISTRATION OF A DRUG BY A MANUFACTURER  
(To be filled in triplicate by applicant)

I/We .....of ..... hereby  
apply for registration of the drug and formulation for local manufacture namely .....  
..... details of which are enclosed herewith.

Signed : .....  
Address : .....  
Designation of applicant : .....

Date : .....

*For official use only*

Application No : .....	Dated : .....
Decision : Registered/Not registered.	Dated : .....
Registration No. : .....	Dated : .....
Fees paid : .....	Receipt No. : .....

Date : .....

Signature : .....  
Authority

Form D Regulation 6(2)

SCHEDULE IV

CERTIFICATE OF REGISTRATION

Certified that the following drug is hereby registered under the Cosmetics, Devices and Drugs Act No. 27 of 1980.

Name of Drug : .....  
Dosage form : .....  
Name of manufacturer : .....  
Country of manufacture : .....  
Name of Importer : .....  
Registration No. : .....  
Date of Registration : .....  
Type of Registration : .....  
    Full Registration : .....  
    Provisional Registration : .....      Period : .....

Schedule :

Full registration shall be valid for a period of 5 years unless earlier suspended or cancelled.  
Provisional registration shall be valid for the period stipulaed.

Date of issue : .....

.....  
Authority.

Form E Regulation 7(3)  
 SCHEDULE IV

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF A DRUG FOR IMPORT/MANUFACTURE

I/We ..... of ..... hereby apply for renewal of registration of the drug for import/manufacture.

Registration : .....

Expiry date of last registration : .....

Signed : .....

Address : .....

Date : .....

Designation of applicant : .....

Form A Regulation 12(1)  
 SCHEDULE V

APPLICATION FOR LICENCE TO IMPORT DRUGS

I/We ..... hereby apply for the import of the drug(s) registered by the authority.

Signed : .....

Address : .....

Date : .....

Designation of applicant : .....

Form B Regulation 16(1)  
 SCHEDULE V

LICENCE TO IMPORT DRUGS

*Licence Number :*

M/s. .... of .....

is/are hereby licensed to import into Sri Lanka during the period for which this licence is in force, the drugs specified below, manufactured by .....

This licence is subject to the conditions prescribed in regulation 16 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act, No. 38 of 1984 and shall be in force for one year from the date of issue, unless it is earlier suspended or cancelled.

Name of drug(s) and dosage forms to which this licence is applied :—

1. ....
2. ....
3. ....

Date of issue : .....

.....  
 Authority.

Form C

Regulation 24(1)

SCHEDULE V

APPLICATION FOR A LICENCE TO IMPORT A LIMITED QUANTITY OF ANY DRUG(S) FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS OR CLINICAL TRIAL

I/We ..... of ..... hereby apply for a licence to import from M/s. .... of ..... the drug(s) specified below for the purpose of test, examination, distribution as samples, analysis or clinical trial.

Name(s) of drug(s) and dosage forms :

1. ....
2. ....
3. ....

Signed : .....

Address : .....

Date : .....

Designation of applicant : .....

Form D

Regulation 25(2)

SCHEDULE V

LICENCE TO IMPORT DRUGS FOR TEST, EXAMINATION, DISTRIBUTION AS SAMPLES, ANALYSIS OR CLINICAL TRIALS

Licence Number :

M/s. .... of .....

..... is/are hereby licensed to import from .....

the drug(s) specified below for the purpose of test, examination, distribution as samples, analysis or clinical trial.

This licence is subject to the conditions prescribed in regulation 26 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act, No. 38 of 1984.

The Licence shall be valid for the importation of one batch of drugs only and be valid for one year from the date of issue.

Name(s) of Drug(s) with quantities which may be imported :

1. ....
2. ....
3. ....

Date of issue : .....

.....  
 Authority.

SCHEDULE V

Form E

Regulation 29

APPLICATION FOR LICENCE TO IMPORT DRUGS FOR PERSONAL USE

I ..... of ..... hereby apply for a licence to import the drug(s) specified below solely for my personal use.

I attach a prescription from a registered medical practitioner in regard to the need for the said drug(s).

Name of drug(s) and quantity : .....

Date : .....

Signed : .....

Name : .....

Address : .....

Form F

Regulation 29

SCHEDULE V

LICENCE TO IMPORT DRUGS FOR PERSONAL USE

Licence Number :

..... of ..... is hereby licensed to import the following drug (s) in the quantities specified.

*Drug(s)*

*Quantity*

This licence is subject to the conditions prescribed in regulation 29 of the Drugs Regulations made under Cosmetics, Devices and Drugs Act No.27 of 1980 as amended by Act, No.38 of 1984 and shall be in force for a period of one year from the date of issue unless it is earlier suspended or cancelled.

Date of Issue :.....

.....  
 Authority.

Form A

Regulation 31  
 Regulation 35

SCHEDULE VI

APPLICATION FOR GRANT/RENEWAL OF A LICENCE TO MANUFACTURE DRUGS BY WAY OF BASIC MANUFACTURE/  
 SEMI-BASIC MANUFACTURE/FORMULATION/REPACKING

I/We ..... of ..... hereby apply for a grant/renewal of a licence to manufacture by way of ..... on premises situated at .....

Name of Drug :.....

Dosage form(s) :.....

Details of the firm required for registration are given in the enclosed form.

Signed :.....

Name and Address : .....

Designation of applicant :.....

Form B

Regulation 33

SCHEDULE VI

LICENCE TO MANUFACTURE DRUGS.

Licence Number :.....

M's..... of ..... is/are hereby licensed to manufacture the drugs specified below at the premises situated at .....

This licence is subject to the conditions prescribed in regulation 34 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act No. 27 of 1980 as amended by Act No. 38 of 1984 and shall be in force for one year from the date of issue, unless it is earlier suspended or cancelled.

Name of drug(s) and dosage form(s) to which this licence is applied.

1. ....
2. ....
3. ....

Date of issue :.....

.....  
 Authority.

Form A Regulation 42.

SCHEDULE VII  
APPLICATION FOR LICENCE TO SELL DRUGS (BY RETAIL)

I/We ..... of ..... hereby apply for a licence to deal in drugs (by retail) on premises situated at .....  
Signed : .....  
Name and Address : .....  
Designation of applicant : .....

*Details required :*

Is Licencee a registered pharmacist : ..... ;  
Or.  
Is the transaction carried out on behalf of licencee by a registered pharmacist : .....  
Name and Address of a registered pharmacist : .....  
Registration No : .....  
Storage facilities available in the premises : .....  
Refrigerator : .....  
Deep freezer : .....  
Air conditioning : .....  
Name and qualification of person(s) supervising distribution and preservation of drug.  
Has a licence been issued before and revoked by the Drugs Authority :

Form B Regulation 44

SCHEDULE VII  
LICENCE TO SELL DRUGS (BY RETAIL)

Licence Number :

M/s. .... of ..... is/are hereby licensed to deal in drugs (by retail) on premises situated at .....

This licence is subject to the conditions prescribed in regulation 46 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No.27 of 1980 as amended by Act, No.38 of 1984 and shall be in force for a period of one year from the date of issue unless it is earlier suspended or cancelled.

Date of issue : ..... Authority.

Form A Regulation 56

SCHEDULE VIII  
APPLICATION FOR LICENCE TO SELL DRUGS (BY WHOLESALE)

I/We ..... of ..... hereby apply for a licence to deal in drugs by (wholesale) on premises situated at .....

Date : ..... Signed : .....  
Name and Address : .....  
Designation of applicant : .....

*Details Required :*

Is licencee a registered pharmacist : ..... ; Or.  
Is the Transaction carried out on behalf of licencee by a registered pharmacist : .....  
Name and address of registered pharmacist : .....  
Registration No. : .....  
Storage facilities available in the premises : .....  
Refrigerator : .....  
Deep freezer : .....  
Air conditioning : .....  
Name and qualification of person (s) supervising distribution and preservation of drug.  
Has a licence been issued before and revoked by the Drugs Authority.



Form B

Regulation 58

SCHEDULE VIII

LICENCE TO SELL DRUGS (BY WHOLESALE)

Licence Number : .....

M/s. .... is/are hereby licensed to deal in drugs (wholesale) on premises situated at .....

This licence is subject to the conditions prescribed in regulation 60 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No.27 of 1980 as amended by Act, No.38 of 1984 and shall be in force for a period of one year from the date of issue unless earlier suspended or cancelled.

Date of issue : .....

Authority

Form C

SCHEDULE VIII

Regulation 61

APPLICATION FOR RENEWAL OF LICENCE TO DEAL IN DRUGS (WHOLESALES/RETAIL)

I/We ..... of .....  
 hereby apply for renewal of licence to deal in drugs by (wholesale/retail) on premises situated at .....  
 Expiry date of last registration : .....

Signed : .....

Name and Address : .....

Designation of applicant : .....

Date : .....

Form A

SCHEDULE IX

Regulation 68

APPLICATION FOR LICENCE TO TRANSPORT DRUGS FOR DISTRIBUTION.

I/We ..... of .....  
 hereby apply for a licence to transport registered drugs.

Status of applicant :

Licensed dealer :

Licensed importer :

Licensed manufacturer :

(Tick off appropriate box.)

Signed : .....

Name : .....

Address : .....

Licence No : .....

Date : .....

Designation of applicant : .....

Form B

SCHEDULE IX

Regulation 69

LICENCE TO TRANSPORT DRUGS FOR DISTRIBUTION

Licence Number :

M/s. ....  
 of ..... is/are hereby licensed to transport Schedule II and Schedule III drugs.

This licence is subject to the conditions prescribed in regulation 70 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No. 27 of 1980 as amended by Act, No. 38 of 1984 and shall be in force for a period of one year from the date of issue unless earlier suspended or cancelled.

Date of issue : .....

Authority

SCHEDULE X

Regulation 74

The package insert shall contain the following information :

(a) *Pharmacology*

- Pharmacological actions.
- Mechanism of action (if known).
- Relevant pharmacokinetic data.

(b) *Clinical Information*

- Indications.
- Contraindications.
- Precautions.
- Warnings.
- Adverse effects.
- Drug interactions.
- Dosage regimen.

- Average dose and dose range for adults and children.
- Dosing interval.
- Average duration of treatment.
- Dosage in special situations e.g. renal, hepatic and cardiac insufficiency.

*Overdosage :*

- Brief clinical description of symptoms.
- Treatment of overdosage.

(c) *Pharmaceutical Information*

- Dosage forms and strengths of different dosage forms.
- Storage conditions and shelf life (expiration date).
- Package sizes.
- Description of product e.g. tablet size, colour, markings etc.
- Name and address of manufacturer (if not given earlier).

Regulations 6  
Regulations 15  
Regulations 25  
Regulations 33  
Regulations 45  
Regulations 59  
Regulations 60

SCHEDULE XI

FEEs

1. *Certificate of Registration.*—The fee for the Certificate of Registration shall be as follows :—

- (1) Rupees five hundred for registration of a drug ;
- (2) Rupees two hundred and fifty for the renewal of registration of a drug ;

Provided that the application for the renewal of registration is made six months before the expiry of the validity of the Certificate of Registration.

(3) A fee of rupees fifty shall be paid for a duplicate copy of the Certificate of Registration if the original is damaged or lost and such copy of the certificate shall bear the words " duplicate copy ".

- 2. *Licence to Deal in Drugs (Retail).*—fee for a licence to deal in drugs (retail) is Rs. 500/- (Five Hundred)
- 3. *Licence to Deal in Drugs (Wholesale).*—Fee for a licence to deal in drugs (Wholesale) is Rs. 1000/-. (One Thousand)
- 4. *Licence to Import Drugs.*— Fee for a licence to import registered drugs is Rs. 1000/-. (One Thousand)
- 5. *Licence Fee to Manufacture Drugs.*—The fee for a licence to manufacture drugs is Rs. 1000/-. (One Thousand)