ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2145/1 - 2019 ඔක්තෝබර් මස 14 වැනි සඳුදා - 2019.10.14

No. 2145/1 - MONDAY OCTOBER 14, 2019

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L. D. B. 9/2016.

NATIONAL MEDICINES REGULATORY AUTHORITY ACT, NO. 5 OF 2015

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under Section142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE (M. P.),
Minister of Health, Nutrition
and Indigenous Medicine.

Colombo
11th October, 2019.

REGULATIONS

1. (1) These Regulations may be cited as National Medicines (Registration and Licensing of Medicine) Regulations, 2019.

(2) These regulations shall apply to all medicines other than the medicines used solely for animals.

1A - PG 004687— 617 (10/2019)

N. B. - The *Gazette Extraordinary* Series No.2144/1 ends with No. 2144/68.
This Gazette Extraordinary can be downloaded from www.documents.gov.lk

PART I

REGISTRATION OF MEDICINES

2. (1) A licenced local manufacturer or an authorized importer of an overseas manufacturer approved by the National Medicines Regulatory Authority (in these regulations referred to as the "Authority") who intends to register a medicine with the Authority shall submit an application to the Authority.

(2) Licensing of local manufactures shall be in accordance with the regulations in Part II of these regulations.

(3) An overseas manufacturer shall appoint an authorized importer to act on his behalf and the appointment or changing of authorized importers shall be carried out according to the guidelines issued by the Authority.

(4) Every authorized importer desirous of registering medicines manufactured in an overseas manufacturing plant shall apply to the Authority for approval of such manufacturing plant before applying for registration of such medicines.

(5) Every such application shall be in such form as may be as determined by the Authority and shall accompany a Site Master File prepared according to the guidelines issued by the Authority.

(6) The fee payable for processing an application for approval of an overseas manufacturing plant shall be as specified in the fees regulations.

(7) On receipt of an application for approval of an overseas manufacturing plant, the Site Master File shall be evaluated and where necessary the manufacturing plant may be inspected by the Authority.

(8) Selection criteria of overseas manufacturing plants for inspection shall be according to the guidelines issued by the Authority.

(9) The fee payable for inspection of a manufacturing plant shall be as specified in the fees regulations.

(10) The Medicines Evaluation Committee, having considered the evaluation report on the Site Master File and the report of any inspection conducted, and

(*a*) if the manufacturer is compliant with facilities and operations conforming to principles of current Good Manufacturing Practices for Pharmaceutical Products as recommended by the World Health Organization or other international agencies such as European Medicines Agency or International Conference on Harmonization, or Pharmaceutical Inspection Co-operation Scheme, may recommend to the Authority to approve such manufacturing plant and the Authority shall inform the authorized importer of such approval; or

(*b*) if the manufacturer is not compliant with the Good manufacturing Practices referred to in 10 (a) may recommend to the Authority to reject such manufacturing plant and the Authority shall inform the authorized importer of such rejection in writing with the reason therefor.

(11) On approval of the manufacturing plant, the authorized importer shall be eligible to apply for registration of medicines manufactured in the manufacturing plant.

(12) Every application for Certificate of Registration by a local manufacturer or an authorized importer shall be substantially in the form set out in Schedule I hereto accompanied by:-

(*a*) The documents and information specified in the guidelines issued by the Authority;
(*b*) The samples of the medicine; and
(*c*) The applicable fee as specified in the fees regulations.

(13) A separate application shall be made in respect of each medicine intended to be registered as specified in the guidelines for registration of medicines issued by the Authority.

3. (1) For the purpose of importing samples of the medicine to be submitted for registration under regulation 2 (12)(b), an authorized importer shall submit an application as may be determined by the Authority together with the applicable fee as specified in the fees regulations.

(2) The samples of medicine imported for the purpose of submitting for registration shall not be sold and only be used for the purpose of registration of such medicine.

4. The Authority shall maintain a register in which every application received for the registration of a medicine shall be recorded. The particulars to be entered in such register shall be specified in the Schedule II hereto.

5. (1) On receipt of an application for a Certificate of Registration of a medicine, such application shall be referred to the relevant Divisions in terms of subsection (4) of section 59 of the Act.

(2) The meetings of the Medicines Evaluation Committee shall be held at least once in every month. The proceedings of meetings shall be recorded in the minutes. The minutes shall include all recommendations and decisions taken and such minutes shall be circulated among the members of the Medicines Evaluation Committee prior to the next meeting.

(3) The Medicines Evaluation Committee shall consider the technical evaluation and analysis reports produced by the Medicines Regulatory Division and National Medicines Quality Assurance Laboratory in making the final recommendation on the application for the Certificate of Registration of a medicine.

(4) The Medicines Evaluation Committee shall follow the guidelines issued by the Authority based on Good Review Practices of the World Health Organization for the evaluation of applications and generation of evaluation reports.

(5) The Medicines Evaluation Committee shall follow the guidelines issued by the Authority on bioequivalence and biowaiver for evaluation of the quality of generic medicines.

(6) The decisions on marketing authorization of medicines by competent authorities of other countries which are accepted by the Authority as “Reference Regulatory Authorities” may be recognized and used by the Medicines Evaluation Committee to assess the efficacy, safety and quality of the medicines in processing applications for registration.

(7) The list of such Reference Regulatory Authorities shall be published regularly by the Authority in the official website of the Authority.

(8) The Authority shall collaborate with entities such as the Medical Research Institute and Epidemiology Unit of the Ministry of Health Sri Lanka, Universities and Professional Colleges to review applications, for registration, by relevant experts.

6. (1) The Authority may call for information additional to those submitted in terms of regulation 2 (12).

(2) If any information is required due to any deficiency in the documents submitted in terms of regulation 2(12), the applicant shall pay a fee for processing such information.

(3) The fee payable for processing such information shall be specified in the fees regulation.

7. The Authority on being satisfied that all requirements for registration of a medicine are fulfilled shall issue a provisional registration –

(*a*) for a period of two years in the case of:-

(i) new molecular entities;
(ii) new dosage forms of already registered molecules;
(iii) new combinations containing already registered molecules;
(iv) new products of a biological origin including new molecular entities;
(v) new product, either a generic or a brand, of an already registered medicine; and
(vi) medicines that have been proposed to be discontinued from use by the Authority in order to give sufficient time to exhaust existing stocks or to allow patients to change to suitable alternatives:

Provided however, the Medicines Evaluation Committee shall have the discretion to decide whether the provisional registration shall be granted for one year or two years based on the evaluation reports;

(*b*) for a period of one year:-

(i) when applying for new registration of a medicine subsequent to the revocation of the suspension of registration of such medicine for a prescribed period of time; and

(ii) when applying for registration of a medicine subsequent to the revocation of suspension of a manufacturer of such medicine.

8. A full registration may be granted to a medicine after the lapse of the period of provisional registration for a period as may be determined by the Authority.

9. Upon the registration of the medicine, the Authority shall issue a Certificate of Registration in the form set out in Schedule III hereto.

10. (1) At the time of registration, the Authority shall classify and register such medicine under the following types: -

(*a*) Medicines specified in Schedule I -

(i) Medicines which may be sold without a prescription and a licence from the Authority for the premises where such medicines are stored for sale;

(ii) Medicines sold only in the original unopened containers or packs of the manufacturer; and

(iii) Medicines that are proven to be stable under the normal storage conditions of Sri Lanka and no special storage conditions are required;

(*b*) Medicines specified in Group A of Schedule II -

Medicines which shall not be sold by a person other than a pharmacist employed in a retail pharmacy licensed by the Authority. These medicines may be sold without a prescription.

(*c*) Medicines specified in Group B or Group C of Schedule II or Schedule III-

Medicines which shall be sold only by a pharmacist employed in a retail pharmacy licensed by the Authority only on a valid prescription from:-

(i) a Medical Practitioner or a Dental Surgeon, registered under the Medical Ordinance (Chapter 105); or

(ii) a Veterinary Surgeon registered under the Veterinary Surgeons and Practitioners Act, No. 46 of 1956 being tendered for the purpose of such medicines.

(2) Medicines registered under each Schedule shall be published by an Order, by the Authority.

11. Every medicine registered under these regulations shall be assigned a number. The Authority shall publish all registered medicines in the website of the Authority.

12. The Certificate of Registration of a medicine shall, unless it is earlier suspended or cancelled in terms of section 65 of the Act, be valid for the period specified therein and shall not be transferrable.

13. The holder of the Certificate of Registration of a medicine (hereinafter referred to as the "holder of certificate") may request in writing to the Authority to issue a licence to import and market the registered medicine in Sri Lanka or manufacture and market the medicine in Sri Lanka as the case may be.

14. The holder of certificate may apply to the Authority, in terms of section 64 of the Act, for renewal of registration.

15. The application form for renewal of registration shall be as may be determined by the Authority and shall be accompanied by the information specified in the guidelines issued by the Authority and the applicable fee as specified in the fees regulations.

16. The holder of the certificate shall comply with the guidelines issued by the Authority on variations and forthwith inform the Authority of any :-

(*a*) information received 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 medicine;

(*b*) decision to withdraw the medicine from Sri Lanka and the reasons for such decision;

(*c*) decision not to market any registered medicine; and

(*d*) decision to terminate his activities as the holder of certificate.

17. If a registered medicine has not been imported to Sri Lanka within two years from the date of registration, the Authority may suspend or cancel the Certificate of Registration of such medicine.

18. If the holder of certificate fails to comply with any of the conditions of registration of such medicine, the Authority may, after giving such holder of certificate an opportunity to show cause, suspend or cancel the Certificate of Registration.

19. Every holder of certificate shall establish a pharmacovigilance system according to the guidelines issued by the Authority in that behalf for collection, collation and monitoring of adverse reactions pertaining to the medicines registered by such person and shall forthwith submit any reports of serious adverse events or reactions to the Authority.

20. Every holder of certificate shall designate a suitably qualified and trained person to be responsible for dealing with pharmacovigilance activities relating to medicines which are registered by him.

21. Every such designated person shall be responsible for collecting and processing data, reports and publications related to all medicines marketed by the holder of certificate and submit comprehensive safety information on such products to the Authority within a period specified in the guidelines.

22. In the event of any administrative or regulatory action been taken on any medicine registered by the holder of certificate due to adverse reaction or any other medicine-related problem, in the country of origin or any other country where the product is marketed or distributed, the holder of certificate shall forthwith inform the Authority of such action.

23. The holder of certificate shall comply with the instructions given by the Authority in respect of any event of an adverse reaction or any other medicine-related problem with respect to the medicines registered by such holder of certificate.

24. The Authority may accept a medicines regulatory authority of another country as a Reference Regulatory Authority if such medicines regulatory authority :-

(*a*) has an official authority to carry out the evaluation and authorization of medicinal products, guaranteeing quality of the medicinal products, placed on the market of the relevant country; and

(*b*) ensure through inspection services that the internationally recognized current Good Manufacturing Practices for Pharmaceutical Products as recommended by international organizations such as the World Health Organization, European Medicines Agency, International Conference on Harmonization or Pharmaceutical Inspection Co-operation Scheme are effectively met by the manufacturers, and issue a certificate of Good Manufacturing Practices.

25. The Authority shall participate in the Collaborative Registration Procedure for the World Health Organization prequalified pharmaceutical products to accelerate registration through improved information sharing with the World Health Organization Prequalification of Medicines Programme.

PART II

MANUFACTURE OF MEDICINES

Licensed Local Manufacturers of Medicines

26. No person shall manufacture any medicine in Sri Lanka except under the authority of a licence issued by the Authority as a licensed local manufacturer of medicines under these regulations.

27. Every person desirous of manufacturing medicines shall apply to the Authority for preliminary approval of such manufacturing plant together with the required information according to the guidelines issued by the Authority, including the site plan, proposed building plan and details of formulations of medicines intended to be manufactured in the proposed manufacturing plant together with the Environment Protection Licence by the Central Environmental Authority of Sri Lanka.

28. (1) Upon receipt of the application for preliminary approval of the proposed manufacturing plant, the Authority shall inspect the premises of the proposed manufacturing plant and if found to comply with the requirements, according to the guidelines issued by the Authority grant approval to import machinery and raw material required for the purpose of Research and Development.

(2) If all requirements for Research and Development purposes are met, and on payment of the applicable fee as specified in the fees regulations,the Authority shall grant approval for development of formulations.

(3) Every person desirous of manufacturing medicines, on successful completion of the research and development and prior to commercial scale manufacture, shall apply to the Authority for a licence to manufacture medicines, accompanied with:-

(*a*) a Site Master File prepared according to guidelines issued by the Authority;

(*b*) Business Registration Certificate issued by the relevant government authority; and

(*c*) any other approvals deemed necessary by the Authority.

(4) Every such application shall be substantially in the form as may be determined by the Authority.

29. The Authority shall upon receipt of an application for licence to manufacture medicines together with the fee as specified in the fees regulations, cause the premises where such medicines are to be manufactured and stored to be inspected, and on being satisfied that all such requirements according to the guidelines recommended by the Authority for current Good Manufacturing Practices, and all the conditions for issuing a licence have been complied with, issue a licence to the applicant to manufacture medicines.

30. (1) The Licence to Manufacture Medicines issued by the Authority under Regulation 29 shall:-

(*a*) be in the form specified in Schedule IV hereto; and

(*b*) be valid only in respect of the premises for which it is issued.

(2) Every person issued with a licence to manufacture medicines under regulation 29 (hereinafter referred to as "a Licensed Local Manufacturer of Medicines") shall employ a registered pharmacist, who is a citizen of Sri Lanka as the Regulatory Affairs Officer. The Regulatory Affairs Officer shall be responsible for the documents pertaining to registration of medicines, manufacturing licences and other correspondence with the Authority regarding technical matters.

Licence to Manufacture Registered Medicines

31. (1) No Licensed Local Manufacturer of Medicines shall manufacture any medicine not registered with the Authority by such Licensed Local Manufacturer of Medicines.

(2) Manufacturing of small quantities of medicines required for research and development and investigational medicinal products required for approved clinical trials may be manufactured with the approval of the Authority without such medicine or product being registered with the Authority.

32. Every Licensed Local Manufacturer of Medicines shall register each medicine he intends to manufacture in commercial scale with the Authority under the provisions of Part I of these regulations.

33. (1) Every Licensed Local Manufacturer of Medicines desirous of manufacturing any registered medicine shall obtain a licence for each such medicine.

(2) Every Licensed Local Manufacturer of Medicines shall make a separate application to the Authority for licence to manufacture each registered medicine. Every such application shall be substantially in the form specified in Schedule V hereto.

34. The Authority shall, upon receipt of an application for a licence to manufacture a registered medicine, compliant with all the requirements as may be specified in the guidelines for the manufacture of such medicine, issue a licence to the Licensed Local Manufacturer of Medicines or reject such application if the Licensed Local Manufacturer fails to comply with such requirements.

35. (1) Every licence to manufacture a registered medicine issued under regulation 34 shall be:-

(*a*) substantially in the form specified in ScheduleVI hereto; and
(*b*) valid only in respect of the products manufactured in the specified premises for which it is issued.

(2) The fee payable in respect of a licence to manufacture a medicine shall be as specified in the fees regulations.

Terms and Conditions of Licence to Manufacture Registered Medicines

36. (1) Every Licensed Local Manufacturer of Medicines shall: -

(*a*) manufacture medicines according to the current Good Manufacturing Practices recommended by the Authority in such a way as to ensure that the medicine conforms to the standards applicable to them as approved by the Authority;

(*b*) provide and maintain such staff, premises, equipment and facilities as are considered by the Authority to be necessary for the manufacture of the medicines undertaken to be manufactured by such Licensed Local Manufacturer of Medicines and shall not carry out such manufacture except at the premises specified in the licence ;

(*c*) maintain such staff, premises, equipment and facilities for the handling and storage of the raw materials and medicines as are considered necessary;

(*d*) provide such information as may be required by the Authority in respect of a medicine manufactured and of the operations carried out in relation to such manufacture;

(*e*) establish a product related complaint handling system inclusive of recording, analysing and corrective measures;

(*f*) inform the Authority before making any material alterations in the premises, plant or machinery used under the licence, or in the operations of which they are used and any changes in any key personnel responsible for :

(i) the production operations; or

(ii) quality control and quality assurance of products manufactured;

(g) inform the Authority before changing the person designated as the “Qualified Person” or the “Authorized person”;

(h) preserve all records including batch manufacturing records and distribution records for a period of two years from the date of expiry of the relevant batch of medicines;

(i) keep readily available for inspection by the Authority or by any other person nominated by the Authority, all records including the details of manufacture of each batch of every medicine that is manufactured, and the tests carried out in respect thereof;

(j) maintain the records in such manner that the records are easily identifiable from the batch number of medicine as shown on each container in which the medicine is sold, distributed or exported;

(k) keep all records in a manner which would facilitate the withdrawal or recall from sale, supply or exportation of any medicine;

(l) allow any officer appointed by the Authority, to enter with or without notice, any premises where-

(i) any medicine is manufactured,

(ii) raw material and other substances used in the manufacture are stored,

(iii) the manufactured medicine is stored or distributed,

for the purpose of inspection and if necessary, taking samples for test, examination or analysis;

(m) allow any person appointed by the Authority, to take copies or make extracts from any records;

(n) submit samples, at different stages of manufacture or of the finished product for testing by a laboratory recognized by the Authority, in Sri Lanka or abroad if the Authority requires to do so;

(o) where the Licensed Local Manufacturer of Medicines has been informed by the Authority that any batch of any medicine in respect of which the licence is issued has been found to be not in conformity with the specifications of the relevant medicine as regards strength, quality, purity or with the provisions of the Act or any regulation, guideline or rules made thereunder, if so directed withhold or withdraw such batch from sale, supply or exportation so far as may be reasonable and practicable, for such period as may be specified by the Authority;

(p) comply with such further requirements if any, applicable to the Licensed Local Manufacturer of Medicines as may be specified in any other regulations made under the Act.

(2) The Authority shall ensure that the tests required to be performed and the corresponding results are communicated to the Licensed Local Manufacturer of Medicines within a reasonable period from the date of receipt of the samples;.

37. Where a Licensed Local Manufacturer of Medicines complies with all the requirements by a manufacturer for export of any medicine, the Authority shall facilitate such export by issuing a Certificate of Good Manufacturing Practice or a Certificate of Pharmaceutical product under the World Health Organization Certification Scheme on the quality of pharmaceutical products moving in international commerce or both if requested by a Licensed Local Manufacturer of Medicines.

38. (1) (*a*) The licence of a Licensed Local Manufacturer of Medicines shall, unless earlier suspended or cancelled be valid for a period of five years from the date specified in the licence.

(*b*) Every application for renewal of licence of a Licensed Local Manufacturer shall be as may be determined by the Authority.

(2) (*a*) Every licence to manufacture a registered medicine by a Licensed Local Manufacturer shall, unless earlier suspended or cancelled be valid for a period of one year as stipulated in the licence.

(*b*) Every application for renewal of licence to manufacture a registered medicine shall be in the form specified in Schedule VII hereto.

39. If any Licensed Local Manufacturer of Medicines fails to comply with any of the conditions of a licence to manufacture any registered medicine, the Authority may, after giving him an opportunity to show cause why such an order may not be made, by an order in writing stating the reasons therefor, suspend such licence for such period as deemed by the Authority or cancel such Licence in respect of all or some of the medicines to which it relates.

40. Every Licensed Local Manufacturer of Medicines shall exhibit the licence issued under regulations 29 to him, in a prominent place in the premises where such medicines are manufactured.

41. The Authority shall keep a register of every Licensed Local Manufacturer of Medicines, and shall enter or cause to be entered therein particulars, pertaining to the Licensed Local Manufacturers of Medicines, which may be determined by the Authority.

42. (1) Every Licensed Local Manufacturer of Medicines shall forthwith inform the Authority in writing of any circumstances or event which may affect the accuracy of any particulars stated by such Licensed Local Manufacturer of Medicines in the application of a licence to manufacture a registered medicine and shall, together with such information furnish such licence to the Authority.

(2) Upon the receipt of any information furnished by a Licensed Local Manufacturer of Medicines as mentioned in Regulation 42 (1), the Authority may make or cause to be made such appropriate alterations as may be necessary in the register and shall issue a new licence to the Licensed Local Manufacturer of Medicines if any amendments are made to the licence.

43. The Authority may revoke the licence issued under Regulation 29 or 34, if the Authority is satisfied that the manufacturer of medicines has acted in contravention of any regulations made relating to manufacture of medicines.

PART III

IMPORT OF MEDICINES

Licensed Importers of Medicines

44. (1) Every holder of certificate of a medicine manufactured by an overseas manufacturer may apply for a licence to import medicine. Every such application shall be in a form as may be determined by the Authority.

(2) Every such applicant shall furnish all such information according to the guidelines issued by the Authority.

45. Every applicant for a licence to import medicine other than an applicant for a licence to import a medicine for test, examination, analysis or clinical trial shall employ a Registered Pharmacist, who is a citizen of Sri Lanka as the Regulatory Affairs Officer.The Regulatory Affairs Officer shall be responsible for the documents pertaining to registration of medicines, import licences and other correspondence with the Authority regarding technical matters.

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

(2) The Authority may reject such application if the requirements and conditions mentioned under Regulation 46(1) are not fulfilled by the applicant and inform the reasons for such rejection to the applicant.

(3) The Authority may also at its discretion, refuse to issue a licence to a company that does not hold more than fifty per centum shares owned by citizens of Sri Lanka.

47. (1) Every licence issued by the Authority to import any medicine shall be in a form as may be determined by the Authority.

(2) The fee payable in respect of a licence to import any medicines shall be as specified in the fees regulations.

Licence to Import a Registered Medicine

48. (1) No person other than a person issued with a licence to import medicine under regulation 46(1) (hereinafter referred to as the "Licensed Importer of Medicines") shall import any registered medicine to Sri Lanka.

(2) No person other than the holder of certificate shall be entitled to import such medicine to Sri Lanka.

(3) Every Licensed Importer of Medicines desirous of obtaining a licence to import any registered medicine shall make a separate application to the Authority in respect of each medicine he intends to import. Every such application shall be in the form as may be specified in Schedule VIII hereto.

(4) Every applicant for a licence to import any registered medicine shall furnish to the Authority, a copy of the Certificate of Registration of the medicine issued under Regulation 9 and any other information as required by the Authority.

49. The Authority shall, upon receipt of an application for a licence to import any registered medicine, on being satisfied that all requirements for issuing a licence for the importation of such medicine have been complied with, issue a licence to the Licensed Importer of Medicines.

50. (1) Every licence issued by the Authority, to import a registered medicine under Regulation 49 shall be in the form specified in Schedule IX hereto.

(2) The fee payable in respect of a licence to import a registered medicine shall be as specified in the fees regulations.

Conditions of Licence to Import Medicines

51. Every Licensed Importer of Medicines shall comply with the following conditions:-

(*a*) every Licensed Importer of Medicines shall allow any officer nominated in that behalf by the Authority, to enter with or without notice any premises where the imported medicine is stored, for the purpose of inspection and taking samples of such medicine for test, examination or analysis if necessary;

(*b*) every Licensed Importer of Medicines shall furnish to the Authority such samples as the Authority may consider adequate, of a medicine imported under a licence, for test, examination or analysis. Every Licensed Importer of Medicines shall, if so required, furnish full particulars of the quality control tests carried out by the manufacturer of the particular batch of any medicine;

(*c*) every Licensed Importer of Medicines shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of any medicine which may be imported under the licence, as are necessary to avoid deterioration of the medicines and shall not use any premises other than the premises which may be approved by the Authority for such purposes;

(*d*) no Licensed Importer of Medicines shall release any vaccine or sera to the market except under the authority of a Lot Release Certificate issued by the Medical Research Institute in terms of the regulations made by the Minister on the lot release procedure of vaccines and sera;

(*e*) every Licensed Importer of Medicines shall, on being informed by the Authority that any part or any batch of a medicine imported has been found by the Authority to be not in conformity with the standards approved by the Authority withhold or withdraw such batch from sale;

(*f*) every Licensed Importer of Medicines shall maintain a record of all particulars of import, sale and supply of medicines by him, and such record shall be open to the inspection of any officer nominated in that behalf by the Authority;

(*g*) every Licensed Importer of Medicines shall adhere to the guidelines issued by the Authority on Good Storage Practices, Good Distribution Practices and Good Pharmacovigilance Practices.

52. (1) The licence to function as a Licensed Importer of Medicines shall, unless earlier suspended or cancelled be valid for a period of five years from the date stipulated in the licence.

(2) The licence to import any registered medicine shall, unless earlier suspended or cancelled be valid for a period of one year from the date specified in the licence.

(3) Every application for renewal of licence to Import Medicines shall be in the form specified in Schedule X hereto.

53. If any Licensed Importer of Medicines fails to comply with any of the conditions of a licence to import a medicine, the Authority may, after giving such licensed importer of medicines an opportunity to show cause why such an order may not be made, by an order in writing stating the reason therefor, suspend such licence for such period as may be determined by the Authority or cancel the licence either in respect of all or some of the medicines relating to such licence.

54. No person shall import any medicine after the date shown on the label, wrapper or container of such medicine, as the date until which the medicine may be expected to retain potency or to acquire toxicity greater than that which is permitted by the specified tests.

55. The Authority shall keep a register of all Licensed Importers of Medicines. The information that shall be entered or cause to be entered therein shall be determined by the Authority.

56. (1) Every Licensed Importer of Medicines shall forthwith inform the Authority in writing of any circumstances or event which may affect the accuracy of any particulars stated by such Licensed Importer of Medicines in the application of a licence to import a registered medicine and shall together with such information furnish such licence to the Authority.

(2) Upon the receipt of any information furnished by a Licensed Importer of Medicines as mentioned in Regulation 56(1) the Authority may make or cause to be made such appropriate alterations as may be necessary in the register and shall issue a new licence to the Licensed Importer of Medicines if any amendments are made in the licence.

57. The Authority may revoke any license licence issued under Regulation 46(1)to a Licensed Importer of Medicines if the Authority is convinced that such Licensed Importer of Medicines has acted in contravention of any regulation contained in this part or any other regulations made pertaining to importation and distribution of medicines.

58. Every Licensed Importer of Medicine shall furnish to the Authority all such information including quantities of medicines imported or supplied by him, purchasing prices of medicines imported by him if directed by the Authority to furnish such information.

PART IV

IMPORT OF MEDICINES FOR TEST, EXAMINATION, ANALYSIS, CLINICAL TRIAL OR DISTRIBUTION AS PHYSICIAN'S SAMPLES

59. (1) Every person desirous of obtaining a licence to import any medicine as a sample for test, examination, analysis, clinical trial or distribution as a physician sample shall make a separate application to the Authority in respect of each medicine intended to be imported. Every such application shall be in the form specified in Schedule XI hereto.

(2) Every applicant for a licence to import any medicine under this regulation shall furnish to the Authority all such information as the Authority may require for the purposes of enabling the Authority to process such application.

60. (1) On receipt of an application for a licence to import any medicine under Regulation 59 the Authority shall, on being satisfied that the conditions of the licence shall be observed if such licence is issued, issue such licence to the applicant.

(2) The quantity allowed to be so imported shall be decided by the Authority.

(3) Every licence issued under this regulation to import medicines for test, examination, analysis, clinical trial or distribution shall be in the form specified in Schedule XII hereto, and shall be valid for the period stipulated in the licence.

(4) Wherever an application is rejected, the Authority shall inform the applicant reasons for such rejection within one month of such rejection.

(5) The fee payable in respect of a licence to import a medicine for test, examination, analysis, clinical trial or as samples for registration or distribution shall be specified in the fees regulations.

61. 1. Every licence to import medicines issued under regulation 60 shall have following conditions:-

(*a*) The holder of such licence shall use the medicines imported under the licence exclusively for the purpose of test, examination, analysis, clinical trial, registration or distribution and shall carry on such test, examination, analysis or clinical trial in the premises specified in the licence or in such other place authorized by the Authority.;

(*b*) Samples of any medicine specified in ScheduleII of an Order made under subsection (2) of section 60 of the Act 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 "Physician's Samples, Not for Sale".

(*c*) The holder of the licence shall allow any officer appointed by the Authority in that behalf to enter with or without notice, any premises where such medicines are kept, for the purpose of inspecting the premises and investigating the manner in which medicines are used and if necessary, taking samples.

(*d*) The holder of the licence shall keep a record and shall report to the Authority of the medicines imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer within one month of such import.

(*e*) The holder of the licence shall comply with any such further requirements if any, as are applicable to holders of licences to import a medicine for test, analysis, examination, clinical trial, distribution samples as may be specified in any regulation made under the Act.

62. A licence issued under Rregulation 60 to import a medicine, may be cancelled by the Authority for breach of any condition subject to which the licence was issued.

PART V

IMPORT OF MEDICINES FOR PERSONAL USE

63. (1) Any medicine imported for personal use by any person shall only be for the exclusive personal use of such person.

(2) The quantity of any single medicine so imported shall not exceed one hundred doses:

Provided however, the Authority may, if the Authority deems it necessary in the circumstances, permit the import of a larger quantity.

64. Any person travelling to Sri Lanka may carry medicines for his personal use, without prior approval of the Authority subject the following conditions:-

(*a*) The quantity of any single medicine so carried shall not exceed the quantity required for the duration of his stay in Sri Lanka or the quantity required up to ninety days whichever is less. Prior approval of the Authority shall be obtained for quantities exceeding ninety day (90) requirements.

(*b*) The medicines shall not include any medicine that must be administered through intramuscular or intravenous routes.

(*c*) The medicine shall not be a medicine specified in Schedule III of any Order published by the Authority under subsection (2) of section 60 of the Act or any medicine that is listed as a narcotic by the International Narcotic Control Board.

(*d*) The medicine shall be packed in the original container. If it is not the original container, it shall be appropriately labelled to identify the name and strength of the medicine, with usage instructions.

65. Every person travelling to Sri Lanka who needs to bring any medicine for his personal use in a quantity in excess of the quantity required for ninety days or a medicine specified in Schedule III of an Order published under subsection (2) of section 60, shall furnish to the Authority all such information as the Authority may require for the purposes granting approval for bringing such quantities or such medicine into Sri Lanka.

PART VI

PHARMACOVIGILANCE

66. (1) The Pharmacovigilance Division of the Authority shall establish a National Pharmacovigilance System including National Pharmacovigilance Centre collaborating with the World Health Organization Programme for International Drug Monitoring.

(2) There shall be a sub committee appointed by the Authority which shall be known as Safety and Risk Evaluation Sub Committee to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication.

(3) A national spontaneous reporting system shall be in place with a national individual adverse reaction reporting system.

(4) The Authority shall develop: -

(*a*) guidelines for pharmacovigilance;

(*b*) a national database for collating and managing adverse reaction reports;

(*c*) a clear communication strategy for routine communication and crisis communication.

(5) The Authority may recognize or rely on vigilance-relevant decisions, reports or information from other countries and regional or international bodies.

(6) The functions under the national pharmacovigilance system shall be:-

(*a*) collecting and managing adverse drug reaction reports, reports of medication errors and suspected counterfeit or substandard medicine to collaborate and harmonize with existing adverse reaction report collection activities within the country (*e.g.* national disease control programmes of the Ministry of Health *etc.*) as well as international cohorts monitoring adverse drug Reactions in defined patients or populations;

(*b*) identifying signals of medicine safety such as unknown or poorly characterized adverse events in relation to a medicine or a combination of medicines or its use;

(*c*) undertaking assessment of risk and options for risk management;

(*d*) identifying any quality problems in medicine resulting in adverse reactions; and more generally, supporting the identification of quality issues of medicine;

(*e*) providing effective communication on aspects related to safety, including dispelling unfounded rumours of toxicity attributed to medicine;

(*f*) applying resulting information from pharmacovigilance for the benefit of public health programmes, individual patients and national policies related to medicine and treatment guidelines.;

(*g*) developing and maintaining drug utilization information.;

(*h*) identifying issues associated with unregulated prescribing and dispensing of medicines.

(7) (*a*) Every manufacturer, importer and holder of certificate shall set up a vigilance system of their medicine and periodically report vigilance data, including zero events, to the Authority according to established requirements.

(*b*) Every manufacturer, importer, distributor and holder of certificate shall appoint a suitably qualified person as the Qualified Person for Vigilance who shall be responsible for all vigilance activities related to the medicine placed on the market.

(8) The Authority shall encourage every physician, pharmacist, other health professional, health worker, health- care institution and consumer to communicate to the Authority any adverse reactions resulting from the use of medicine that they may be aware.

(9) For the purpose of these regulations, medicine related problems include but not limited to lack of efficacy, interactions between medicines, medication errors, counterfeit or substandard misuse or abuse of medicines.

(10) No person shall deliberately refrain from disclosing such information known to him with regard to a medicine related problem.

PART VII

ADVERTISING OF MEDICINES

67. (1) No person shall advertise any medicine:-

(*a*) in contravention of the provisions of the Act or regulations made thereunder;

(*b*) which is not registered with the Authority.

(2) No person shall publish any advertisement on medicines, which is not approved by the Authority.

(3) The fee payable in respect of processing an advertisement shall be as specified in fees regulations.

68. No person shall import into Sri Lanka;

(*a*) any advertising material of any medicine which is not registered with the Authority;

(*b*) any advertising material of any medicine registered in Sri Lanka in contravention of the provisions of the Act or any regulations made thereunder.

69. There shall be a sub committee appointed by the Authority which shall hereinafter be referred to as the "Advertisement Evaluation Sub Committee" for the purpose of screening and granting approval for all advertisements before publishing such advertisement.

70. No person shall send any advertising material about any medicine to the Medical, Dental, Veterinary, Pharmaceutical and allied professions which is false, misleading or inconsistent with the particulars contained in the summary of product characteristics approved by the Authority.

71. (1) No person shall advertise any medicine specified in Schedules II and III of an Order made under subsection (2) of section 60 of the Act 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 such professions.

(2) Any medicine referred to in regulation 71 (1) may only be advertised through the media if it is only intended to inform the public of its availability or its price, and only with the prior approval of the Authority regarding the contents of such advertisement.

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

73. (1) Every advertisement of any medicine shall contain the generic name of the medicine.

(2) The generic name shall appear as prominently as the brand name. Where no generic name is available such as in the case of certain medicine combinations, the generic names of the important constituents shall be given.

74. (1) Every person desirous of advertising any medicine to the general public through mass media shall submit an application to obtain the prior approval of the Authority for such advertisement.

(2) Every such application shall be in a form as may be determined by the Authority.

(3) Every applicant for approval of any advertisement shall furnish to the Authority all such information as the Authority may require for the purpose of enabling the Authority to process such application.

75. (1) The Authority shall, upon receipt of an application for approval of an advertisement refer such application to the Advertisement Evaluation Sub Committee for evaluation and report.

(2) The Authority shall, on being satisfied that all the conditions for approving the advertisement are complied with, authorize such advertisement subject to any conditions specified in the letter of authorization.

76. (1) The Authority shall issue guidelines relating to the advertising of medicine.

(2) Every advertisements shall conform to the guidelines issued by the Authority.

77. 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 VIII

LABELLING AND OTHER INFORMATION OF MEDICINES

78. (1) The Authority shall from time to time publish guidelines for labelling.

(2) The following condition shall be applicable relating to labelling of medicines:-

(*a*) The container of every medicine imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label bearing the following clearly indicated thereon:

(i) the generic name or the approved name found in official pharmacopoeias or formularies with the source stated in abbreviations (e.g. BP, USP etc.);

(ii) the brand name, if any,

(iii) a list of the active ingredients, if applicable, with the International Non-proprietary Names (INNs), indicating, the amount of each active ingredient present in each dosage unit (e.g. per 5 mL etc.)

(iv) a statement of the net contents (e.g. number of dosage units, weight or volume);

(v) any special storage conditions or handling precautions that may be necessary;

(vi) any warnings and precautions that may be necessary;

(vii) the date of manufacture;

(viii) the date of expiry;

(ix) the batch number assigned by the manufacturer;

(x) the name and address of the manufacturer and the company responsible for placing the product on the market;

(xi) details of certain excipients such as preservatives and colourants as required by the Authority;

(xii) registration number issued by the Authority;

(*b*) The container of every medicine, specified in Schedule II of an order made under subsection (2) of section 60 of the Act shall be accompanied by a product information leaflet containing information specified in Schedule XIII hereto.;

(*c*) The container of every medicines classified under Schedule I or Group A of ScheduleII of an order made under subsection (2) of section 60 of the Act shall accompany a patient information leaflet.

79. Every patient information leaflet shall be in English, Sinhala and Tamil languages giving specific information on the safe and effective use of the relevant medicine,specified in Schedule XIV hereto.

80. Every patient information leaflet shall be presented in a legible format, in simple language readily comprehensible to the consumers.

81. Pictorials may be used in the patient information leaflet to demonstrate the correct usage of certain dosage forms such as inhalers, ophthalmic products and suppositories.

82. Every information provided in the patient information leaflet shall be scientifically accurate and consistent with the product information leaflet and labels of the relevant medicine.

83. The Authority may from time to time determine the medicines that shall require patient information leaflets.

84. (1) Where a prescription contains a medicine which has to be prepared or has to be taken out of the original labelled container for dispensing, the every pharmacist shall dispense the medicine in a suitable container labelled clearly with the following information in Sinhala, Tamil or English as requested by of the patient:-
.

(*a*) Name of patient;

(*b*) Name of medicine; Generic name and Brand name, if any;

(*c*) Dosage form;

(*d*) Strength of a unit;

(*e*) Number of units per one time of administration;

(*f*) Frequency of administration;

(*g*) Duration of treatment;

(*h*) Total number of units dispensed;

(*i*) Directions for preparation (if applicable);

(*j*) Route of administration;

(*k*) Selected special instructions (E.g. Before or after meals) if applicable.

(2) In addition to the information specified in regulation 84 (1) every label of Medicine:-

(*a*) for external application shall also contain the following:-

"FOR EXTERNAL USE ONLY"

(*b*) for physician's samples shall also contain the following:-

"PHYSICIAN'S SAMPLES NOT FOR SALE"

PART IX

PROCEDURE FOR TAKING MEDICINES SAMPLES FOR INVESTIGATION, EXAMINATION OR ANALYSIS

85. Every Authorised Officer who obtains a sample of any article for test, examination or analysis shall notify the person or owner from whom the sample was obtained of his intention to submit a sample thereof to the Authority for examination or analysis by an Approved Analyst.

86. If in the opinion of the Authorized Officer, division of the procured quantity would not interfere with any test, examination or analysis shall:-

(*a*) divide the sample into three parts;

(*b*) seal the three parts separately with seal of the Authorized Officer;

(*c*) permit the person or the owner from whom the sample was procured to place the seal or thumb impression of such person if such person 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 sub section (1) of section 127 of the Act; and

(*f*) forward one part of the sample under appropriate storage conditions, with a description of such sample and an extract of the relevant portion of the label, to the Approved Analyst for test, examination or analysis.

87. If in the opinion of the Authorized Officer, division of the procured quantity would interfere any the test, examination, or analysis, he shall seal the entire quantity and permit the person or the owner from whom the sample was obtained to place his seal or thumb impression if he so desires to do so and forward the same to the Authority for examination or analysis by an Approved Analyst.

88. Any Authorized Officer purchasing any quantity of a sample for test, examination or analysis, shall tender the cost of the sample to the person or owner from whom the sample was obtained.

89. Every Authorized Officer shall follow the guidelines issued by the Authority regarding procedure of collecting samples for test, examination or analysis.

PART X

RECALL OF MEDICINES

90. The Authority shall recall any medicine for which a notice has been issued by the Authority to ban or withdraw from use in terms of Section 108 of the Act, if the medicine does not meet the required standard or its continued use would cause serious health problems to the persons using the medicine.

91. The Authority may recall any medicine: –

(*a*) on a report or certificate issued by an additional approved analyst or the approved analyst;

(*b*) on the recommendation of the Medicines Evaluation Committee;

(*c*) on the recommendation of the Safety of Medicines and Risk Evaluation Sub Committee; or

(*d*) on safety alerts issued by the World Health Organization or any other National Regulatory Agency.

92. (*a*) The Authority shall recall such medicine by issuing a pharmaceutical product alert notice and such recall shall be published in the website of the Authority. If the Authority deems it necessary, such notices shall be broadcast and or published to the general public through mass media.

(*b*) The Authority shall also issue a pharmaceutical product alert notice on receipt of reliable information of a counterfeit, smuggled or prohibited medicine in circulation.

93. (1) Any recall may be a permanent or temporary removal in order to correct a particular product defect such as a labelling error.

(2) Any recall shall be enforced on part of a consignment, one or more batches, or on the entire product, depending on the extent of the defect.

94. (1) It shall be the responsibility of holder of certificate to recall every defective batch, consignment or entire product of the particular defective medicine from the circulation.

(2) Every holder of certificate for any medicine shall voluntarily recall a medicine in part or whole if any evidence appears casting doubts on its quality, efficacy or safety.

(3) Every holder of certificate shall inform the Authority within twenty four hours of initiating such voluntary recall.

(4) Every holder of certificate shall furnish all such information relevant to the recalls as required by the Authority.

(5) Every recall shall be carried out by the holder of certificate within the time frame specified in the recall guidelines issued by the Authority as applicable to each class of defect and levels of recall.

(6) Every holder of certificate shall: -

(i) ensure that a recall is carried out effectively within the given time frame in levels specified in the recall guidelines issued by the Authority;

(ii) inform Medical Supplies Division and State Pharmaceutical Corporation to ensure recall from the state sector circulation;

(iii) collaborate with the Authority on action taken to avoid or reduce risks posed by the specific batch or entire product;

(iv) liaise with the manufacturer, if the holder of certificate is not the manufacturer of the medicine to investigate the reasons for the reported health risk or defect and to carry out corrective and preventive actions;

(v) rectify the problem and obtain the approval of the Authority before re-starting the supply of the recalled medicine to the market;

(vi) provide analytical certificates for new batches as requested by the Authority; and

(vii) release new batches of the medicine to the market only after obtaining the approval of the Authority.

95. (1) In the event of any recall, the Authority shall: -

(*a*) suspend or cancel the Certificate of Registration of the product in terms of Section 65 of the Act;

(*b*) carry out a Good Manufacturing Practices inspection of the manufacturing plant if deems necessary by the Authority;

(*c*) suspend the Certificate of Registration and any related licence for a period as may be determined by the Authority if the Authority is of the opinion that: -

(i) the quality defects or health risks are persistently reported;

(ii) the defects are due to negligence or deliberate omissions of the manufacturer; or

(iii) if the findings of the Good Manufacturing Practices inspection are not satisfactory;

(2) If the Authority is satisfied that adequate corrective and preventive actions has been taken by the manufacturer which shall be confirmed by a Good Manufacturing Practice inspection of the manufacturing plant, the suspension may be revoked.

PART XI

LICENSING OF PHARMACIES

96. (1) Every person who intends to carry on a pharmacy shall apply to the Authority for approval of the location where the pharmacy is to be carried out as per the guidelines issued by the Authority for establishment of a pharmacy.

(2) On receipt of such application, the Authority shall inspect the location and on being satisfied that such location meets the requirements set out in the guidelines issued by the Authority for the purpose of establishing a pharmacy, approve such location.

(3) On completion of the preliminary work, the applicant shall apply to the Authority for a licence to sell therapeutic goods by retail with such information as may be required for the purpose of enabling the Authority to process such application including details of the pharmacist who shall be responsible for the operations of the retail pharmacy.

(4) Every such application shall be substantially in the form specified in Schedule XV hereto.

97. Every applicant for a license to carry on a pharmacy shall comply with the following:-

(*a*) the applicant shall be a registered pharmacist who is a citizen of Sri Lanka or a person or a corporate fully owned by Sri Lankan citizen employing a registered pharmacist to be responsible for all operations of the retail pharmacy relating to therapeutic goods;

(*b*) where therapeutic goods are to be sold or stored by the same organization or person for sale at more than one outlet, a separate application shall be made and a separate licence shall be obtained in respect of each such outlet including different outlets in the same premises.

98. The Authority shall on being satisfied that all the conditions for a pharmacy have been complied with, issue a licence to the applicant:

Provided however, the Authority may refuse to issue a licence to any person where any licence issued to him previously by the Authority has been revoked.

99. (1) Every licence issued by the authority under regulation 98 shall:

(*a*) be substantially in the form specified in Schedule XVI hereto;

(*b*) be valid only in respect of the premises for which it is issued; and

(*c*) not be transferable without the prior written approval of the Authority.

(2) The fee payable in respect of a licence to sell therapeutic goods by retail shall be as specified in the fees regulations.

Conditions of Licence to Sell Therapeutic Goods by Retail

100. (1) Every person to whom a licence is issued under Regulation 98 to carry on a pharmacy (hereinafter referred to as a "Licensed Retail Dealer'') shall –

(*a*) comply with the guidelines issued by the Authority relating to community pharmacy practice;

(*b*) if he is not a pharmacist shall engage the services of a pharmacist to be responsible for the pharmacy operation (hereinafter referred to as "Responsible Pharmacist").

(*c*) shall exhibit in a prominent place in the pharmacy-

(i) the license issued to him under Regulation 98;

(ii) the original of Certificate of Registration of the Responsible Pharmacist issued by the Sri Lanka Medical Council or a copy certified by the Authority; and

(iii) a photograph of the pharmacist on duty;

(2) Every responsible pharmacist shall-

(*a*) not sell any therapeutic good which is not registered by the Authority;

(*b*) shall inform the Authority of any matter that he may become aware, while carrying out the duties as a Responsible Pharmacist, which may cause a threat to public health;

(*c*) maintain the premises and carry out functions according to the guidelines issued by the Authority on Good Pharmacy Practices, Good Storage Practices and Good Distribution Practices;

(*d*) not dispense of electronic prescriptions nor engage in home delivery of therapeutic goods without the prior written approval of the Authority.

(*e*) ensure that dispensing or home delivery of therapeutic goods to patient or customer are carried out by a pharmacist.

101. (1) The licence for the sale of therapeutic goods by retail shall unless it is earlier suspended or cancelled, be valid for a period of one year.

(2) Where an application for renewal of a licence for the sale of therapeutic goods by retail is not made before three months from the date of expiry, such licence shall be deemed to have automatically been cancelledat the end of the validity period of the current licence.

(3) Any application for the renewal of such license shall be in the form specified in Schedule XVII hereto.

102. (1) If any Licenced 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 given, by an order in writing stating the reasons therefor, suspend such licence for such period as determined by the Authority or cancel it.

(2) Any person who is aggrieved by the decision of the Authority made under regulation 102 (1) may appeal in terms of section 122 of the Act.

103. The Authority shall keep a list of all Licenced Retail Dealer and shall enter or cause to be entered therein particulars as may be determined by the Authority pertaining to the licensed retail pharmacy.

104. (1) Every Licensed Retail Dealer shall forthwith inform the Authority in writing of any circumstances or events which may affect the accuracy of any particulars stated in the licence to sell therapeutic goods by retail and at the same time forward the licence to the Authority.

(2) Upon receipt of any information furnished by a Licensed Retail Dealer the Authority may make, or cause to be made such appropriate alterations as may be necessary in the register of licenced retail pharmacies and issue a new licence with necessary amendments to such licensed retail dealer.

(3) The fee payable in respect of any amendments in a licence to sell therapeutic goods by retail shall be as specified in fees regulations.

105. Any Licensed Retail Dealer who has under his control any shop or any other place of business shall sell any registered medicine specified in Schedule II and Schedule III of the an Order made under subsection (2) of Section 60 of the Act only to the following persons:-

(*a*) a medical practitioner, dental surgeon or pharmacist registered under the Medical Ordinance (Chapter 105)for the purpose of supplying to patients during their practice;

(*b*) a veterinary surgeon registered under the Veterinary surgeons and Practitioners Act, No.46 of 1956 for the purpose of treating animals during his practice; or

(*c*) any person who produces a valid prescription from a registered medical practitioner, dental surgeon or veterinary surgeon.

106. (1) Every licensed Retail Dealer shall maintain a register of medicines sold by him on prescriptions including electronic prescriptions referred to as the "Prescription Register".

(2) The format of such register and details to be recorded therein shall be as may be determined by the Authority and such records may be maintained as an electronic database.

107. The Authority may revoke any licence issued under regulation 98 if the Authority is satisfied that the retail pharmacy has acted in contravention of the Act or any regulation relating to sale of therapeutic goods by retail.

PART XII

WHOLESALE DEALERS OF THERAPEUTIC GOODS

108. No person shallsell (by wholesale) any registered therapeutic good except under the authority of a licence issued in that behalf, under these regulations.

109. (1) Every person desirous of obtaining a licence for sell (by wholesale) any registered therapeutic goods shall apply to the Authority in the form specified in Schedule XVIII hereto.

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

110. Every applicant for a licence to sell (by wholesale) of any registered therapeutic good shall comply with the following requirements:-

(*a*) the premises in which the sale of registered therapeutic goods is carried out shall be adequate to the stocks of therapeutic goodsand equipped with proper storage facilities for preserving the properties of the therapeutic goods and shall be in charge of a registered pharmacist.;

(*b*) Where where any registered therapeutic good 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 license shall be obtained in respect of each such premises.

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

Provided, however that, the Authority may refuse to issue a licence to any person

(*a*) whose previous licence was revoked;

(*b*) convicted for drug addiction ; and

(*c*) being a company that does not hold more than fifty *per centum* of shares owned by citizen of Sri Lanka.

(2) The Authority shall, on being satisfied that all the conditions for the issuing of a licence to sell (by wholesale) of any therapeutic goods have been complied with, issue a licence to the applicant.

112. (1) Every licence to sell (by wholesale) sale therapeutic goods issued by the Authority under regulation111 shall be-

(*a*) in the form specified in Schedule XIX hereto;

(*b*) be valid only in respect of the premises for which it is issued.

(*c*) unless it is earlier suspended or cancelled, be valid for a period of one year from the date stipulated in the licence.

(2) The fee payable in respect of such license shall be as specified the fees regulation.

Conditions of Licence to sell (by Wholesale) Any Therapeutic Good

113. Every person issued with a license to sell (by wholesale) any therapeutic goods issued under Regulation 111 (hereinafter referred to as "Licensed Wholesale Dealer") shall:-

(*a*) comply with the requirements stated in the guidelines issued by the Authority for Good Storage Practices, Good Distribution Practices and Good Pharmacovigilance Practices.

(*b*) not exhibit or offer for sale or sell therapeutic good which is -

(i) bearing the State logo or any mark indicating State property without the prior approval of the Authority;

(ii) smuggled or counterfeit;

(*c*) allow any Authorised Officer appointed in that behalf by the Authority to enter with or without notice during reasonable hours, any premises where therapeutic goods are stored or sold for the purpose of inspecting and taking samples of therapeutic goods for investigation, test, examination or analysis;

(*d*) on a request made in that behalf and on payment of the relevant fee, furnish to the Authority, from any batch of each therapeutic good a sample of such amounts as the Authority may consider adequate for test, examination, or analysis to be made;

(*e*) if the Authority so directs, not sell or offer for sale, any batch of a therapeutic good in respect of which samples are furnished until a decision is given by the Authority authorizing the sale of such therapeutic goods of that batch;

(*f*) on being informed by the Authority that any part of any batch of a therapeutic good has been found by the Authority to be not in conformity with the specified standard of strength, quality or 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 therapeutic goods already issued from that batch ;

(*g*) maintain a record of all particulars of receipts and sales made by him and such records shall be open to inspection by any Authorized Officer.

(2) The Every Authorized Officer have right shall detain to seize or detain any therapeutic good which is not authorized to be marketed by the Authority;

114. (1) Where an application for renewal of a licence for the sale (by wholesale) of therapeutic goods is not made three months before its date of expiry such licence shall be deemed to have automatically been cancelled at the end of the validity period of the current licence.

(2) An application for renewal of such licencse shall be in the form specified in Schedule XX hereto.

115. (1) If any Licensed Wholesale Dealer fails to comply with any of the conditions of the licence for the wholesale sale of therapeutic goods the Authority may, after giving him an opportunity to show cause why such an order may not be made, by an order in writing stating the reasons therefor, suspend such licence for such period as of the opinion of the Authority or cancel it in respect of either all or some of the therapeutic goods to which such licence relates.

(2) Any person who is aggrieved by the decision of the Authority made under regulation 115 (1) may appeal in terms of section 122 of the Act.

116. Every Licensed Wholesale Dealer shall exhibit the licence issued to him under regulation 111 in a prominent place in the premises at which he sells medicines, together with the original of the Certificate of Registration of the pharmacist issued by the Sri Lanka Medical Council or a copy certified by the Authority.

117. The Authority shall keep a list of all Licensed Wholesale Dealers and shall enter or cause to be entered therein particulars pertaining to Licensed Wholesale Dealer which as may be determined by the Authority.

118. (1) Every Licensed Wholesale Dealer shall forthwith inform the Authority in writing of any circumstances or event which may occur that may affect the accuracy of any particulars stated by such Licensed Wholesale Dealer in the application for a licence for wholesale sale of therapeutic goods and shall at the same time forward the licence to the Authority.

(2) Upon the receipt of any information furnished by a licensed wholesale dealer as mentioned under Regulation 118, the Authority may make or cause to be made such appropriate amendments in the register and shall issue a new licence to such Licensed Wholesale Dealer with necessary amendments.

(3) The fee payable in respect of any amendments in a licence to sell (by wholesale) by therapeutic goods shall be as specified in feesregulations.

119. Any Every Licensed Wholesale Dealer shall sell any registered medicine specified in Schedule II and III of an Order made under sub section (2) of section 60 of the Act only to the following persons:-

(*a*) a medical practitioner or dental surgeon registered under medical ordinance, [Chapter 105] for use during their practice;

(*b*) a veterinary surgeon registered under the veterinary surgeons & practitioners Act, No. 46 of 1956 for use during his practice;

(*c*) a licensed retail dealer who holds a valid licencefrom the Authority; or

(*d*) a licensed wholesale dealer who holds a valid licence from the Authority.

(*e*) a person who has a valid approval granted by the Authority.

120. Every Licensed Wholesale Dealer shall maintain a record of all particulars of receipts, sale and supply of therapeutic goods by him under the following headings and such records shall be open to inspection by any officer nominated on that behalf by the Authority and such record may be maintained as an electronic database.

(*a*) Name of the therapeutic good (Generic/ Brand);

(*b*) Name of manufacturer;

(*c*) Date of purchase;

(*d*) Quantity received /purchased;

(*e*) Source of purchase;

(*f*) Purchased price;

(*g*) Number and date of invoice;

(*h*) Batch number (s) /expiry dates; and

(*i*) Names of persons to whom the therapeutic goods were distributed including their addresses and an identification number such as National Identity Card, Passport number.

121. (1) The Authority may revoke any licence for wholesale sale of any therapeutic good if the Authority is satisfied that the wholesale dealer has acted in contravention of the Act or any regulation contained in this Part or any other regulation pertaining to sale of therapeutic goods by wholesale.

(2) Any person who is aggrieved by the decision of the Authority made under Regulation 121 (1), may appeal in terms of section 122 of the Act.

PART XIII

TRANSPORT OF THERAPEUTIC GOODS FOR DISTRIBUTION

122. No person shall transport any therapeutic good other than those classified by the Authority as safe for the general use for the purpose of distribution to medical practitioners, dental surgeons, veterinary surgeons or to licensed retail or wholesale dealers, except under the authority of a license issued on that behalf under these Regulations.

123. (1) Every Licensed Retail Dealer or Licensed Wholesale Dealer, Licensed importer orLicensed manufacturer of therapeutic goods desirous of obtaining licence to transport any registered therapeutic good for the specific purpose of distribution to medical practitioners, dental surgeons, veterinary surgeons or to licensed retail or wholesale dealers shall make an application to the Authority.

(2) Such Licensed Retail Dealer or Licensed Wholesale Dealer, Licensed Importer or Licensed Manufacturer may appoint an agent to carry out the distribution.

(3) No person other than a Licensed Wholesale Dealer shall be appointed as such agent (hereinafter referred to as “Distributor”).

(4) EveryLicensed Wholesale Dealer appointed as a Distributor shall be a person who is a citizen of Sri Lanka or a company having more than fifty one *per centum* shares owned by Sri Lankan citizens.

(5) Every application for a licence to transport therapeutic goods for distribution shall be in the form specified in Schedule XXI hereto.

(6) (*a*) Every applicant for a license to transport therapeutic goods shall furnish to the Authority all such information as the Authority may require for the purpose of enabling the Authority to process of such application.

(*b*) Every applicant shall declare all information required in the application form including the details about the Distributor if any, including geographical areas such as districts and towns assigned to him for such distribution.

124. (1) The Authority shall, upon receipt of an application for a licence to transport therapeutic goods shall cause the vehicles assigned for such transport to be inspected, before issuing a licence.

(2) The Authority shall, on being satisfied that all the conditions for issuing a licence have been complied with, issue a license to the applicant or may reject such application if the applicant does not comply with such requirements.

125. (1) Every licence issued by the authority under Regulation 124 shall be substantially in the form specified in Schedule XXII hereto.

(2) The licence to transport therapeutic goods shall, unless it is earlier suspended or cancelled be valid for a period of one year from the date stipulated in the licence.

(3) The fee payable in respect of a license to transport therapeutic goods shall be as specified in fees regulations.

Conditions of a Licence to Transport Therapeutic Goods

126. (1) Every Distributor shall: -

(*a*) follow Good Distribution Practice guidelines issued by the Authority;

(*b*) ensure that every vehicle used to transport therapeutic goods shall be adequately equipped with proper storage facility to preserve the quality of the therapeutic goods and maintain proper storage conditions at the time during transport.

(*c*) ensure that the person responsible for the therapeutic goods during transport shall be a competent to supervise and control the distribution and preservation of the therapeutic goods during transport;

(*d*) allow any Authorized Officer to stop any vehicle in which therapeutic goods are transported, to inspect the vehicle and therapeutic goods and taking samples for investigation, test, examination or analysis.

(2) No Distributor shall-

(*a*) transport any therapeutic good bearing the State logo or any other mark indicating State property:

Provided however, this regulation does not apply to transport medicines in State sector vehicles or the vehicles transporting therapeutic goods to State sector institutions by licensed distributors, licensed manufacturers and licenced importers or any other person with the approval of the Authority ;

(*b*) transport therapeutic goods which are not registered by the Authority or therapeutic goods imported or manufactured without a licence issued on that behalf by the Authority or any smuggled or counterfeit therapeutic good;

(*c*) transport poisonous substances such as pesticides, herbicides, insecticides or any other substance that could affect the quality and safety of therapeutic goods together with such therapeutic goods in the same vehicle.

127. The Authority may revoke any license to transport therapeutic goods issued under Regulation 124 if the Authority is satisfied that the Distributor has acted in contravention of any regulation made under the Act.

PART XIV

DISPOSAL OF THERAPEUTIC GOODS

128. (1) Any therapeutic good that fails to conform to the specified standards, or which are expired or banned, damaged, spoilt, unwanted or confiscated by the Authority or any samples of therapeutic goods remaining after use shall be destroyed.

(2) In the event of a licensed manufacturer, importer, wholesaler or retailer having a stock of therapeutic goods to be disposed of, such manufacturer, importer, wholesaler or retailer shall obtain prior approval from the Authority for such disposal.

129. (1) The Authority shall publish guidelines based on the guidelines published by the Word Health Organization for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies and such guidelines shall be followed in disposal of therapeutic goods.

(2) The guidelines issued by the Authority relating the disposal of therapeutic goods shall be followed in disposal of therapeutic goods.

(3) Every such destruction shall be carried out under the supervision of an officer appointed by the Authority, in an environmentally responsible manner and avoiding any risk of such therapeutic good being reused.

PART XV

WAIVER OF REGISTRATION OF THERAPEUTIC GOODS

130. (1) Every supplier of any theraputic good which is exempted for registration shall-

(*a*) take the full responsibility regarding the quality, safety and efficacy of the therapeutic goods supplied;

(*b*) be responsible to inform the prescribers, dispensers and users that the particular therapeutic good has not been evaluated by the Authority and that the supplier takes the full responsibility regarding the quality, safety and efficacy of the medicine.

(*c*) be responsible to inform the Authority immediately of any adverse reaction occurs with the use of the therapeutic good supplied and shall have a mechanism for obtaining such information;

(*d*) submit routine reports on details of distribution of the therapeutic goods supplied under this regulation time to time using the form developed by the Authority.

(2) The Authority shall not be responsible for the quality, safety and efficacy of any therapeutic goods which is not registered with the Authority.

PART XVI

INSPECTION

131. (1) The Authority shall issue guidelines for the following:-

(*a*) Good Manufacturing Practices;

(*b*) Good Laboratory Practices;

(*c*) Good Clinical Practices;

(*d*) Good Distribution Practices;

(*e*) Good Storage Practices;

(*f*) Good Pharmacy Practices;

(*g*) Good Pharmacovigilance Practices.

(2) The Divisions of the Authority with relevant expertise shall be responsible for inspecting related entities for the compliance to relevant good practice guidelines.

(3) The inspections shall be carried out routinely, prior to licensing, or for investigation of a specific issue with or without notice.

(4) The same criteria shall be used for the inspections of all private, public, domestic and foreign entities.

(5) Planning for inspections shall be on a risk-based approach.

132. (1) The Inspectorate and Enforcement Division of the Authority shall be responsible for inspecting relevant entities for the adherence to legal requirements set out in the Act and regulations made thereunder and, investigating any issues pertaining to implementation of the legal provisions as may be authorized and directed by the Authority.

(2) Whenever necessary or relevant, the Authority may collaborate with other organizations such as Provincial Health Authorities, Sri Lanka Customs, the Department of Police, National Dangerous Drugs Control Board and Consumer Affairs Authority, for the purpose of inspection and any investigation under the provisions of the Act and the regulations made thereunder.

(3) Inspection reports and expert reports in relation to licensing activities may be made available in the official website as determined by the Authority.

(4) The Authority shall establish a post-market surveillance system in order to strengthen the regulatory control activities and sampling at all entry points and all levels of the supply chain including transit.

PART XVII

WEBSITE OF THE AUTHORITY

133. (1) There shall be an electronic page in the website of the Authority to facilitate better communication with the general public, health professionals, and pharmaceutical industry.

(2) The Authority shall publish and maintain updated, national registers of licensed manufacturers, importers, wholesale dealers, distributors, pharmacies, marketing authorization holders and registered therapeutic goods.

(3) The Authority shall publish the following in the website of the Authority: -

(*a*) every regulation and guideline made under the Act;

(*b*) any other regulatory bodies recognized by the Authority;

(*c*) any information on substandard and falsified therapeutic goods and medicinal products withdrawn from the market by the Authority;

(*d*) any decisions on authorization or rejection;

(*e*) any information on the risks associated with medicines sold illegally to the public;

(*f*) any notice on public awareness programmes conducted by the Authority;

(*g*) every national legislation applicable to pharmacies and therapeutic goods.

(4) There shall be an area available on the website for quality and safety alerts, communications, important information to promote the rational use of the medicine and for lodging complaints.

(5) There shall be a database of all applications received, approved, refused, suspended or withdrawn, alone with their essential documentation.

PART XVIII

GOOD REGULATORY PRACTICES

134. The Authority shall publish Good Regulatory Practice guidelines in its website and follow such guidelines relating to matters specified in Schedule XXIII.

135. In these regulations-

"Act" means the National Medicines Regulatory Authority Act, No. 5 of 2015;

"Collaborative Registration Procedure" means a procedure to accelerate registration through improved information sharing with the World Health Organization Prequalification of Medicines Programme;

"Good Manufacturing Practices" shall have the same meaning assigned to it under the Act;

"Local Manufacturer" means a person or a company involved in manufacturing of medicines within Sri Lanka;

"NMQAL" shall have the same meaning assigned to it under the Act;

"Medicine" shall have the same meaning assigned to it under the Act;

"Site Master File" means a document prepared by a manufacturer which provides information about the production and control of manufacturing operations

"Pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other (medicine)related problem.

"Fees regulations" means the Registration and Licensing of Medicines (fees) Regulations, No. 02 of 2017 published in the Gazette Extraordinary No. 2023/30 of June 14, 2017.

"World Health Organization Prequalification of Medicines Programme" means a programme of the World health Organization that helps ensure that medicines supplied by procurement agencies meet acceptable standards of quality, safety and efficacy.

"World Health Organization Prequalified Medical Products" means medical products that meet international norms and standards of which the quality, efficacy and safety has been assessed, inspected and controlled.

136. Drugs Regulations, No. 38 of 1984 published in *Gazette* Extraordinary No. 378/3 of December 2, 1985 is hereby rescinded without prejudice to anything done thereunder.

Regulation 2 (12)

Schedule I

APPLICATION FOR GRANT / RENEWAL OF A CERTIFICATE OF REGISTRATION OF A MEDICINE BY A LOCAL MANUFACTURER /AN AUTHORIZED IMPORTER

I/We,……of…….hereby apply for a Certificate of Registration of the medicine specified below details of which are enclosed herewith.

A. Name and address of manufacturer of the medicine:

……
………..

B. Type of application (check the box applicable)

1. New application ☐
2. Renewal application ☐
3. Variation to existing registration ☐ (If selected, complete the information below)

- Previous registration number :…….
- Previous registration type (Full) ☐ (Provisional) ☐
- Brief description of proposed variation : …….
- Reasons for variation :……..

C. Details on the product

1. Proprietary name (trade name) :……
2. Approved generic name (s) (use INN if any):……..
3. Standard claimed (BP, IP, Ph.Eur., USP,etc.):…….
4. Strength(s) per dosage unit:……
5. Dosage form :…….
6. Route of administration:……..
7. Packaging and pack size(s) :…….
8. Therapeutic category :……..

D. Details of the applicant (check applicable box)

1. Local manufacturer ☐ Authorized importer ☐

(a) Name :……
(b) Mailing address:……
(c) Telephone number /Fax number:…….
(d) E mail:…….
(e) Website:……..

E. Information submitted with the application

Modules of Common Technical Dossier

- Module 1 (annex or page No.):……..
- Module 2 (annex or page No.):……..
- Module 3 (annex or page No.):……..
- Module 4 (annex or page No.):……..
- Module 5 (annex or page No.):……..

F. Samples : Submitted ☐ number of samples …….

Not submitted ☐

Declaration

I, the undersigned, certify that all the information in the accompanying documentation concerning the application for Certificate of Registration of the above medicine is correct and true, and reflects the total information available.

Signature:…….

Regulatory Affairs Officer:…….

Name :……..

Date:…….

Regulation 4

Schedule II

Particulars to be entered in the register of applications for registrations of medicines

1. Date of receipt
2. Application number
3. Name of manufacturer
4. Country of manufacture
5. Authorized importer
6. Generic name of medicine
7. If the medicine is a combination product, generic names of active ingredients
8. Brand name of medicine (if any)
9. Dosage form of medicine
10. Strength of medicine
11. Type of application
    (*a*) new
    (*b*) renewal
12. Type of medicine
    (*a*) new molecular entity
    (*b*) new dosage form of an already registered molecular entity
    (*c*) new combination consisting of already registered molecular entity(ies)
    (*d*) new product of a biological origin
    (*e*) new product (branded or generic) of an already registered entity(ies)

Regulation 9

Schedule III

CERTIFICATE OF REGISTRATION OF A MEDICINE

Generic Name:……

Brand Name : ……

Dosage form: ……. Shelf Life : ……

Pack Type:……

Pack Size(s) :……

Name & Address
of Manufacturer :……

Name & Address
of Importer :……

Registration No:…… Date of Registration: ……..

Type of Registration:…….…… Period of Validity: ……...…….

Previous Registration No. (if applicable) : ……..

Schedule: …….…….....

Maximum retail price per unit:……..

Date of issue of certificate :.....

Number and date of receipt for fees paid:……

…..……..……..

National Medicines Regulatory Authority

Regulation 29

Schedule IV

LICENCE FOR A LICENCED LOCAL MANUFACTURER OF MEDICINES

Licence Number …….

M/s…….. of ……hereby licenced as a Local Manufacturer of Medicines and authorized to manufacture products specified under the categories mentioned below at the premises situated at …….

This licence is subject to conditions prescribed in Regulation 36 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

List of product categories (s) permitted to manufacture

1. …….....
2. …….....
3. …….....

Validity period of the licence

Date of issue :

Number and date of receipt for fees paid:

……..……..……..……..……..……..

National Medicines Regulatory Authority

Regulation 33 (2)

Schedule V

APPLICATION FOR LICENCE TO MANUFACTURE A REGISTERED MEDICINE

I/We,……of……hereby apply for a licence to manufacture the medicine specified below on premises situated at …….

Name of Medicine: …….....

Dosage form: …….....

1. Details of manufacturing site

1.1 Name:

1.2 Address:

1.3 Telephone No.:

1.4 Email address:

1.5 Fax No.:

2. Other information submitted as annexes.

2.1 Copy of valid licence issued by the Authority as a Licenced Manufacturer of Medicine

Submitted ☐ Not submitted ☐

2.2 Copy of valid Certificate of Registration of the medicine: Submitted ☐ Not submitted ☐

Signed: ……..

Regulatory Affairs Officer

Name : ……

Date: …….

Regulation 34

Schedule VI

LICENCE TO MANUFACTURE A REGISTERED MEDICINE

Licence Number :

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

This licence is subject to conditions prescribed in Regulation 36 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

Name of medicine:

Dosage form:

Shelf Life :

Period of validity of the licence:

Date of issue :

Receipt no and date for fees paid :

……

National Medicines Regulatory Authority

Regulation 38 (2)

Schedule VII

APPLICATION FOR RENEWAL OF A LICENCE TO MANUFACTURE A REGISTERED MEDICINE

I/We,……of……hereby apply for renewal of a licence to manufacture the medicine specified below on premises situated at ……..

Name of Medicine: ……

Dosage form: ……..

1. Details of manufacturing site

1.1 Name:

1.2 Address:

1.3 Telephone No.:

1.4 Email address:

1.5 Fax No.:

2. Other information submitted as annexes.

2.1 Copy of valid licence issued by the Authority as a Licenced Manufacturer of Medicine

Submitted ☐ Not submitted ☐

2.2 Copy of valid Certificate of Registration of the medicine: Submitted ☐ Not submitted ☐

2.3 Copy of the previous licence to manufacture the medicine mentioned in this application

Signed: ……..

Regulatory Affairs Officer

Name : ……

Date: ……..

Regulation 48 (3)

Schedule VIII

APPLICATION FOR LICENCE TO IMPORT A REGISTERED MEDICINE

I/We ……of ……hereby apply for a licence to import the medicine specified below.

Details of the medicine:

Generic name:……..

Brand name (if any) :……..

Dosage form:……..

Pack type :…….

Pack size(s):……..

Shelf life :……..

Name and Address of manufacturer:…….

Price Details:

Maximum retail price approved by the National Medicines Regulatory Authority of Sri Lanka

Annexes:

- Valid Certificate of Registration
- Previous import licence (if any)
- Details of previous imports (if any)

Signed: ……..

Regulatory Affairs Officer

Name : ……

Date: …….

Regulation 49

Schedule IX

LICENCE TO IMPORT A REGISTERED MEDICINE

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 medicine specified below.

This licence is subject to conditions prescribed in Regulation 51 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

.

Names of medicine:……..

Dosage form:……

Pack size(s):…….

Shelf-life:……

Name of manufacturer:……

Address of manufacturer :……..

Period of validity of the licence:

Date of issue :

Number and date of receipt for fees paid:

……

National Medicines Regulatory Authority

Regulation 52(3)

Schedule X

APPLICATION FOR RENEWAL OF LICENCE FOR A LICENCED IMPORTER OF MEDICINES

I/We……..……. of ……..…… hereby apply for renewal of licence for a licensed importer of medicines.

1. General Information

1.1 Particulars of the Company/Organization

1.1.1 Name of applicant company/organization

1.1.2 Business model of the company/organization
(e.g. private limited company, public limited company, joint venture, sole proprietorship, partnership etc.)

1.1.3 Postal address (registered office)

1.1.4 Postal address (operational office)

1.1.5 E mail address

1.1.6 Telephone number(s)

1.1.7 Fax number(s)

1.1.8 Address(es) of Warehouse(s)

1.2 Particulars of Key Personel of the Company

1.2.1 Names and addresses of Board of Directors/Partners of the company etc. as applicable

1.2.2 Name of the regulatory pharmacist responsible for liaising with NMRA

1.2.3 Sri Lanka Medical Council (SLMC) registration number of the regulatory pharmacist

1.2.4 Telephone number(s) (mobile) of the regulatory pharmacist

1.2.5 Email address of the regulatory pharmacist

1.2.6 Name of the pharmacist responsible for pharmacovigilance/post marketing surveillance

1.2.7 SLMC registration number of the pharmacist responsible for pharmacovigilance/post marketing surveillance

1.2.8 Telephone number(s) (mobile) of the pharmacist responsible for pharmacovigilance/post marketing surveillance

1.2.9 Email address of the pharmacist responsible for pharmacovigilance/post marketing surveillance

2. Annexes

2.1 A declaration by the responsible person certifying that the information furnished are true and accurate

2.2 Copy of business registration certificate issued by the relevant government authority

2.3 List of key persons employed (indicating the name, designation, qualification, and experience of each person)

2.4 Post marketing surveillance plan of the company

2.5 Recall procedure of the company

2.6 List of manufacturers by whom the applicant has been appointed as the authorized importer in Sri Lanka.

…….

Signed

(Responsible Officer)

Name:……..

Designation:……

Date:……..

Regulation 59 (1)

Schedule XI

APPLICATION FOR LICENCE TO IMPORT A MEDICINE AS SAMPLES FOR TEST/ EXAMINATION/ANALYSIS/CLINICAL TRIAL/DISTRIBUTION AS PHYSICIANS SAMPLES

I/We ……. of …….....…….. hereby apply for a licence to import from ……

the medicine specified below as samples for the purpose of test/ examination/analysis/clinical trial/distribution as physicians samples.

Generic name of the medicine :……

Brand name (if any):……..

Dosage form and Strength:……

Quantity:……..

Signed: ……..

Regulatory Affairs Officer

Name : ……

Date: ……..

Regulation 60 (1)

Schedule XII

LICENCE TO IMPORT A MEDICINE AS SAMPLES FOR T EST/ EXAMINATION/ ANALYSIS/CLINICAL TRIAL/ DISTRIBUTION AS PHYSICIAN'S SAMPLES

Licence Number :.....

M/s..... of..... is/are hereby licensed to import from .....the medicine specified below for the purpose of test/ examination/ analysis/ clinical trial/ distribution.

This licence is subject to conditions prescribed in Regulation 61 of the National Medicines (Registration and Licensing of Medicine) Regulations 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

Generic name of medicine:

Brand name (if any): .....

Quantity: .....

Pack size(s): .....

Period of validity of the licence: ...

Date of issue: .....

Receipt No. for fees paid and Date:

.....

National Medicines Regulatory Authority.

Schedule XIII

Regulation 78 (2)

Product Information Leaflet

Information included :

(*a*) Generic or official name of the drug product, the dosage form, and the strength.

(*b*) Net content of the active substance(s).
When an active substance is present as a salt, this should be clearly indicated.

(*c*) Brand or proprietary name, if any.

(*d*) Product Description – a description of the relevant physical and chemical characteristics of the drug product and a description of the appearance of the product (colour, markings etc.) should be given.

(*e*) For products to be reconstituted before use, the appearance before reconstitution should be stated. If a diluent/ solvent is accompanied with product, a physical description of diluent/solvent should be stated.

(*f*) If applicable, information on pH and osmolarity should be provided.

(*g*) For tablets designed with a score line, information on the purpose of the score-line should be given, e.g. 'the score line only serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses', or 'the tablet can be divided into equal halves'.

(*h*) Excipients contained in the product, of which the knowledge of presence is important for the safe and effective use of the medicinal product. (e.g. preservatives, colourants, antioxidants etc.)

(*i*) Pharmacodynamics/Pharmacokinetics – information to be mentioned in this section include:

- The pharmaco-therapeutic group and if available, the ATC code
- Mechanism of action of each drug substance
- Pharmacokinetic properties of each drug substance
- Clinical trial information relating to clinical efficacy and safety; and
- Relevant pharmacogenetic information from clinical studies with data showing a difference in benefit or risk to a particular genotype or phenotype.

(*j*) Indication and usage – the therapeutic indication(s) of the product.
Information shall include a concise statement of each of the medicine's approved indications, briefly noting any major limitations of use for any or all of its indications. If multiple indications exist, the information be presented in a bulleted format.

(*k*) Dosage and administration – the information required include, as appropriate:

- A concise summary of the recommended dosage regimen (e.g., starting dose, dose range, titration regimens, route of administration)
- Critical differences among population subsets
- Information on dose adjustments in special populations, e.g. elderly, children, renal insufficiency, hepatic insufficiency and other concomitant diseases and therapies
- Maximum recommended/tolerated daily dose and the maximum dose for an entire course of therapy;
- Monitoring requirements: advices relevant for dosage adjustment from monitoring of clinical symptoms and signs and/or laboratory investigations, when appropriate.
- Other pertinent information, such as relationship to meals and compatibility with other drugs and fluids

Reference to a dosing regimen for an unapproved indication is not acceptable

(*l*) Method/Route of Administration – only standard abbreviations should be used. Non-standard or complicated routes of administration should be carefully explained to avoid confusion.

(*m*) Contraindications – situations where patients should never or generally not be treated with the medicine.

(*n*) Warnings and Precautions – circumstances where caution is required to ensure the safe and efficacious use of the product.
Mention if appropriate, possible effects on the ability to drive vehicles or operate machinery.

(*o*) Interactions – forms of interactions with other medicines and other forms of interaction (e.g. with alcohol, food varieties) with clinical significance.

(*p*) Use during Pregnancy/Lactation

(*q*) Adverse Effects/Undesirable Effects – a description of the adverse reactions under normal use of the medicine and, if necessary, action to be taken by the patient. Provide an indication of severity, clinical importance and frequency, whenever possible.

(*r*) Overdose and Treatment – symptoms, signs and recommended treatment of overdose or accidental poisoning.

(*s*) Method of preparation – if applicable, the complete method of reconstitution or dilution should be stated. If not accompanied with the product, the names of suitable diluents or solvents to be indicated.
The appearance of the product after reconstitution should be stated. As appropriate, the information on in-use shelf-life after dilution or reconstitution or first opening should be provided in this section or the section “Shelf life”.

(t) Incompatibilities (for injections only)

(u) Storage Condition – the storage condition must be consistent with the conclusion of the stability testing and the conditions stated on the product label and/or outer carton.

(v) Shelf Life – the shelf life must be based on stability data furnished in the dossier and consistent with that stated on the product label and/or outer carton.

The information on in-use shelf-life after dilution or reconstitution or first opening should be provided (if applicable).

(w) Available pack size(s) - All pack sizes intended to be marketed should be listed. Reference should be made to the primary container closure system (e.g. glass vials, PVC/Aluminium blister, Aluminium/Aluminium blister, HDPE bottle, ampoule, etc.).

(x) Any other components accompanying the product should be indicated (e.g. solvent, syringe, measuring cup, needles, etc.). The primary container closure system of the diluent/solvent provided with the drug product should also be described.

(y) The name and address of the manufacturer, batch releaser or product owner. The site address should be compatible with the address indicated in the COPP and labels.

(z) The date on which the leaflet was last revised.

Regulation 79

Schedule XIV

Patient Information Leaflet

Information included :

(*a*) Name of the medicine (generic and brand if applicable), dosage form, strength, net content of active ingredient(s), details of certain excipients such as preservatives and colourants as required by the Authority, and a description of the appearance of the product

(*b*) Any specific age groups for which the medicine is intended to, if applicable

(*c*) What is this medicine used for?

(*d*) How much and how often should the medicine be taken, and how long the course of treatment will last?

(*e*) Any other specific directions about how to use the medicine

(*f*) Symptoms of serious or frequent possible adverse effects/undesirable effects and what to do if such effect is experienced

(*g*) When this medicine should not be used?

(*h*) What other medicines or food should be avoided while taking this medicine

(*i*) What should be done, if a dose is missed?

(*g*) Any risks to the mother and the fetus or the infant from the use of the medicine during pregnancy or breast-feeding.

(*k*) Information for any other special groups of patients, if applicable

(*l*) Any other precautions that should be taken while taking this medicine

(*m*) Signs and symptoms of overdose and what to do if more than the recommended dose has been taken

(*n*) How should the medicine be stored?

(*o*) Information on in-use shelf-life after dilution, reconstitution, or first opening, if applicable

(*p*) General advices e.g. ‘keep away from children’, as required by the Authority

(*q*) The name and address of the manufacturing site

(*r*) The name and address of the marketing authorization holder

If the product is sold without a separate leaflet, the information that is required in the Patient Information Leaflet be stated on the outer carton or the primary label.

Regulation 96 (4)

Schedule XV

APPLICATION FOR LICENCE TO SELL THERAPEUTIC GOODS BY RETAIL

I/We, ... of ..... here by apply for a licence to establish a pharmacy on premises situated at .....

Name of the pharmacy:

Part 1. Information about the location

1.1 Address:

1.2 Medical Officer of Health (MOH) Division :

1.3 Divisional Secretariat:

1.4 Existing pharmacies within the radius of 1000 meters:

Name of the pharmacy	Distance to the proposed pharmacy in meters
1.	
2.	
3.	

Part 2. Business information (check the box applicable):

2.1 Type of business:

(a) Individual ☐ Name of business:.....

(b) Body corporate ☐ Name of body corporate :.....

(c) Private limited company Name of company:.....

(d) Particulars of Directors / Secretary /Owners.....

Part 3. Details of the applicant:

3.1 (*a*) . Name of applicant:

(*b*) . Designation:

(*c*) . National Identity Card No :

(*d*) . Mailing address:

(*e*) . E-mail address:

(*f*) . Telephone No:

3.2 Details of Responsible pharmacist

(*a*) . Name of Responsible Pharmacist:

(*b*) . Sri Lanka Medical Council Registration No.

(*c*) . National Identity Card No

(*d*) . Mailing address:

(*e*) . E-mail address

(*f*) . Telephone No

Part 4. Information about the pharmacy:

4.1 **Premises :**

(*a*) . community pharmacy (individual standalone pharmacy) ☐

(*b*) . hospital premises ☐

(*c*) . supermarket ☐

4.2 Intended business hours : from: ..... To: .....

4.3 Type of activities to be carried out:

(i) . Sale of (a) medicines ☐ (*b*) medical devices ☐ (*c*) borderline products ☐ (*d*) cosmetics ☐

(ii) . Compounding ☐

(iii) . Home delivery ☐

(iv) . Dispensing e-prescriptions ☐

Documents to be submitted with the application:

1 . Any information required as per the guidelines issued by the Authority for the establishment of a pharmacy

2 . Certificate of Registration of the Responsible Pharmacist issued by the Sri Lanka Medical Council (SLMC)

3 . Proof of academic qualifications based on which the SLMC registration was granted

4. 3.5 cm X 4.5 cm size photograph of the Responsible Pharmacist

Declaration

I, the undersigned, certify that all information in this application for licence of a pharmacy to sell therapeutic goods by retail on the above mentioned premises is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature: .....

Applicant:.....

Name:.....

Designation: .....

Date:.....

Regulation 98

Schedule XVI

LICENCE TO SELL THERAPEUTIC GOODS BY RETAIL

Licence No .....

M/S ..... of..... is/are hereby licenced to sell therapeutic goods by retail at

the premises situated at.....

This licence is subject to conditions prescribed in Regulation 100 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

Business hours : from ..... a.m. to ..... p. m.

Functions permitted by the Authority:

(i) Sale of (a) medicines ☐ (b) medical devices ☐ (c) borderline products ☐ (d) cosmetics ☐

(ii) Compounding ☐ (iii) Home delivery ☐ (iv) Sale of on e-prescription ☐

Details of the Responsible Pharmacist:

(*a*) Name : .....

(*b*) Sri Lanka Medical Council registration number.....

(*c*) Photograph of the Responsible Pharmacist

(3.5 cm x 4.5 cm)

Date of issue :

Period of Validity :

Receipt No. and date for fees paid :

.....
National Medicines Regulatory Authority

Regulation 101 (3)

Schedule XVII

APPLICATION FOR RENEWAL OF LICENCE TO SELL THERAPEUTIC GOODS BY RETAIL

I /We ..... of..... hereby apply for renewal of licence of the pharmacy, ... situated at .....

Previous licence number : .....

Part 1. Information about the location

1.1 Address : .....

1.2 Medical Officer of Health (MOH) Division: .....

1.3 Divisional Secretariat: .....

1.4 Existing Pharmacies within the radius of 1000 meters.

Name of the pharmacy	Distance to the proposed pharmacy in meters
1.	
2.	
3.	

Part 2. Business Information (check the box applicable)**:**

2.1 Type of business

(i) Individual ☐ Name of business: .....

(ii) Body Corporate ☐ Name of body corporate: .....

(iii) Private limited company ☐ Name of Company: .....

(iv) Particulars of Directors/Secretary/Owners: .....

Part 2.3. Details of the applicant:

3.1 (*a*) Name of applicant: .....

(*b*) Designation: .....

(*c*) National Identity Card No.: .....

(*d*) Mailing address: .....

(*e*) E-mail address: .....

(*f*) Telephone No. : .....

3.2 Details of Responsible pharmacist

(*a*) Name of Responsible Pharmacist: .....

(*b*) Sri Lanka Medical Council Registration No. : .....

(*c*) National Identity Card No. : .....

(*d*) Mailing address: .....

(*e*) E-mail address: .....

(*f*) Telephone No. : .....

Part 4. Information about the pharmacy :

4.1 **Premises** :

(a) community pharmacy (individual standalone pharmacy) ☐

(b) hospital premises ☐

(c) supermarket ☐

4.2 Intended business hours :

from :..... To :.....

4.3 Type of activities to be carried out :

(i) Sale of (a) medicines ☐ (b) medical devices ☐ (c) borderline products ☐ (d) cosmetics ☐

(ii) Compounding ☐

(iii) Home delivery ☐

(iv) Dispensing e-prescriptions ☐

4. Documents to be submitted with the application:

1. Business Registration Certificate issued by the relevant Authority
2. Any other information required as per the guidelines issued by the Authority for the establishment of a pharmacy
3. Certificate of Registration of the responsible pharmacist issued by Sri Lanka Medical Council (SLMC).
4. Proof the academic qualifications based on which the SLMC registration was granted.
5. 3.5 cm X 4.5 cm size photograph of the Responsible Pharmacist

Declaration

I, the undersigned, certify that all information in this application for licence to sell therapeutic goods by wholesale on the above mentioned premises is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature: .....

Applicant: .....

Name: .....

Designation: .....

Date: .....

Regulation 109(1)

Schedule XVIII

APPLICATION FOR A LICENCE TO SELL THERAPEUTIC GOODS BY WHOLESALE

I /We, ……..……of ……here by apply for a licence to sell medicine by wholesale on premises situated at ……

Name of the wholesale establishment:……..

Part 1. Information about the location

1.1 Address:……

1.2 Medical Officer of Health (MOH) Division :…….

1.3 Divisional Secretariat:……..

Part 2. Business information (check the boxapplicable):

2.1 Type of business:

(i) Individual ☐ Name of business:……..

(ii) Body corporate ☐ Name of body corporate :……..

(iii) Private limited company ☐ Name of company:……..

(iv) Particulars of Directors / Secretary /Owners…….

Part 3. Details of the applicant:

3.1 (a) Name of applicant:……

(b) Designation :…….

(c) National Identity Card No……

(d) Mailing address:……

(e) E-mail address …….

(f) Telephone No. …….

3.2 Details of Responsible pharmacist

(a) Name of Responsible Pharmacist:……

(b) Sri Lanka Medical Council Registration No. ……..

(c) National Identity Card No …….

(d) Mailing address:……....

(e) E-mail address …….

(f) Telephone No. …….

4. **Information about the wholesale business:**

4.1 Types of activities:

(i) Storage ☐

(ii) Distribution (direct) ☐

(iii) Distribution through agents (distributors) ☐

Details of distributors:

Name of distributor	Geographical area covered
1.	
2.	
3.	

4. **Documents to be submitted with the application:**

1. Business Registration Certificate issued by the relevant Authority
2. An A4 size layout plan of the wholesale premises
3. Certificate of Registration of the responsible pharmacist issued bySri Lanka Medical Council.
4. 3.5 cm X 4.5 cmsize photograph of the Responsible Pharmacist

Declaration

I, the undersigned, certify that all information in this application for licence to sell therapeutic goods by wholesale on the above mentioned premises is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature:…….

Applicant:……

Name :……..……..

Designation:…….…….

Date:……

Regulation 111 (2)

Schedule XIX

LICENCE TO SELL THERAPEUTIC GOODS BY WHOLESALE

Licence No .....

M/S ..... of ..... is/are hereby licensed to sell therapeutic goods by wholesale at the premises situated at .....

This licence is subject to conditions prescribed in Regulation 113 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

Functions permitted by the Authority:

(i) Storage ☐

(ii) Distribution ☐

Details of the Responsible Pharmacist:

(*a*) Name : .....

(*b*) Sri Lanka Medical Council registration number : .....

(*c*) Photograph of the Responsible Pharmacist: .....

(3.5 cm x 4.5 cm)

Date of issue :

Period of Validity :

Receipt No. and date for fees paid:

.....
National Medicines Regulatory Authority

Regulation 114(2)

Schedule XX

APPLICATION FOR RENEWAL OF LICENCE TO SELL THERAPEUTIC GOODS BY WHOLESALE

I /We, ……of ……hereby apply for renewal of licence to sell medicine by wholesale on premises situated at ……..

Name of the wholesale establishment:……..

Previous licence No.:……

Part 1. Information about the location

1.1 Address:……..
1.2 Medical Officer of Health (MOH) Division :…….
1.3 Divisional Secretariat:……..

Part 2. Business information (check the boxapplicable):

2.1 Type of business:

(i) Individual ☐ Name of business:……..

(ii) Body corporate ☐ Name of body corporate :……..

(iii) Private limited company ☐ Name of company:……..

(iv) Particulars of Directors / Secretary /Owners…….

Part 3. Details of the applicant:

3.1 (a) Name of applicant:……

(b) Designation :…….

(c) National Identity Card No…….

(d) Mailing address:……..

(e) E-mail address …….

(f) Telephone No. ……

3.2 Details of Responsible pharmacist

(a) Name of Responsible Pharmacist:……

(b) Sri Lanka Medical Council Registration No. …….

(c) National Identity Card No ……..

(d) Mailing address:……..

(e) E-mail address …….

(f) Telephone No. ……

Part 4. Information about the wholesale business:

4.1 Types of activities:

(i) Storage ☐

(ii) Distribution (direct) ☐

(iii) Distribution through agents (distributors) ☐

Details of distributors:

Name of distributor	Geographical area covered
1.	
2.	
3.	

Documents to be submitted with the application:

1. Business Registration Certificate issued by the relevant Authority
2. An A4 size layout plan of the wholesale premises
3. Certificate of Registration of the responsible pharmacist issued bySri Lanka Medical Council.
4. 3.5 cm X 4.5 cm size photograph of the Responsible Pharmacist

Declaration

I, the undersigned, certify that all information in thisapplication for licence to sell therapeutic goods by wholesale on the above mentioned premises is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature:……

Applicant:……

Name :……..

Designation:……

Date:……

Regulation 123(5)

Schedule XXI

APPLICATION FOR LICENCE TO TRANSPORT THERAPEUTIC GOODS FOR DISTRIBUTION

I /We ..... of .....hereby apply for a licence to transport therapeutic goods

Part 1. Details of the applicant:

1.1 (*a*) Name of applicant:.....

(*b*) Designation :.....

(*c*) National Identity Card No:.....

(*d*) Mailing address:.....

(*e*) E-mail address:.....

(*f*) Telephone No:.....

Part 2. Details of business

2.1 Sale of therapeutic goods by retail ☐

Licence no. for sale of therapeutic goods by retail issued by the Authority:.....

2.2 Sale of therapeutic goods by wholesale ☐

Licence No. for sale of therapeutic goods by wholesale issued by the Authority:.....

Part 3. Therapeutic goods intended to be transported.

Biological Products ☐

Vaccines ☐

Medical devices ☐

Medicines ☐

Part 4. Details of vehicles to be used in transport

Type of vehicles	Car	Van	Freezer truck
Vehicle registration number			
1.			
2.			
3.			

(Add more lines if necessary)

Declaration

I, the undersigned, certify that all information in this application for licence to transport therapeutic goods for distribution is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature: .....

Applicant: .....

Name : .....

Designation: .....

Date: .....

Regulation 124(2)

Schedule XXII

LICENCE TO TRANSPORT THERAPEUTIC GOODS FOR DISTRIBUTION

Licence Number: .....

Vehicle Number: .....

M/s .....of ..... is/are hereby licensed to transport following categories of therapeutic goods for distribution.

1. .... 2. ....

3. ..... 4. ....

This licence is subject to conditions prescribed in Regulation 126 of the National Medicines (Registration and Licensing of Medicine) Regulations, 2019 made under the National Medicines Regulatory Authority Act, No. 5 of 2015 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

Date of issue :

Period of validity :

Receipt No. and date for payment of fees :

.....
National Medicines Regulatory Authority

Regulation 134

Schedule XXIII

GOOD REGULATORY PRACTICES

(1) Conflict of Interest and Secrecy / Confidentiality

Members of the Authority, officials, experts and other employees of the Authority shall, at the beginning of their functions in areas covered by the provisions of this act, declare the absence of any conflict of interest. If a conflict of interests arises, it must be immediately declared for appraisal and decision. Declarations relating to conflicts of interest are duly published.

As stated under Section 24 of the Act, all members and all officers and employees of the NMRA shall, before entering upon duties, sign a declaration pledging to observe strict secrecy / confidentiality in respect of all matters connected with the affairs of the Authority except;

(*a*) when required to do so by a court of law; or

(*b*) for the purpose of exercising or performing the functions under this Act, or any other written law.

(2) Good Review Practices

The Authority shall follow Good Review Practices recommended by the World Health Organization in making relevant regulatory decisions.

(3) Code of Conduct of NMRA staff

The staff of the Authority shall follow the basic principles of ethical behaviour at all times in terms of Integrity, Accountability, Independence and Impartiality, Respect for the dignity, worth, equality, diversity and privacy of all persons and Professional commitment.

(5) Publication of regulatory Decisions

Decisions on the authorization, amendment, suspension, revocation or declarations of the expiry of a marketing authorization may be published in the website and other appropriate media and where justified.

(4) Quality assurance

(*a*) The Authority shall undertake the responsibility of ensuring the quality of marketed therapeutic goods by checking their quality and other means deemed appropriate.

(*b*) The National Medicines Quality Assurance Laboratory shall provide laboratory access for testing of therapeutic goods whereas the Medical Research Institute of the Ministry of Health shall be responsible for testing of vaccines and sera including lot release.

(*c*) The National Medicines Quality Assurance Laboratory and the Medical Research Institute shall function as Additional Approved Analysts under the Act, and as such the test reports issued by these two institutions are legally acceptable.

(*d*) The National Medicines Quality Assurance Laboratory shall be responsible for establishing a network among the recognized laboratories local, regional or international and in addition, shall be responsible for all activities pertaining to collecting of samples of therapeutic goods, sending those to other recognized laboratories for testing and organizing payments required for such activities.

(*d*) The Authority may recognize and use laboratory reports of the reference regulatory authorities and local, regional and international laboratories accepted by the Authority. The list of such laboratories shall be published in the website of the Authority.

(*e*) The National Medicines Quality Assurance Laboratory shall be represented in the Good Manufacturing Practice inspections carried out by the Authority and also in pharmacovigilance activities in relation to quality of medicines.

(*f*) In addition to quality testing of therapeutic goods at pre and post marketing stages, the National Medicines Quality Assurance Laboratory shall provide test reports on samples submitted by both private and public sector institutions, health professionals and consumers according to the guidelines published in the website.

(7) Dissemination of information

The Authority shall be responsible for ensuring adequate transparency by disseminating to health professionals and the general public, by disseminating and / or publishing and keeping up-to-date, manufacturers, wholesale distributors, pharmacies, importers and marketing authorization holders as well as information on the quality and safety of therapeutic goods in the public interest.

Decisions to suspend or revoke the marketing authorization shall be notified to the entity as a matter of urgency and on the grounds of public health such decisions shall be given due publicity.

(5) Quality Management System (QMS)

(1) The NMRA shall establish and maintain a quality management policy to facilitate mutual confidence and recognition with other authorities or relevant international organizations and also the important consistent quality regulatory services delivery in the regulation of therapeutic goods,.

(2) A Quality management systems including the risk management principles shall be applied and realized.

(3) The quality management system shall include :

(*a*) documented statements of a quality policy and quality objectives ;

(*b*) a quality manual;

(*c*) documented regulatory processes and Standard Operating Procedures; and

(*d*) documents, including records, determined by the Authority to be necessary to ensure the effective planning, operation and control of its processes.

(6) Target processing timelines

The NMRA shall endeavour to meet the target processing timelines for applications as provided below:

Type of Application	**Processing Timeline (No. of Working Days**
Preliminary screening of a registration dossier for completeness	15
Evaluation of a registration dossier	300
Evaluation of a registration dossier on priority basis	180
Evaluation of additional data	180
Evaluation of Site Master File	180

Application for approval of formulation development	90
Application for Certificate of a Pharmaceutical Product (CoPP)	10
Application for approval of an overseas manufacturer	180
Application for personal user licence	02
GMP inspection report (from the date of inspection)	30
Application for retail pharmacy licence	180
Application for renewal of retail pharmacy licence	120
Application for wholesale licence	120
Application for renewal of wholesale licence	120
Application tor transport licence	60
Application for a licensed manufacturer of medicine	10
Application for manufacture of registered medicine	10

(*a*) These timeframes shall:

(i) apply to working days only, and exclude public holidays and weekends ;

(ii) only commence once an application has been accepted for processing and following payment of the processing fee.

(*b*) The deadline is suspended whenever the NMRA request the applicant additional data or requiring the correction of deficiencies found during the inspection.

(*c*) Although the Authority is required to complete the assessment within the specified timeframes, applicants should not presume the outcome of an application.

(*d*) The Authority or its staff are not liable to a person for loss, damage or injury of any kind that is caused by or arises from a failure to decide an application within the specified timeframe.

10-1009

PRINTED AT THE DEPARTMENT OF GOVERNMENT PRINTING, SRI LANKA.