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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B. 4/2007(II)

THE AYURVEDA ACT, No. 31 OF 1961

REGULATIONS made by the Minister of Health under Section 82 of the Ayurveda Act, No. 31 of 1961 read with Sections 7 (g) 10, 77 and Part VI of the aforesaid Act.

Dr. RAMESH PATHIRANA,
Minister of Health.

03.04.2024,
Colombo.

REGULATIONS

1. These regulations may be cited as the Ayurveda Code for Ayurveda Medicine and Surgery Regulations, 2024 and shall come into operation on 08th April 2024 (hereinafter referred to as the “appointed date”).

PART I

ESTABLISHMENT OF THE AYURVEDA MEDICINE AND PRODUCTION REGULATORY COUNCIL

2. (1) There shall be established for the purposes of Ayurveda Act, No. 31 of 1961 (hereinafter referred to as the “Act”), an Ayurveda Medicine and Production Regulatory Council (hereinafter referred to as “the Regulatory Council”).



(2) The Regulatory Council shall, by the name assigned to it by sub-regulation (1), be a body corporate and shall have perpetual succession and a common seal and may sue and be sued in that name.

3. For the purposes of these regulations (hereinafter referred to as “the Code”) -

- (a) the articles, substances or drugs as specified in Part II of Schedule I hereto are hereby declared as “declared article, substance or drug”; and
- (b) the plants as specified in the Part I of Schedule I hereto are hereby declared as “declared medicinal plants”;

in terms of the provisions of paragraphs (a) and (j) of Subsection (1) of Section 77 of the Act.

4. The objects of the Regulatory Council shall be to -

- (a) regulate all matters relating to the cultivation of declared medicinal plants and the manufacturing, preparation, importation, exportation, purchasing, storing, distribution, sale, advertising, transportation, supply and quality control of any Ayurveda product or any declared article, substance or drug :

- (i) which are used in Ayurveda medicine and used in Ayurveda surgery; or

- (ii) which may be obtained over the counter without a prescription;

- (b) the regulation of all matters relating to:

- (i) the cultivation of declared medicinal plants; or

- (ii) the manufacturing, preparation, importation (other than Cannabis), exportation, purchase, storage, distribution, sale, advertising, transportation, supply and quality control of Cannabis, opium and poisons, minerals, animal matter, goods or other dangerous drugs as determined by the Regulatory Council,

to the extent they are required in Ayurveda medicine and surgery;

- (c) the regulation of all matters relating to obtaining of the registration, approval, or issuance of licences, certificates, or permits, as the case may be, required to carry out activities referred to under preceding paragraphs (a) or (b) subject to the provisions of the Act and, any regulations made thereunder and in accordance with the provisions of any other written law, subject to such terms and conditions relating to such registration, approval or as specified in such licences, certificates or permits;

- (d) monitoring and overseeing of activities carried out by the persons who obtained registration, or approval or the holders of licences, certificates and permits referred to in paragraph (c) with a view to maintain the standards of products and services provided by them;

- (e) the reference of any matter under its purview and to obtain recommendations on such matters from any authority including-

- (i) the Technical Committee on Ayurveda Medicine;
 - (ii) the Committee on Evaluation of Ayurveda Manufactories and Stores;
 - (iii) the Committee on Investigation of Ayurveda Manufactories, Stores and Markets; and
 - (iv) the Committee of Officials for the Evaluation of Medicinal Plants;

established under this Part;

- (f) the carrying out of the surveys on quality, safety and adverse effects of any declared article, substance, drug or Ayurveda product available in the market;
- (g) the documentation of information pertaining to all registration, approval, or issuance of licences, certificates, or permits issued by the Regulatory Council annually.

5. The Regulatory Council shall consist of-

- (a) the following *ex-officio* members, namely:
 - (i) the Commissioner-General of Ayurveda (hereinafter referred to as the “Commissioner-General”); and
 - (ii) the Additional Commissioner-General (Technical) of Ayurveda appointed under Subsection (2) of Section 3 of the Act;
- (b) The following members appointed by the Minister, namely;
 - (i) Four Ayurveda Practitioners attached to the Department of Ayurveda, qualified in Ayurveda, Siddha, Unani and Deshiya Chikithsa system of medicine disciplines, respectively;
 - (ii) Three Senior Academics who are Professors or senior Lecturers in the subjects of Materia Medica, or Pharmaceutics in Ayurveda, Siddha and Unani disciplines in a recognized State University;
 - (iii) Four Registered Ayurveda Practitioners; and
 - (iv) Four persons excelled in, and representing the fields of Law, Accounting, Management and Chemistry, respectively.

6. (1) The Commissioner-General shall be the Chairman of the Regulatory Council.

(2) Members of the Regulatory Council shall elect one member among themselves as the Vice Chairman of the Regulatory Council.

(3) Chairman of the Regulatory Council, or in his absence, the Vice Chairman of the Regulatory Council shall preside at every meeting of the Regulatory Council.

(4) In the absence of the Chairman and the Vice Chairman at any meeting of the Regulatory Council, any member elected by the members present shall preside at such meeting of the Regulatory Council.

7. The quorum for any meeting of the Regulatory Council shall be nine members.

8. (1) The Additional Commissioner-General of Ayurveda (Technical) shall be the Secretary to the Regulatory Council and shall, subject to the general directions of the Regulatory Council, be responsible for the administration of the affairs of the Regulatory Council.

(2) The officers and employees of the Technical Division in the Department of Ayurveda shall, as it may consider necessary, assist the Regulatory Council in carrying out its functions under the Act.

9. Any person –

- (a) if such person is not or ceases to be a citizen of Sri Lanka;

- (b) if such person is or becomes a member of Parliament or a Provincial Council or any Local Authority;
- (c) if such person has any financial or other interest as is likely to affect the discharge by him of his functions as a member of the Regulatory Council;
- (d) who holds ownership of an institution engaged in pharmaceutical industry;
- (e) who has been engaged in any employment or consultancy service in an institution engaged in pharmaceuticals industry, other than a Government institution;
- (f) if such person is under any law in force in Sri Lanka or in any other country found or declared to be of unsound mind;
- (g) if such person is an undischarged bankrupt; or
- (h) if such person is serving or has served a sentence of imprisonment imposed by any court in Sri Lanka or any other country,

shall be disqualified from being appointed or continue to be a member of the Regulatory Council.

10. Every appointed member of the Regulatory Council shall, unless he vacates office earlier by death, resignation or removal, hold office for a period of three years, and unless removed from office shall be eligible for re-appointment, for not more than one further term, whether consecutive or otherwise.

11. (1) Any appointed member of the Regulatory Council may at any time, resign his office by letter in that behalf addressed to the Minister, and such resignation shall take effect from the date on which the resignation is accepted in writing by the Minister.

(2) The Minister may, for reasons assigned therefor, remove any appointed member from office. An appointed member who has been removed from office shall not be eligible for re-appointment as a member of the Regulatory Council or to serve the Regulatory Council in any other capacity.

(3) In the event of the vacation of office by death, resignation or removal of any appointed member, the Minister shall, subject to paragraph (b) of regulation 5, appoint another person to fill such vacancy and such person shall hold office for the un-expired period of the term of office of the member whom he succeeds.

(4) Where any appointed member of the Regulatory Council is temporarily unable to perform the duties of his office on account of ill health or any other cause or if he is absent from Sri Lanka for a period of not less than three months, the Minister shall, having regard to the provisions of regulation 5, appoint any other person to act in place of such member during his absence.

(5) Where any appointed member of the Regulatory Council fails to attend three consecutive meetings of the Regulatory Council without obtaining prior excuse for such absence from the Chairperson such member shall be deemed to have vacated his office at the conclusion of the third meeting of such consecutive meetings and the Minister shall appoint another person to fill such vacancy in the manner provided by regulation 5.

12. (1) The Regulatory Council may subject to the provisions of the Act, make rules in respect of any matter relating to administration of the affairs of the Regulatory Council including, to-

- (a) regulate its own procedure in regard to its meetings and transaction of business at such meetings;
- (b) regulate the procedure relating to any matter referred to –

- (i) the Technical Committee on Ayurveda Medicine;
- (ii) the Committee on Evaluation of Ayurveda Medicine Factories and Stores;
- (iii) the Committee on Investigation of Ayurveda Manufactories, Stores and Markets; and
- (iv) the Committee of Officials for the Evaluation of Medicinal Plants.

(2) Every rule made by the Regulatory Council shall be subject to the provisions of Subsections (2) and (3) of Section 49 of the Act.

13. The Powers and Functions of the Regulatory Council shall be –

- (a) to issue registration, approval or issuance of licences, certificates or permits, as the case may be, relating to matters specified under section 77(1) of the Act for which a licence or a permit is required, including –:
 - (i) the cultivation of declared medicinal plants and manufacturing, preparation, purchase, storage, distribution, sale, advertising, transportation, supply and dispensing of any declared article, substance or drug;
 - (ii) the importation and exportation of any declared article, substance or drug;
 - (iii) the cultivation, storing, distribution, transportation of Cannabis and manufacturing, exportation, storing, distribution, transportation and sale of cannabis related declared article, substance or drug and Ayurveda products, of which the cultivation, importation, exportation, transportation, sale, storing and distribution has been restricted by any other Act or law;
 - (iv) the importation, exportation, storing or distribution, as the case may be, of any dangerous drug, including opium, extracted *Paripaka* spirit, or any poisons, minerals or animal materials of which the importation, exportation, sale, storing and distribution has been restricted by any other Act or law;
 - (v) the advertising in print or electronic media including social media of any Ayurveda product or any declared article, substance or drug which could be sold over the counter, for the purpose of promoting directly or indirectly such Ayurveda product, or such declared article, substance or drug.
- (b) registration of-
 - (i) any Ayurveda product under the Act;
 - (ii) any Ayurveda manufactory under the Act;
 - (iii) an Ayurveda pharmacy under the Act;
 - (iv) a distributor of any declared article, substance or drug under the Act; or
 - (v) an Ayurveda drug store, under the Act,

for the purposes of Ayurveda medicine and surgery on recommendations of the Technical Committee on Ayurveda Medicine and the Committee of Officials for the Evaluation of Medicinal Plants.

- (c) the issuance of instructions, guidelines and rules on recommendations of the Technical Committee on Ayurveda Medicine to the effect that any declared article, substance or drug that may be obtained from the open market without medical recommendations is suitable for human consumption;

- (d) the issuance of instructions, guidelines and rules, on recommendations of the Technical Committee on Ayurveda Medicine, for cultivation of declared medicinal plants and for the importation, exportation, storage, transportation, sale, distribution and dispensing of declared article, substance or drug and Ayurveda products used in Ayurveda medicine and surgery;
- (e) the issuance of instructions, guidelines and rules, on recommendations of the Technical Committee on Ayurveda Medicine, for cultivation of declared medicinal plants and for the importation, exportation, storage, transportation, sale, distribution and dispensing of declared article, substance or drug and Ayurveda products including opium, Cannabis, extracted *Paripaka* spirit, dangerous drugs, poisons, minerals and animal materials, used in Ayurveda medicine and surgery;
- (f) to prepare, compile and publish standards relating to declared article, substance or drug;
- (g) to make guidelines, rules and recommendations relating to registration, approval or issuance of licences, certificates or permits under this Code;
- (h) to issue instructions to the Technical Committee on Ayurveda Medicine, the Committee on Evaluation of Ayurveda Manufactories and Stores, or the Committee on Investigation of Ayurveda Manufactories, Stores and Markets relating to-
 - (i) the inspection of manufactories and stores; and
 - (ii) the testing of the quality and standards of declared articles, substances or drugs or Ayurveda products in the market to ensure the maintenance of quality and standards recommended by the Regulatory Council;
- (i) to issue instructions to the Technical Committee on Ayurveda Medicine, the Committee on Evaluation of Ayurveda Manufactories and Stores, the Committee on Investigation of Ayurveda Manufactories, Stores and Markets or the Committee of Officials for the Evaluation of Medicinal Plants relating to-
 - (i) the inspection of cultivation fields and stores; and
 - (ii) the testing of the quality and standards of fields of declared medicinal plants, crops and the declared articles, substances or drugs or Ayurveda products made out of such crops, to ensure the maintenance of quality and standards recommended by the Regulatory Council;
- (j) to temporarily suspend or cancel registration, approval or issuance of licences, certificates or permits in pursuance of any report of the the Committee on Investigation of Ayurveda Manufactories, Stores and Markets;
- (k) to assure public health in pursuance of recommendations made by the the Committee on Investigation of Ayurveda Manufactories, Stores and Markets by taking measures to enquire into the safety operation, quality and stability necessary for human consumption of declared article, substance or drug available for sale in the open market and the advertisements made in relation to such declared article, substance or drug without obtaining prior written approval of the Regulatory Council;
- (l) issue recommendations to the Secretary to the Ministry of the Minister for releasing from Sri Lanka Customs the raw materials, packing materials and machinery required for local production of any declared article, substance or drug upon request made therefor by a manufactory registered under the Regulatory Council for the importation of same;
- (m) to declare the local and overseas laboratories qualified for testing the standards, safety operations and quality of any declared article, substance or drug;

- (n) to appoint any other committee or committees as required for effective achievement of the objectives of the Regulatory Council;
- (o) to determine, with the concurrence of the Ministry of Finance the charges for services rendered by the Regulatory Council;
- (p) to obtain relevant information and data from the manufacturers, importers, exporters, wholesale dealers, retail pharmacists, prescribers, dispensers and any other person involved in the manufacture or sale of any Ayurveda product in Sri Lanka or any other country who may assist in the determination of the quality or price of a single Ayurveda product or a group of such products;
- (q) to recommend to the relevant manufactories the reduction or increase in prices or the maintenance of any existing price of any Ayurveda product or a group of such products in consultation with relevant authorities;
- (r) to monitor the price fluctuations of any Ayurveda product, where necessary;
- (s) to collect data on the use of any Ayurveda product or a group of such products in Sri Lanka;
- (t) to recommend to the manufactories, the methods of determining the introductory price and maximum retail price of any Ayurveda product and price revisions of such product and, to provide advice to such manufactories on any other matter relating to pricing of such product;
- (u) to take into consideration from time to time, any Ayurveda product which shall be subject to revision of prices;
- (v) the inspection of any fields of declared medicinal plants cultivated under this Code;
- (w) to make rules in respect of matters referred to in regulation 12; and
- (x) generally, to do such other acts and things as authorized by the Act and by these regulations to facilitate the proper discharge of the functions of the Regulatory Council.

14. (1) The seal of the Regulatory Council –

- (a) shall be determined by the Regulatory Council and may be altered in such manner as may be determined by the Regulatory Council;
- (b) shall be in the custody of such person as the Regulatory Council may determine, from time to time; and
- (c) shall not be affixed to any instrument or document except with the sanction of the Regulatory Council and in the presence of two members of the Regulatory Council who shall sign the instrument or document in token of their presence.

(2) The Regulatory Council shall maintain a register in respect of the instruments and documents to which the seal of the Regulatory Council is affixed.

(3) In issuing any registration, approval or issuance of licences, certificates or permits under these regulations, the Seal of the Regulatory Council, the Official stamp of the Chairman and the official stamp of the Secretary shall be affixed to such approval, permit, licence or certificate.

15. Any Member, officer or employee of the Regulatory Council shall, before entering upon his duties, sign a declaration pledging himself to observe strict secrecy in respect of all matters connected with the working of the Regulatory Council and shall by such declaration pledge himself not to disclose any matter which may come to his knowledge in the discharge of his functions, except—

- (a) when required to do so by a court of law; or
- (b) in order to comply with any of the provisions of the Act or these regulations.

16. (1) The Financial Year of the Regulatory Council shall be the calendar year.

(2) The Regulatory Council shall cause proper books of accounts to be kept of the income and expenditure, assets and liabilities and all other financial transactions of the Regulatory Council.

(3) The provisions of Article 154 of the Constitution relating to the audit of accounts of public corporations shall apply to the audit of accounts of the Regulatory Council.

(4) All expenses incurred in the implementation of the duties and functions of the Regulatory Council shall be paid out of the Consolidated Fund.

(5) All revenue collected by the Regulatory Council shall be credited to the Consolidated Fund.

(6) The Members of the Regulatory Council shall be paid remuneration in terms of the provisions of section 45 of the Act.

17. (1) There shall be appointed a Technical Committee on Ayurveda Medicine (hereinafter referred to as the “Technical Committee”) which shall be responsible in making recommendations to the Regulatory Council in respect of cultivation of declared medicinal plants, importation, exportation, storage, sale and distribution and dispensing of any declared article, substance or drug, as the case may be.

(2) The Technical Committee shall be comprised of-

- (a) one *ex-officio* member who shall be the Additional Commissioner-General of Ayurveda (Technical); and
- (b) eight other members appointed by the Chairman of the Regulatory Council, from among the members appointed to the Regulatory Council under regulation 5 (b).

(3) The Additional Commissioner-General of Ayurveda (Technical) shall be the Chairman of the Technical Committee. The members of the Technical Committee shall select one member from among themselves as the Secretary of the Technical Committee.

(4) The quorum for any meeting of the Technical Committee shall be five members.

18. The Powers and Functions of the Technical Committee shall be –

- (a) to make the public aware of the required standards of Ayurveda products;
- (b) to evaluate the applications referred to it and make recommendations relating to the registration, approval or issuance of licences, certificates or permits under the Code;
- (c) to make recommendation to the Regulatory Council on suspension or cancellation of such registration, approval or licences, certificates or permits;

- (d) to obtain reports from relevant sectors relating to the standards and quality of declared article, substance or drug and Ayurveda products and issue recommendations; and
- (e) to make recommendations in respect of any other matter referred to it by the Regulatory Council for the purposes of this Code.

19. (1) There shall be appointed an Committee on Evaluation of Ayurveda Manufactories and Stores (hereinafter referred to as the “Evaluation Committee”) which shall be responsible in making recommendations to the Regulatory Council prior to registration or issuance of approvals, permits, licences or certificates in respect of manufactories of declared article, substance or drug or in respect of any imported or exported article, substance or drug which is declared under this Code, on any standards required to be complied with by such manufactory, importer or exporter of such Ayurveda article, substance or drug.

(2) The Evaluation Committee shall be comprised of-

- (a) the Additional Commissioner-General General of Ayurveda (Technical) who shall be the *ex-officio* member who shall serve as the Chairman of the Evaluation Committee;
- (b) six other members appointed by the Chairperson of the Regulatory Council on the recommendation of the Regulatory Council including three members selected from among the members appointed to the Regulatory Council under regulation 5 (b).

(3) The members of the Evaluation Committee shall select one member among themselves as the Secretary of the Evaluation Committee.

(4) The quorum for any meeting of the Evaluation Committee shall be four members.

20. The powers and functions of the Evaluation Committee shall be –

- (a) to carry out site inspections of the manufactories, in relation to which references of application for registration or renewal have been made and to issue recommendations in respect thereof to the Regulatory Council;
- (b) to carry out raids and sudden inspection of licenced manufactories as instructed by the Regulatory Council or the Technical Committee; and
- (c) to report to the Regulatory Council of any misconduct of the Chief Medical Officer or any other staff member of a licenced manufactory, which has been noticed or detected during a site visit, raid or inspection.

21. (1) There shall be appointed a Committee on Investigation of Ayurveda Manufactories, Stores and Markets (hereinafter referred to as the “Investigation Committee”) which shall be comprised of-

- (a) the Additional Commissioner-General of Ayurveda (Technical) who shall be the *ex-officio* member who shall serve as the Chairman of the Investigation Committee; and
- (b) six other members appointed by the Regulatory Council on the recommendation of the Regulatory Council including four Ayurveda Practitioners nominated by the Commissioner-General.

(2) The Members of the Investigation Committee shall elect one member from among themselves as the Secretary of the Investigation Committee.

(3) The quorum for any meeting of the Investigation Committee shall be four members.

22. The powers and functions of the Investigation Committee shall be:-

- (a) either on its own motion or on a complaint or request made to the Commissioner-General to carry out inspections, raids and investigations, prior to or after the registration, approval or issuance of licences, certificates or permits -
 - (i) for the cultivation of any declared medicinal plant;
 - (ii) to manufactories, stores and pharmacies;
 - (iii) for the distribution, transportation, exportation and importation of any declared article, substance or drug,
- (b) for the testing of the quality of declared article, substance or drug in the market and make recommendations to the Regulatory Council accordingly.

23. (1) There shall be established a Committee of Officials for the Evaluation of Medicinal Plants (hereinafter referred to as the “Medicinal Plants Evaluation Committee”) –

- (a) to evaluate and recommend the project report with related to the cultivation and harvesting of Cannabis; and
- (b) to coordinate with the Department of Ayurveda and the Regulatory Council concerning the matters pertaining to provision of security to and the evaluation of, projects related to Cannabis.

(2) The Medicinal Plants Evaluation Committee shall be comprised of –

- (a) the Commissioner-General who shall serve as the Chairman of the Medicinal Plants Evaluation Committee;
- (b) a Senior Assistant Secretary nominated by the Secretary to the Ministry of the Minister;
- (c) the Commissioner-General of Excise appointed under section 7 of the Excise Ordinance (Chapter 52) or his nominee;
- (d) the Inspector-General of Police appointed under Article 41A of the Constitution or his nominee;
- (e) Director-General of the Board of Investment, appointed under section 6 of the Board of Investment Law, No. 4 of 1978, or his nominee;
- (f) Additional Commissioner-General (Technical) of Ayurveda; and
- (g) three members of the Regulatory Council who shall be nominated by the Minister.

(3) The quorum for any meeting of the Medicinal Plants Evaluation Committee shall be five members.

PART II

LICENCE TO MANUFACTORIES OF ANY DECLARED ARTICLE, SUBSTANCE OR DRUG

24. (1) No person shall commence or continue with the operation of any manufactory to be engaged or engaged in manufacturing any declared article, substance or drug in Sri Lanka except under the authority of a valid licence issued name of a valid business registration by the Regulatory Council in the under these regulations.

(2) Where the name of a registered business includes the word ‘Ayurveda’, or ‘herbal’ such business is required to be registered with the Department of Ayurveda, prior to applying for a licence in respect of such registered business.

(3) Valid Environmental Protection Licence (EPL), Environmental Impact Assessment (EIA) or Initial Environmental Examination (IEE) permit shall be required to be obtained from relevant authorities, where necessary, in respect of such manufactory prior to applying for a licence.

25. (1) On or after the appointed date, every application for registration of any manufactory of any declared article, substance or drug shall be made to the Regulatory Council in the Form A as specified in the Schedule II hereto.

(2) Every applicant-

- (a) shall take all necessary precautions to ensure that his manufactory be -
 - (i) sufficiently spacious and ventilated;
 - (ii) covered with a boundary wall for the safety of production process;
 - (iii) completely prevented and protected from animals and birds being entering;
 - (iv) not located in an area vulnerable to floods and other natural disasters;
 - (v) not in the close proximity to open garbage dumping sites and public toilets;
 - (vi) away from the factories, agro-chemical sales outlets, chemical mixing stations, funeral parlours and vehicle service stations, as determined by the Regulatory Council as unsuitable to be in the vicinity;
- (b) shall possess a business registration certificate issued by an authorized institution in his name;
- (c) shall possess an Agreement entered into between him and a registered Ayurveda Practitioner which is valid for not less than three years; and
- (d) shall have obtained any other approval deemed necessary by the Regulatory Council in respect of the manufactory.

(3) Every applicant who has complied with sub-regulation (2) may apply for registration accompanied by required documents and information according to the guidelines issued by the Regulatory Council from time to time, including the site plan, proposed building plan and details of declared article, substance or drug intended to be manufactured in the proposed manufacturing plant and a description of the sub-units in the proposed manufactory together with a processing fee determined by the Regulatory Council.

26. (1) Upon receipt of the application for approval of the proposed manufacturing plant, the Regulatory Council shall, at the next meeting of the Regulatory Council to be held after the receipt of such application, either-

- (a) refer the application to the Technical Committee or to any other institution approved by the said Technical Committee, for recommendation; or
- (b) reject the application assigning reasons therefor.

(2) The Regulatory Council may, upon receipt of recommendations of the Technical Committee and where it deems necessary, require the applicant to furnish further information relating to a matter or matters specified in the said recommendations.

(3) Upon the receipt of such recommendations and on considering such recommendations and information furnished by the applicant and, on being satisfied that the manufacture all guidelines for Good Manufacturing Practices recommended by the Regulatory Council have been complied with, the Regulatory Council shall -

- (a) (i) issue the required licence to the applicant with a registration number on payment of the relevant fee as specified in the Schedule III hereto; or
- (ii) for reasons to be recorded by the Regulatory Council, refuse to issue such licence;
- (b) where a licence is issued to the applicant by the Regulatory Council under sub paragraph (i), of paragraph (a), the Regulatory Council may issue any letter or letters of recommendations to relevant

authorities for the purpose of obtaining or importation of any machinery and raw material required for the manufacturing process involved in the manufacture of such declared article, substance or drug or any of them, as the case may be.

27. Any applicant, whose application has been rejected due to the non-fulfilment of the requirement may appeal to the Regulatory Council requesting for the issuance of a licence upon fulfilling the necessary requirements.

28. Every licence issued under regulation 26 shall be-

- (a) substantially in the form specified in Schedule IV hereto;
- (b) where the manufactured item is an Ayurveda drug, in addition to requirements specified under regulation 29, subject to such terms and conditions specified therein;
- (c) valid only for the manufacture of the Ayurveda article, substance or drug in respect of which approval was sought; and
- (d) valid only for the period specified therein.

29. Every manufactory issued with a licence to manufacture any declared article, substance or drug (hereinafter referred to as “a Licenced Manufactory”), shall -

- (a) have its name board to be clearly and conspicuously displayed together with the registration number and contact details in identifiable letters and figures, at the entrance of the manufactory;
- (b) exhibit the Licence and the valid Certificate of Registration issued by the Ayurveda Medical Council to the Ayurveda Medical Practitioner, with whom the Licenced Manufacturer has entered into an agreement, which shall be valid for the period of the licence;
- (c) practice Good Manufacturing Practices recommended by the Regulatory Council in accordance with the guidelines issued by the Regulatory Council;
- (d) provide and maintain such number of staff, premises, equipment and facilities as are considered to be necessary for the manufacture of any Ayurveda article, substance or drug undertaken to be manufactured by such Licenced Manufacturer and shall not carry out such manufacture except under the required medical supervision and at the premises specified in the licence ;
- (e) maintain such staff, premises, equipment and facilities for the handling and storage of the raw materials and medicines as are considered necessary;
- (f) not issue any production to the market except under the approval of the Chief Medical Officer of such manufactory;
- (g) ensure that such declared article, substance or drug manufactured in such manufactory in commercial scale are in accordance with the provisions of these regulations.
- (h) provide such information as may be required by the Regulatory Council in respect of any declared article, substance or drug manufactured at such manufactory and of the operations carried out in relation to such manufacture;
- (i) establish a product related complaint handling system inclusive of recording, analysing and taking corrective measures;

- (j) inform the Regulatory Council 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) the quality control and quality assurance of products manufactured;
- (k) preserve all records including batch manufacturing records and distribution records for a period of five years from the date of expiry of the relevant batch of any declared article, substance or drug prepared at the manufactory;
- (l) keep readily available for inspection by the Regulatory Council or Evaluation Committee or by any other person nominated by the Regulatory Council, all records including the details of manufacture of each batch of every declared article, substance or drug that is manufactured at the manufactory, and the tests carried out in respect thereof;
- (m) maintain the records in such manner which would enable the records to be easily identifiable from the batch number of medicine as shown on each container in which the medicine is sold, distributed or exported;
- (n) keep all records in a manner which would facilitate the withdrawal or recall from sale, supply or exportation of any declared article, substance or drug.

30. (1) The Regulatory Council shall maintain an updated register of every Licenced Manufacturer which shall contain such particulars pertaining to the Licenced Manufacturers as may be determined by the Regulatory Council.

(2) Every Licenced Manufactory shall furnish to the Regulatory Council such particulars required by the Regulatory Council from time to time and where there is any change in the particulars, inform such particulars forthwith to the Regulatory Council.

(3) Upon the receipt of any particulars furnished by a Licenced Manufactory under sub-regulation (2), the Regulatory Council shall make or cause to be made such appropriate alterations as may be necessary in the relevant register.

31. (1) A licence issued under regulation 26 shall be renewable on an application made in that behalf to the Regulatory Council in the Form A as specified in Schedule II hereto within a period of ninety days prior to the expiry of such licence.

(2) A licence shall be renewed by the Regulatory Council, only if it is satisfied that the Licenced Manufactory has adhered to the standards in accordance with the guidelines issued by the Regulatory Council and, where the manufactured item is a declared drug, in addition to the requirements specified under regulation 29 the Regulatory Council shall satisfy that the provisions of the Act and any other written law and such terms and conditions specified in the licence have been complied with.

32. (1) Upon the receipt of an application for renewal of a licence under regulation 31 the Regulatory Council shall, within thirty days of the receipt of such application, either-

- (a) refer the application to the Evaluation Committee or to any other institution approved by the said Technical Committee, for recommendation; or
- (b) reject the application assigning reasons therefor.

(2) The Regulatory Council shall, where it deems necessary may require the applicant to furnish further information relating to a matter or matters specified in the recommendations within a specified time.

(3) Upon the receipt of such recommendation and on considering such recommendations, and information furnished by the applicant and, on being satisfied that all guidelines of the Regulatory Council for Good Manufacturing Practices recommended by the Regulatory Council have been complied with, the Regulatory Council shall -

- (a) renew such licence for a period of one year on payment of the relevant fee as specified in the Schedule III hereto; or
- (b) for reasons to be recorded by the Regulatory Council, refuse to renew the licence-

33. Where the Regulatory Council has refused to renew the licence issued to a Licenced Manufactory, the Regulatory Council shall-

- (a) strike off the name of such Manufactory from the register of manufactories;
- (b) take such measures as the Regulatory Council deems appropriate, in respect of the items that have been already manufactured but not issued to the market and the items that are still in the process of being manufactured.

34. (1) The Regulatory Council may suspend or cancel the licence issued under regulation 26, if the Regulatory Council is satisfied that the Licenced Manufacturer has violated the provisions of the Act or, regulations or rules made thereunder or any of the terms and conditions of such licence.

(2) Where a licence has been suspended, the Regulatory Council shall, within fourteen days of such suspension refer the matter to the Investigation Committee for investigation and recommendation.

(3) Upon the receipt of recommendations by the Investigation Committee, the Regulatory Council may revoke the approval, permission, licence or certificate remove the suspension and permit to resume work of the manufactory.

PART III

REGISTRATION OF AYURVEDA PRODUCTS

35. (1) Every Ayurveda product prior to being issued to the market as an item ready for human consumption, shall be registered with the Regulatory Council under the provisions of this Part.

(2) Every applicant who intends to register an Ayurveda product with the Regulatory Council shall-

- (a) have a Licenced Manufactory registered for the purpose;
- (b) make an application to the Regulatory Council in the Form B specified in Schedule II hereto;
- (c) submit all such information, as may be determined by the Regulatory Council time to time.
- (d) provide samples of the Ayurveda product as may be required by the Regulatory Council; and
- (e) pay a processing fee as may be determined by the Regulatory Council.

(3) Registration procedure for an imported Ayurveda product shall be as specified in Part IV hereto.

(4) A separate application shall be made in respect of each Ayurveda product intended to be registered.

36. An Ayurveda product applied for registration shall be-

(a) made by the use of one or more ingredients or medicinal items contained in-

- (i) the Ayurveda Pharmacopoeia published from time to time by the Department of Ayurveda, Sri Lanka;
- (ii) Siddha Pharmacopoeia published from time to time by the Department of Ayurveda, Sri Lanka;
- (iii) Unani Pharmacopoeia published from time to time by the Department of Ayurveda, Sri Lanka;
- (iv) Pharmacopoeia of Ayurveda, Siddha and Unani approved by the Government of India; or
- (v) Traditional Medicinal Systems of medicine contained in the Pharmacopoeias in other Countries as approved by the respective governments;

(b) made by the use of one or more of the pharmaceuticals considered as a botanical, mineral or zoological, which are traditionally used in the *Deshiya Chikitsa* systems of medicine and surgery of Sri Lanka;

(c) referred to in the authentic or classical books accepted in the systems of Ayurveda, Siddha, Unani, and *Deshiya Chikitsa* systems of medicine and surgery;

37. On receipt of an application for the registration of an Ayurveda product, the Regulatory Council shall, within a period of thirty days of such receipt, refer the matter to the Technical Committee for recommendation and report.

38. The Technical Committee on consideration of information furnished in such application, shall inform the Regulatory Council of its recommendation within a period of thirty days of receipt of such application.

39. Upon the receipt of such recommendation, the Regulatory Council may, either issue a Certificate of Registration in the form as specified in Schedule IV hereto, on payment of a relevant fee as specified in Schedule III hereto or for reasons to be recorded by the Regulatory Council refuse to issue a Certificate of Registration to the applicant.

40. Every Certificate of Registration, unless it is suspended or cancelled earlier, shall be valid for a period of three years, in respect of a local product and for a period of one year in respect of an imported product and shall be subject to such terms and conditions specified therein.

41. The Regulatory Council may suspend or cancel a Certificate of Registration issued under regulation 39, if the Regulatory Council is satisfied that the holder has violated the provisions of the Act or, regulations or rules made thereunder or any of the terms and conditions of such Certificate of Registration.

42. (1) A Certificate of Registration issued under regulation 39 shall be renewable on an application in Form B as specified in Schedule II hereto being made in that behalf to the Regulatory Council not later than ninety days before the expiry of the validity period of such Certificate and on payment of the relevant renewal fee as specified in Schedule III hereto.

(2) A Certificate of Registration issued under regulation 39 shall be renewed by the Regulatory Council, if the Regulatory Council is satisfied that the holder of such Certificate of Registration has complied with the provisions of the Act, regulations and rules made thereunder and the terms and conditions specified in the Certificate of Registration.

43. Packing, labelling and the contents of the brochure to be provided with an Ayurveda product shall be as specified in the Schedule V hereto.

PART IV

REGISTRATION OF AN IMPROVED AYURVEDA PRODUCT

44. Every imported Ayurveda product shall be registered in accordance with the provisions of this Part.

45. (1) Every Ayurveda product imported to the country shall be manufactured in a licenced manufactory of the respective country and shall have been approved for the respective period of validity by the relevant authority of such country which has the power to determine the quality of the product.

(2) The manufacturer of the Manufactory referred to in sub-regulation (1) shall appoint a Sri Lanka business entity registered with the Department of Ayurveda as its local authorized agent.

(3) Where any authorized agent intends to import an Ayurveda product to Sri Lanka, he shall, through a registered Ayurveda practitioner apply to the Regulatory Council in the Form C specified in the Schedule II hereto together with –

- (a) the documents and information specified in the guidelines issued by the Regulatory Council;
- (b) the samples of the Ayurveda product obtained in terms of regulation 53 and the dossier, if applicable; and
- (c) the applicable fee as specified in Schedule III hereto,

for a licence for such importation.

(4) Separate applications shall be made in respect of each Ayurveda product intends to be imported.

46. The Regulatory Council shall maintain a register in which every application received for the registration of an Ayurveda product intends to be imported, shall be recorded. The particulars to be entered in such register shall be determined by the Regulatory Council.

47. (1) Every application submitted to import an Ayurveda product shall be accompanied with following documents: -

- (i) a Free Sale Certificate issued by the relevant authority of the respective country;
- (ii) Performa Invoice;
- (iii) Fund Transfer document;
- (iv) Commercial Invoice;
- (v) Packing List;
- (vi) Copy of Bill of Lading or the Airway Bill;
- (vii) A document to prove the country of origin;
- (viii) Material Safety data Sheet;
- (ix) Relevant analytical and safety reports;
- (x) any other document as are required to import the Ayurveda product or as may be determined by the Regulatory Council;

(2) Documentary evidence to show that the relevant product contains the following accepted percentages of constituents: -

- (a) (i) where the product is a food item and not a formula in any Code of medicine or a recognized original edition, has herbal extracts, minerals or animal material as active component in percentage as may be determined by the Regulatory Council from time to time;

- (ii) where the product is a cosmetic compound and not a formula in any Code of medicine or a recognized original edition, contains herbal extracts, minerals or animal material as active components in percentage as may be determined by the Regulatory Council from time to time;
- (b) has a coating produced using chemicals and whether such chemical for coating had been extracted naturally;
- (c) where it contains one or more chemicals has been confirmed to be of good quality, performance and soundness for human consumption with medical reports or two recognized research articles relating to researches conducted in terms of methodology recognized by a recognized government institute or university and published in peer reviewed journal in the country of production; and
- (d) has been proved as suitable for human consumption upon testing for toxicity.

48. (1) The Regulatory Council shall within thirty days of the receipt of such application to import an Ayurveda product, refer such application to the Technical Committee for recommendation.

(2) The Technical Committee shall within a period of sixty days of such reference submit its recommendations to the Regulatory Council, in writing.

(3) The Regulatory Council, upon the receipt of such recommendation shall either-

- (a) approve the importation of a sample of the relevant product subject to provisions of any applicable written law; or
- (b) reject such application assigning reasons therefor.

(4) The Regulatory Council may, prior to the issuance of licence and where it deems necessary, call for further information, in addition to those submitted together with the application.

(5) Prior to the issuance of licence, the Regulatory Council shall consider whether the Ayurveda product intended to be imported may cause an adverse impact on the local manufacturer and whether they are in accordance with the relevant standards specified in the guidelines of the Regulatory Council.

(6) The Regulatory Council shall, on being satisfied that all the requirements for the importation of the Ayurveda product referred to in the application has been fulfilled, issue a licence to the applicant to import the Ayurveda product in the form as specified in the Schedule IV hereto, on payment of the relevant fee as specified in the Schedule III hereto or for reasons to be recorded by the Regulatory Council, refuse to issue a licence.

49. Every licence to import an Ayurveda product shall unless it is suspended or cancelled earlier, be valid for a period of one year and shall be subject to such terms and conditions specified therein.

50. (1) Where the holder of a licence to import any Ayurveda product has violated the provisions of the Act or, regulations or rules made thereunder or any of the terms and conditions of such licence, the Regulatory Council shall suspend or cancel the licence issued under regulation 48 and require the holder to withdraw the Ayurveda product imported under such licence from the market at his own expense and in accordance with the procedure as determined by the Regulatory Council.

(2) Where any Ayurveda product registered to be imported under these regulations has not been imported in to Sri Lanka within one year from the date of registration for such importation, the Regulatory Council may suspend or cancel the licence issued in respect of such product.

51. A licence issued under regulation 48 shall be renewable on an application being made in that behalf to the Regulatory Council not later than ninety days prior to the expiry of such licence and on payment of the relevant renewal fee as specified in the Schedule III hereto.

52. (1) An application to import a sample of an Ayurveda product shall be made in Form D of Schedule II hereto, together with such other particulars as may be determined by the Regulatory Council.

(2) The Regulatory Council shall, upon and within thirty days from the receipt of such application to import a sample of an Ayurveda product, refer such application to the Technical Committee for its recommendation.

(3) The Technical Committee shall within a period of sixty days of such reference submit its recommendations to the Regulatory Council, in writing.

(4) The Regulatory Council shall, upon the receipt of such recommendation, either-

- (a) approve importation of such sample subject to provisions of any applicable written law; or
- (b) reject such application assigning reasons therefor.

(5) The Regulatory Council shall issue to the applicant a letter of authority for the importation of such sample which shall include –

- (a) the name and description of the product; and
- (b) the period of validity of such authorization.

53. (1) A sample of Ayurveda product imported for the purpose of submitting for registration shall not be sold in any manner whatsoever and shall only be used for the purpose of registration of such Ayurveda product with the Regulatory Council.

(2) Every imported sample of the Ayurveda product specified above, shall be in accordance with standards as specified in the guidelines issued by the Regulatory Council.

(3) Any such sample imported without obtaining prior approval of the Regulatory Council shall be destroyed or caused to be destroyed by such Council. Any person who imports such samples without a valid licence shall be dealt with in terms of the provisions of the Customs Ordinance (Chapter 235).

(4) Where it is found that such sample or a full consignment of such Ayurveda product is not suitable for human consumption, the Regulatory Council shall have power to order the destruction of such sample or the full consignment as the case may be, in accordance with the applicable law and expenses incurred in the destruction of such sample or such full consignment shall be borne by the importer.

54. The Regulatory Council shall maintain a register of letters of authority issued in respect of samples referred to in regulation 53, in which particulars of such samples intended to be imported shall be recorded. The particulars to be entered in such register shall be determined by the Regulatory Council.

55. Packing and labelling of and the contents of the brochure to be provided with an imported Ayurveda product, shall be as specified in Schedule V hereto.

PART V

EXPORTATION OF AYURVEDA PRODUCTS

56. Every Ayurveda product prior to exportation shall be registered with the Regulatory Council, in terms of the provisions of Part III of this Code.

57. A separate application shall be made to the Regulatory Council, in respect of every Ayurveda product intended to be exported, along with such required documents as may be determined by the Regulatory Council for the purposes of desk review and making its recommendation to relevant authorities.

58. Upon the receipt of approval from the Regulatory Council the person who intends to export an Ayurveda product shall apply for same to the Export Development Board established under section 3 of the Sri Lanka Export Development Act, No.40 of 1979.

PART VI

STANDARDS FOR AYURVEDA PHARMACIES

59. No pharmacy shall sell any Ayurveda drug or any other Ayurveda product if such pharmacy has not been registered under these regulations for the purpose.

60. (1) Every application for the registration of an Ayurveda Pharmacy shall be made by a person who has a valid business registration with the relevant authority and who has entered into a valid agreement for at least one year, with an Ayurveda pharmacist who has registered with the Ayurveda Medical Council for the purpose of carrying on an Ayurveda Pharmacy.

(2) A registered Ayurveda Practitioner shall be entitled to apply for the registration of an Ayurveda pharmacy.

(3) Every application made for the registration of an Ayurveda pharmacy shall be made to the Commissioner-General in Form E as specified in the Schedule II hereto together with the other required documents as specified by the Regulatory Council.

(4) Upon the receipt of documents for registration, the Commissioner-General shall inspect or cause to be inspected the site intended for the setting up of the pharmacy prior to registration.

(5) The Commissioner-General, on being satisfied with the relevant documents submitted and the outcome of the site inspection, shall register such pharmacy for a period of one year upon the payment of a fee as specified in the Schedule III hereto and issue him a registration number.

(6) Every registration of a pharmacy shall be subject to such terms and conditions as may be specified by the Regulatory Council and is renewable upon application made therefor three months prior to the expiry of such registration. In the event of a renewal of its registration, the registration of the business shall be in the name of the applicant and a valid agreement between the applicant and any Ayurveda Pharmacists registered with the Ayurveda Medical Council shall be in existence for the period for which renewal is sought.

(7) The Commissioner-General shall maintain a register of all registered pharmacies containing information including the names of the proprietor, address of the Business Registration and address of the location of the pharmacy and the contact details of such pharmacy, and particulars of the registered pharmacist as required by the Regulatory Council.

61. Every Registered Ayurveda pharmacy shall,

- (a) display a name board indicating the words “Ayurveda Pharmacy” in all three languages, the registration number of such pharmacy, and the qualification of the registered pharmacist for selling Ayurveda products, declared articles, substances or drugs either retail, wholesale or both;
- (b) where in any such pharmacy Ayurveda products, declared articles, substances or drugs are sold wholesale, also have to be registered as an Ayurveda drug store;
- (c) ensure that-
 - (i) the Ayurveda products which are sold in such pharmacy are duly registered with the Regulatory Council;
 - (ii) each category of Ayurveda products, articles, substances or drugs are separately stored to prevent mixing up;
- (d) its Certificate of Registration as an Ayurveda pharmacy which shall contain the photograph of the Ayurveda Pharmacist and the relevant certificate of business registration be displayed clearly in the premises;
- (e) ensure that the pharmacist shall not engage in any promotional activity or propaganda which is likely to motivate the consumers for the use of any particular drug or product sold therein;
- (f) ensure the advertisements, posters and papers are displayed only within the premises and the pharmacist does not engage in promotional or advertising activity of any form therein;
- (g) ensure that where any supermarket intends to sell Ayurveda products in its business premises such supermarket, adheres to the standards and regulations in force in respect of Ayurveda pharmacies.

62. The premises of any Registered Ayurveda pharmacy shall, -

- (a) have considerable space and shall be fit for systematic and methodical continuance of activities of such Ayurveda Pharmacy;
- (b) where drugs are required to be mixed, possess sufficient space dedicated for that purpose;
- (c) be compartmentalized into two separate divisions for end products and dry medicines;
- (d) be facilitated to store cosmetics and other non-medicinal materials separately, if any;
- (e) where materials and equipment required for demonology are sold, be facilitated to allocate a separate space for the purpose;
- (f) have buildings designated in such a way so as not to expose medicinal materials to dust, smoke, sharp sun rays and unclean air;
- (g) take steps to keep light, ventilation, temperature and humidity in conditions appropriate for pharmacies: air condition facilities must be provided to areas requiring such facilities;
- (h) possess a minimum space of not less than 25 square feet, to be kept available as a waiting space for consumers;

- (i) have a building structure planned in such a way so as to avoid or minimize the risk of drugs being mixed with unnecessary substances;
- (j) have separate facilities to store expired or damaged articles, substances or drugs;
- (k) provide physical facilities to enable cleaning in accordance with the cleaning methodologies employed by pharmacies;
- (l) be planned with maximum provisions to prevent entrance of termites, insects, birds, rats and pet animals by following suitable precautionary measures and standard sanitation systems shall be used for the purpose comprised with washing and sanitary facilities established in the pharmacy and the storing premises in a manner easy to reach;
- (m) be in a building over 10 feet in height-
 - (i) with walls and the ceiling painted with a paint containing no heavy metal and peeling proof;
 - (ii) with the floor properly finished without defects by applying materials easy to clean, non-reactive to medicines and non-slippery;
 - (iii) with a roof permanently fixed using long-lasting material suitable for a pharmacy;
 - (iv) without crevices between roof cover and walls;
 - (v) with a heat resistant fixed to the roof to control the inside temperature;
 - (vi) with a ceiling easy to clean and having no adverse impact on the Ayurveda products sold; and
- (n) be equipped with fire extinguishers;

63. Every registered Ayurveda pharmacy shall be adequately staffed with Ayurveda pharmacists who work on fulltime basis and supporting staff working under supervision of such pharmacists.

64. (1) Every member of the staff having responsibility in the issuance of drugs on a prescription in a Registered Ayurveda Pharmacy shall-

- (a) be of sound physical health;
- (b) be dedicated to provide an agreeable, flexible and friendly service;
- (c) wear a suitable uniform and a card for identification; and
- (d) not consume liquor, cigarettes, chews of betel or narcotics during working hours.

(2) It shall be the duty of every member referred to in sub-regulation (1) to check the prescription prior to the issuance of Ayurveda drugs to a patient;

65. (1) Utmost care shall be taken in preventing growth of microbes in Ayurveda drugs which can cause adverse effects on such drugs.

(2) Ayurveda drugs for internal medication and external medication shall be clearly separated from each other and “Ayurveda drugs for external medication only” shall be written in a clearly visible manner in red colour in the area where Ayurveda drugs for external medication are exhibited for sale.

(3) Ayurveda drugs shall be arranged neatly in the display racks according to their usage and the same Ayurveda drug which is available in packings of different sizes, shall be placed in the same area and shall be clearly separated from each other according to the sizes of the packing.

(4) The price marked on the packing or label of the end product of the Ayurveda drug shall not be disfigured or changed and Ayurveda drugs of which the labels are unidentifiably disfigured or torn or the packing has been damaged or date of expiring has passed shall not be placed for sale.

(5) A retail price index shall be exhibited for all dry, raw or crude Ayurveda drugs kept for sale in a sales center.

(6) Only the end products of Ayurveda drugs registered with the Regulatory Council shall be stored or sold.

(7) Ayurveda drugs shall be taken for sale only from suppliers registered with the Regulatory Council.

(8) A register containing information of cultivators or collectors of raw materials, including the small scale or home garden cultivators shall be maintained and updated.

(9) Only natural, clean and sanitary dry, raw or crude materials shall be sold.

(10) In compounding medicine, a sanitary and clean process shall be followed.

(11) Ayurveda declared articles including equipment shall be obtained for sale only from manufacturers registered with the Regulatory Council.

66. Ayurveda declared articles, substances or drugs shall-

- (a) be issued only upon medical recommendations and shall be issued only against a prescription bearing the stamp (with registration No. of the medical Regulatory Council) of an Ayurveda practitioner registered with the Ayurveda Medical Council;
- (b) where it has been prescribed by a specially qualified Ayurveda practitioner, it shall only be issued with a prescription of such a practitioner: A separate register shall be maintained to keep record of the issuance of such drugs;
- (c) be issued with only the ingredients referred to in the prescription and in the manner prescribed therein;
- (d) be handled following approved sanitation methods;
- (e) not be issued in breach of the recommendations given in a prescription issued by the practitioner;
- (f) be packed in packings approved for the package of food and medicines and a packing shall not be re-used;
- (g) not be issued where there is a difficulty in reading the medical prescription or when the prescription is unintelligible or where there is a doubt about the drugs prescribed;
- (h) not be substituted if the stocks are available or if the Ayurveda practitioner had underlined the drug in his prescription;

- (i) be issued with necessary instructions written on the cover in which the drugs are contained indicating the dosage and the manner of use in terms of the relevant medical prescription;
- (j) where the practitioner has not given special instructions to follow in using a relevant drug, be issued with standard instructions in terms of the Code of Medicine;
- (k) where issuance of the drug is limited by law, not be issued on a prescription and each time of issue shall be recorded in a register giving the details of the amount issued, name of the practitioner, registration No. and name and age of the patient; and
- (l) be issued with a detailed bill on the medicines issued.

67. Every pharmacy which intends to sell, collect or store materials restricted by any other law shall obtain registration, approval or licences, certificates or permits required to carry on such activity or activities.

68. Every registered Ayurveda pharmacy shall maintain a separate register to keep records relating to –

- (a) staff management;
- (b) medical prescriptions;
- (c) bills received on purchasing stocks of medicine;
- (d) *Rasa* drugs;
- (e) the sale of drugs, Ayurveda products other than *rasa drugs*;
- (f) sale of *visha* and *upavisha*;
- (g) drug bulk purchase bills;
- (h) sale of imported medicine; and
- (i) any other relevant document.

69. (1) Every Ayurveda pharmacist employed in a registered Ayurveda pharmacy shall, prior to issuance of any Ayurveda product, take appropriate measures to ensure that any requested Ayurveda product is or is not a material restricted by-

- (a) the Poisons, Opium and Dangerous Drugs Ordinance (Chapter 218);
- (b) the Explosives Ordinance (Chapter 183);
- (c) the Customs Ordinance (Chapter 235);
- (d) Excise Ordinance (Chapter 52);
- (e) the Fauna and Flora Protection Ordinance (Chapter 469); and
- (f) the Penal Code (Chapter 19).

(2) Every Ayurveda pharmacist shall take every precautionary measures in respect of the issuance of any such restricted material as required by the provisions of the respective laws specified under sub regulation (1).

PART VII

AYURVEDA DRUG STORES

70. (1) Every Ayurveda drug store shall be operated under the authority of a licence issued by the Commissioner-General of Ayurveda.

(2) The following institutions or persons, namely-

- (a) a manufactory of medicine;
- (b) a hospital registered under the Department of Ayurveda;
- (c) a sales outlet of medicine;
- (d) suppliers of end products or dry products of declared articles, substance or drugs, Ayurveda products, as the case may be;
- (e) an importer or exporter or a distributor of medicines registered with the Department of Ayurveda;
- (f) a registered Ayurveda practitioner; or
- (g) a company registered under the Companies Act, No. 07 of 2007 or any other relevant authority to carry on a business of a drug store,

shall be eligible to obtain a licence to operate an Ayurveda drug store.

71. (1) Every applicant who intends to apply to obtain a licence to operate an Ayurveda drug store shall-

- (a) possess a business registration made with regard to same, in the name of the applicant; and
- (b) an agreement for a duration of not less than one year signed between the applicant and an Ayurveda Pharmacist registered with the Ayurveda Medical Council.

(2) Activities of an Ayurveda drug store shall be carried out under the supervision of an Ayurveda Pharmacist registered with the Ayurveda Medical Council. An Ayurveda Pharmacist shall sign an agreement only in respect of one Ayurveda drug store.

72.(1) Every application to register an Ayurveda drug store shall be made to the Regulatory Council in Form E as specified in the Schedule II hereto along with the required particulars.

(2) Upon the receipt of an application for registration, the Commissioner-General shall inspect or cause to inspect the site of the drug store prior to issue registration.

(3) The Commissioner-General, being satisfied with the documents submitted and the outcome of the site inspection, shall register such Ayurveda drug store for a period of one year upon the payment of a fee as specified in the Schedule III hereto and issue him a registration number.

(4) Every registration shall be subject to such terms and conditions and may be renewable upon application made therefor three months prior to the expiry of registration.

(5) The Commissioner-General shall maintain a register of all registered Ayurveda drug stores which shall contain information including the name of the proprietor, address and the contact details of such Ayurveda drug store.

73. Every Ayurveda drug store shall-

- (a) clearly display a name board conspicuously indicating the name of the store and the registration number, in all three languages;

- (b) store only the items purchased or obtained from manufactories and importers registered with the Regulatory Council;
- (c) issue items only on internal written directives of the institution which purchases or obtains same, of which records shall be kept in registers maintained for such purpose by the store;
- (d) take precautionary measures to prevent unauthorized persons entering the store premises;
- (e) in the absence of instructions relating to storing, follow relevant standards prescribed by the Ayurveda Code or consult the Regulatory Council.

74. (1) An Ayurveda drug store shall not be located in the close proximity of-

- (a) yards of garbage disposal;
- (b) public toilets;
- (c) agrochemical sales outlets;
- (d) institutions mixing chemicals;
- (e) funeral parlors and morgues;
- (f) vehicle service stations;
- (g) factories (such as tile, plastic, fuel refineries etc.) that immethodically or carelessly emit smoke, dust, carbon and heat unless it is covered or properly sealed; and
- (h) animal farms,

and any other place in the vicinity of which the Regulatory Council determines as unsuitable to carry on a medicinal store.

(2) Where any place referred to in sub-regulation (1) is subsequently established near an Ayurveda store, such store shall take all precautionary measures to minimize impact caused by such place to the items stored in such store.

(3) Where the premises of an Ayurveda store is located in an area identified as vulnerable to floods and other natural disasters, precautionary and preventive measures shall be adopted by such store for the safety of items stored in such store.

75. Every premises used as an Ayurveda drug store shall-

- (a) be sufficiently spacious;
- (b) have separate entrances for input and output of materials as recommended by the Regulatory Council based on the capacity and facilities for loading and unloading at such entrances;
- (c) have quarantine units set up outside the store premises;
- (d) keep samples of primary materials in another site under appropriate conditions or separately in the premises itself;
- (e) have two areas allocated separately to store end-products of medicine and dry medicines: In the event where raw medicines are to be stored, a separate area shall be used for the purpose under appropriate environmental conditions. All these areas shall have separate entrances and shall not be connected to each other internally;
- (f) be housed in a building –
 - (i) with walls and the ceiling painted with a paint containing no heavy metal and peeling proof;
 - (ii) with the floor properly finished without defects by applying materials easy to clean, non-reactive to medicines and non-slippery;

(iii) without crevices between roof cover and walls;

- (g) designated in a manner so as not to expose medicinal materials to dust, smoke, sharp sun rays and unclean air;
- (h) take steps to keep light, ventilation, temperature and humidity in conditions appropriate for places storing drugs and air condition facilities must be provided to areas requiring such facilities;
- (i) which has a building structure planned in a manner so as to avoid or minimize the risk of drugs being mixed with unnecessary substances;
- (j) which possesses separate facilities to store expired or damaged drugs;
- (k) having maximum provisions to prevent entrance of termites, insects, birds, rats and pet animals by following suitable precautionary measures and standard sanitation systems for the purpose comprised with washing and sanitary facilities established in the store and the storing premises in a manner easy to reach;
- (l) with facilities to store-over active materials, radioactive materials, dangerous drugs, hazardous materials, sensitive objects, substances that may be misused and inflammable and explosive materials separate from each other.

76. In the storage of drugs, a quarantine unit shall be located for the purpose of to-quarantining all Ayurveda drugs (raw materials, packing materials) prior to they being transferred to the store.

77. (1) The quarantine unit shall follow standard quarantine procedure under the supervision of a registered pharmacist.

(2) Medicines shall be stored by using packing meant for food and medicinal items only. Medicine shall be supplied only by using the standard food or medicine transportation methodologies specified in the guidelines prepared by the Regulatory Council.

(3) A standard, certified collection of samples applicable for identification of materials shall be maintained in every store.

(4) Where further testing is required for proper identification of medicines at a situation of uncertainty, recommendations shall be sought by reference of such samples to a laboratory approved by the Regulatory Council.

(5) A separate store shall be available for the temporary storage of Ayurveda drugs until they are quarantined.

(6) Quarantined medicines shall be sent to the store, only after being properly labelled and certified.

(7) Quarantine registers containing particular of the medicines quarantined shall be maintained properly at the stores.

78. (1) Every Ayurveda article, substance or drug used for the production process, intermediate products and as packing materials of drugs, as determined by the Regulatory Council from time to time, shall be stored separately in terms of the Model Standards for Ayurveda drug stores as specified in the guidelines prepared by the Regulatory Council.

(2) Only the raw materials received from registered suppliers or end products of Ayurveda drugs and articles of licenced manufactories shall be stored in any Ayurveda drug store.

(3) Environmental conditions conducive for storing shall be maintained. Air conditioning and refrigeration

facilities shall be made available to store drugs which required to be stored under air-conditioning or refrigeration.

(4) The materials stored shall be stacked in racks with shelves or stages so as not to contact with the floor.

(5) The store premises must be clean and be devoid of waste and pests. Cleaning and observation spaces shall be made available in storing and a standard sanitation process shall be available with clear instructions on cleaning methodologies.

(6) Raw materials shall be stored only in their natural clean state and different types of medicinal raw materials shall be labelled and stored separately

(7) All end products of Ayurveda drugs shall be categorized as botanical, mineral or zoological or the like and shall be stored separately.

(8) Hyperactive materials, radioactive materials, drugs specified in Part IX of these regulations, hazardous materials, sensitive objects, substances that may be misused and inflammable and explosive materials shall be stored in areas allocated to such materials and shall be maintained with caution and subject to hazardous preventive methodologies in terms of relevant local or international rules and regulations.

(9) Storing shall be done in a manner so as to prevent mixing of raw materials, inter contact and internal spoiling.

(10) When the same medicine is separated according to its quantity, it shall be packed in the same area marking due separations in respect thereof.

(11) In a store, regular stock-taking shall be carried out.

(12) (a) Where a label of an Ayurveda drug contains information different from the actual information that can be related to the drug, measures shall be taken to examine whether a mixing or an incorrect issuance had taken place.

(b) An Ayurveda drug which is different from the information contained in the label shall be identified by adopting the guidelines prepared by the Regulatory Council.

(13) After an issuance of a medicine making a portion of such medicine to remain, the remaining portion of the medicine shall be stored in such a way so as not to be spoiled and decomposed, and shall be safely packed and labelled. The raw material of which a portion remains shall be first issued at the next issuance.

(14) Under any circumstance, any material with a damaged-packing shall not be issued. Where required, such material shall be referred to Quality Control Unit for necessary testing of its condition. All actions taken in that respect shall be recorded and registered.

(15) Proper precautionary measures shall be taken to prevent issuance of outdated materials. Expired, damaged, rejected or re-called medicines shall not be kept in the store. Such materials shall be stored in a separate place till they are disposed of and a separate register shall be maintained to keep records of such items and monthly reports shall be sent to the Regulatory Council in that regard. Expired or damaged medicines shall be disposed of methodically under approval of the Regulatory Council.

(16) A systematic methodology shall have to be developed to issue Ayurveda drugs on 'First in First out (FIFO)' basis without surpassing standards to be maintained relating to such drugs.

79. (1) Every Ayurveda store shall –

- (a) keep records in order to enable the re-testing of the existing temperature and humidity;
- (b) check all pertinent equipment at proper intervals and keep records thereof;

- (c) record in graphs the fluctuations of store temperature, to enable proper observation; and
- (d) calibrate measuring equipment at regular intervals.

(2) All records referred to in sub-regulation (1) shall be kept safe for a period of one year from the date of expiry of that medicine or any other period provided by the existing rules and regulations.

80. (1) Every Ayurveda Store, in addition to the records referred to in regulation 79 shall-

- (a) keep written records on activities performed in the premises;
- (b) keep records in both written and electronic form of all items stored including instructions relating to recommended conditions of storing, precautionary measures, observations and the dates to re-check; and
- (c) keep records of every issuance including the particulars of the item, its quality, amount, supplier, batch number of the supplier, date received, and date of expiry.

(2) The records referred to in sub-regulation (1) shall be kept in a specific system of identification either based on batch numbering or a similar system:

81. (1) Raw materials and Ayurveda drugs shall be stored in packings in a manner that would prevent reacting with each other and being protected from external risks.

(2) Every packing referred to in sub-regulation (1) shall have labels clearly indicating the name of the item, batch number, date of expiry and the date for re-checking, condition for special packing in terms of the Registration Number of the Medicine. The abbreviations, names or codes that have not been approved by the Regulatory Council shall not be used in the labels.

(3) Receipt orders received pertaining to raw materials and medicines, shall be tested and confirmed at every order.

(4) Packing shall be physically tested and confirmed with respect to every order of raw materials and products.

(5) Uniformity of any stock shall be tested and confirmed. In case a stock consists of products belonging to several batch numbers, they shall be duly separated.

(6) All containers shall be well examined for cleanliness and where a broken or damaged container or a container which is below the required standards is found in a stock, the entire stock shall be kept in the quarantine premises for further investigations.

(7) (a) Qualified and trained staff shall take samples of the stocks when necessary.

(b) Samples must be taken in terms of the written instructions provided by the Regulatory Council and the containers into which samples are taken shall be properly labelled.

(c) The samples so taken shall be quarantined. Batch separation process shall continue even in the process of storing.

(8) Raw materials or Ayurveda drugs shall be kept in a quarantine store until they are approved or rejected by an authorized officer.

82. (1) The store premises shall be cleaned in terms of standard sanitation procedures in order to prevent damages likely to be caused by animals including termites, insects, birds and rats and written records shall be kept of the procedures and methods used for sanitation.

(2) Every packing container shall be cleaned before and after every use in terms of the standard methodologies applicable in respect thereof.

(3) Every precautionary measure shall be taken to prevent growth of microbes, in order to minimize its impact on medicines.

83. (1) Every Ayurveda Store shall be-

(a) supervised by an Ayurveda Pharmacists registered under the Act who shall be responsible for the activities carried out in the stores;

(b) staffed with a qualified person possessing knowledge on Ayurveda drug;

(2) The staff shall be –

(a) provided with a proper training on methodologies, regulations and safety measures of storing medicine;

(b) informed and trained on optimum protection of personal health and sanitation; and

(c) provided with a protective uniform suitable for their work.

84. The following registers shall be maintained in the stores and shall be regularly updated:-

(a) staff management register;

(b) register of issuance of stocks;

(c) register of wholesale and retail purchasing stocks of medicine and bills;

(d) Rasa stock register;

(e) Register on the sale of other than *rasa* products; and

(f) Register on the sale of imported medicine.

Part VIII

STANDARDS FOR DISTRIBUTION

85. For the purposes of this Part –

“Distribution” means, the process of supply, purchasing, keeping (other than in a store), sale, importation, exportation and transportation of the declared article substance or drug or any Ayurveda product mentioned from the manufactory up to the point of handing over to the beneficiary and, however it does not mean directly handing over the item to the beneficiary.

86. Any person or institution engaged in the distribution of any declared article, substance, drug or Ayurveda product (hereinafter referred to as the “Registrant”) shall be registered with the Regulatory Council. The registration shall be annually renewed.

87. Every registered manufactory who wishes to apply for registration for the distribution of declared article, substance, drug or Ayurveda product shall apply to the Regulatory Council for the purpose in the application in Form G as specified in Schedule II hereto.

88. Every Registrant referred to in regulation 86 or a registered manufactory referred to in regulation 87 shall submit information of the process of distribution and other relevant information as required by the Regulatory Council.

89. Every Distribution outlet shall-

- (a) display a name board or name boards, as the case may be, at the main entrance open to the main road in an identifiable manner containing the name of the registered institution and the words “a distributor registered with the Department of Ayurveda” in all three languages along with registration number in terms of recommendations of the Regulatory Council;
- (b) have sufficient infrastructure facilities determined by the Regulatory Council; and
- (c) clearly display a Certificate of Registration of Distribution issued by the Regulatory Council in the Head Office and regional Office of the registered institution.

90. (1) The capacity of distribution, media and transportation methodologies utilized by the person or institution registered for distribution shall be to the satisfaction of the Regulatory Council.

(2) Instructions of the Regulatory Council shall be followed in situations which hampers distribution process due to natural disasters or similar unpredictable situations. In case of an emergency, precautionary and quarantine measures shall be followed to prevent their impact on the distribution process.

(3) All parties engaged in the process of distribution shall abide by regulations applicable for distribution and made under this Part.

(4) Regulations applicable for distributions made under this Part shall be complied with even in the distribution and transportation of donations to people affected by disasters.

91. Registration for distribution shall be valid only for distribution of approved products registered with the Regulatory Council.

92. Where a registered distributor seeks assistance of an external party to distribute products, vehicles suitable for the purpose shall be utilized and shall make sure that the quality of the products are not be affected by the transportation, humidity, temperature, physical contact and the process of distribution.

93. Every distributor at the time of registration for distribution under this Part shall submit to the Regulatory Council information relating to-

- (a) written objectives and requirements of the distributor properly stated and approved by the Regulatory Council;
- (b) methodology available to keep relevant manufacturers and the Regulatory Council immediately informed of unauthorized distributions suspected or confirmed;
- (c) approved methodologies for all administrative and technical activities to ensure that products were undertaken from authorized suppliers and distributed to authorized institutions;
- (d) mechanism to be followed in the exchange of distributions at distribution exchanges;
- (e) written methodology to confirm unauthorized distributions or the stations suspected on such unauthorised distributions; and
- (f) methodology to be in place for distributors to measure quality of distributions in order to check damages likely to be caused to such distributions.

94. (1) Where registration is sought in respect of distribution of declared articles, substances or drugs or Ayurveda

products, vehicles with appropriate enclosed partitions or separate vehicles for each item shall be used in order to prevent items getting mixed up with each other.

(2) Where the vehicles used for distribution belong to a third party or are hired, the applicant shall submit a letter of consent from the vehicle owner along with a copy of his National Identity Card, a copy the revenue licence and certificate of registration of the vehicle to the Regulatory Council along with the application for registration for such distribution.

(3) In case of a change of the ownership of a vehicle approved by the Regulatory Council for distribution under this Part or where a new vehicle is purchased, information in that regard shall be submitted to the Regulatory Council within fourteen days of the occurrence of such change.

95. A registered distributor shall -

- (a) be responsible for the entire process of distribution made under this Part;
- (b) clearly provide written instructions to and raise awareness of relevant individuals, making such individuals understand the distribution process;
- (c) appoint a person in the institution responsible and authorized for ensuring implementation of distribution process and maintenance thereof in terms of these regulations;
- (d) appoint managers and technical officers having the authority and facilities required for identification of deviation from optimum process and its rectification;
- (e) not entrust to an individual an unbearable amount of responsibility which may affect the quality of the item distributed;
- (f) take steps to avoid conflicts of interests or commercial, political, financial or other influences upon people and management which are likely to have an adverse impact on the quality of the distribution service or the item distributed;
- (g) ensure that the staff observes personal health and cleanliness;
- (h) follow defence strategies in a manner not to damage persons, property and stability of the environment; and
- (i) take appropriate measures under the existing laws in order to prevent instances of damaging and spoiling distributions, substitution or transportation of unauthorized substances.

96. (1) Every registered distributor shall deploy properly trained and qualified staff to carry out distribution activities.

(2) Special training shall be given to those who are distributing dangerous material and the Regulatory Council shall be reported of such trainings.

(3) All members of the staff of a registered distributor shall be clad in a uniform suitable for the task.

(4) The health and hygiene of the members of the staff shall be properly preserved specially when they are engaged in duty.

97. (1) All vehicles used for distribution shall, at all times, keep the distribution licence issued in respect of the vehicle, in the vehicle, in order to be produced at an emergency check.

(2) Vehicles used for transportation shall be suitable for the relevant distribution purposes.

(3) Storing facilities shall be available in the packaging space of the vehicle used for distribution, in a condition suitable for the relevant category of products.

(4) Only the Categories of declared articles, substances or drugs that do not have adverse effect on each other when kept together in the same environment shall be transported in the same vehicle.

(5) Purpose specific vehicles or single vehicles with doors and compartments separated shall be used for distribution of more than one category of product.

(6) Raw opium or cannabis shall be transported in terms of the provisions of Part IX of this Code.

(7) During transportation any expired or damaged Ayurveda product, article, substance or drug shall be separately stored.

(8) During transportation over active materials, radioactive materials, dangerous drugs, hazardous materials, sensitive objects, substances that may be misused and inflammable and explosive materials shall be kept separate from each other.

(9) Structure of the vehicle used for transportation shall be designed to minimize risks and mistakes. It shall also be in a condition easy to clean and not easily dirtied. It shall also have an opening applied with filters preventing entry of dirt from outside and maintain a proper ventilation. Doors shall be able to be closed tightly.

(10) It is suitable to maintain an electronic tracking device and a remote vehicle identifying system through a global positioning system (GPS).

(11) Every registered vehicle shall be expeditiously removed from transportation upon being dilapidated. Such vehicles shall not be re-used without being adequately repaired. Long term decay of a vehicle shall be informed to the Regulatory Council.

(12) The frame of a vehicle shall be finished heat resistant. Insulators shall be installed in every vehicle to prevent heating from sun rays.

(13) Vehicles shall have special facilities for storing (such as uniform temperature, humidity etc.) and facilities pertaining to transportation of required category of materials. Measuring devices shall be available for measuring those conditions. Relevant measurements shall be recorded at equal durations of time.

(14) In case where materials requiring refrigeration facilities are to be transported, refrigerators with suitable temperature controls shall be fixed under transportation environment.

(15) Areas for parking vehicles, containers and operating equipment shall not be placed at close proximity of open garbage dumping sites and public toilets. It shall also be a place away from other factors such as Agro-chemical sales outlets, chemical mixing stations, funeral parlours and vehicle service stations as determined by the Regulatory Council to be unsuitable for running a medicine manufactory

(16) The vehicles used for transportation shall be kept away from the likely intrusion of animals.

(17) Cleaning substances and disinfectants shall be used on the vehicle in such a manner so as not to contaminate the materials stored in the vehicle.

(18) Vehicles shall not be released to unauthorized persons.

Part IX

PROVISIONS PERTAINING TO OPIUM AND DANGEROUS DRUGS

98. Notwithstanding anything contained in Chapter III and IV of the Poisons, Opium and Dangerous Drugs Ordinance (Chapter 218) the Commissioner-General, under the authority of the Minister for the purpose of giving force and effect to these regulations in terms of subsection (2) of section 77 of the Act shall-

- (a) import raw or prepared opium;
- (b) appoint such number of officers of the Department of Ayurveda as opium officers;
- (c) issue licences to registered Ayurveda Practitioners, pharmacies and stores for the purposes of preparation of Ayurveda drugs and storage, transportation, distribution and issuance of raw or prepared opium, for the requirements in Ayurveda drugs; and
- (d) maintain regional opium deposits for rations of opium as needed for the purposes of Ayurveda medicine and surgery out of the Central deposit of opium maintained by the Commission General.

99. (1) Every such deposit referred to in regulation 98 (d) shall be regulated subject to a procedure prepared by the Regulatory Council which shall contain criteria, guidelines, conditions for supervision and regulations pertaining to maintenance of any Opium deposit.

(2) The Commissioner-General shall maintain or cause to maintain records relating to-

- (a) sources and amounts of the provision of opium to that deposit; and
- (b) parties to whom such deposits were issued and amounts so issued shall be clearly recorded and maintained.

(3) The Provincial Commissioner of Ayurveda, subject to the direction of the Commissioner-General, shall be responsible for the maintenance and supervision of the deposits in the Province.

(4) The Regulatory Council shall make rules relating to the issuance and use of opium by the deposits.

(5) The Commissioner-General, on recommendations of the Regulatory Council, shall appoint Provincial Commissioner of Ayurveda as the Chief Regional Opium Officer.

(6) The Chief Regional Opium Officer shall establish the Regional Opium Board for the relevant district comprising of the following:-

- (a) *ex-officio* members:-
 - (i) District Secretary to serve as the Chairman of the Board;
 - (ii) Provincial Commissioner of Ayurveda;
 - (iii) Medical Superintendent of District Ayurveda Hospital;
 - (iv) Superintendent of Police;
 - (v) Director General of the National Dangerous Drugs Control Board or his representative; and
 - (vi) District Excise Officer nominated by the Director General of Excise Act;
- (b) Three Ayurveda Practitioners of *Deshiya Chikithsa* appointed by the Commissioner-General.

(7) Opium shall be issued by the Regional Opium Board to registered Ayurveda Practitioners who have been issued with a licence therefor, by the Commissioner-General.

100. (1) Any Ayurveda Practitioner who wishes to have an opium licence shall apply to the Commissioner-General in the Form H specified in the Schedule II hereto.

(2) The Commissioner-General, upon receipt of the application, in addition to information submitted in the application, shall require the applicant to submit further information, which he deems necessary for the issuance of the licence.

(3) The Commissioner-General shall, prior to issuing the licence, refer the application to Regional Opium Board of the relevant District for clearance and recommendations.

(4) After due consideration of the facts of the application, information submitted by the applicant and the recommendation made by Regional Opium Board of the relevant district, the Commissioner-General shall-

(a) issue the applicant a licence in the Format of the Certificate as specified in the Schedule IV hereto for the purchase of opium upon the payment of a fee specified in the Schedule III hereto; or

(b) reject the application with reasons assigned therefor.

(5) Every licence issued under sub-regulation (4) (a) shall be valid for a period of one year and may be renewed upon application to that effect made to the Commissioner-General in the Form H specified in the Schedule II hereto, prior to three months of the date of expiry of such licence.

(6) The Commissioner-General of Ayurveda, by taking into consideration the previous records of the Licence holder, may renew the licence upon payment of a fee specified in the Schedule III hereto for a further period of not less than one year. Where the application for renewal is not made prior to three months of its date of expiry, the applicant shall pay a late fee to be determined by the Commissioner-General.

(7) A holder of a licence shall purchase opium before the expiry of the period of validity of such licence. Where he purchases such opium after the expiry of such period of validity, he shall be liable to pay a penalty as determined by the Commissioner-General.

101. (1) The Commissioner-General shall cancel the licence issued under regulation 100 where,

(a) the holder of the licence has neglected compliance with any provisions of this Act, the Poison, Opium and Dangerous Drugs Ordinance (Chapter 218), or these regulations or any conditions stipulated in a licence subject to which such opium licence has been issued; or

(b) manufacturing activities performed by using opium have been terminated; or

(c) opium issued has not been used properly in the production process in respect of which such licence was issued.

(2) The Commissioner-General, prior to cancellation of a licence under paragraph (a) or (c) of sub-regulation (1) shall notify the holder, of the suspension of the licence requiring him to show cause within thirty days of issuance of such notice, as to why his licence shall not be cancelled.

(3) Where the holder of a licence-

(a) fails to respond to the notice referred to in sub-regulation (2) within the stipulated time period; or

(b) does not provide a valid explanation to the satisfaction of the Commissioner-General,

the Commissioner-General shall, forthwith cancel the licence and notify the holder of such cancellation.

(4) In the event of a cancellation of a licence, the holder of such cancelled licence shall return to the Commissioner-General opium, if any, purchased under the cancelled licence and in his custody, with immediate effect.

102. (1) An Ayurveda Practitioner holding an opium licence referred to as 'licensed Ayurveda Practitioner' in regulations 103, 104 and 105 may be permitted to receive opium, transport, keep in possession, store, use for products and to produce medicines containing opium subject to conditions specified from time to time by the Commissioner-General.

(2) Every Ayurveda practitioner holding an opium licence shall-

- (a) be responsible for the opium in his custody;
- (b) supervise the storing and transportation of opium and production of drugs using opium issued to him; and
- (c) submit to the Commissioner-General an annual report on the types and amounts of medicine produced by the use of such amounts of opium, under his supervision and responsibility.

(3) The Regulatory Council shall keep a register of Ayurveda Practitioners holding opium licences, which shall be updated from time to time.

103. Any licenced Ayurveda Practitioner violating provisions of the Act, or these regulations or any conditions stipulated in the licence relating to opium, opium licence or any matters incidental thereto shall be guilty of an offence under the respective laws and shall be dealt with accordingly. The Commissioner-General shall blacklist any such person, who has been convicted by a Court of law upon finding guilty of committing an offence relating to opium under these regulations.

104. (1) A licenced Ayurveda Practitioner shall make a request for opium in the specified form to the Regulatory Council, to be used in production purposes.

(2) The Regulatory Council shall levy a fee determined by the Regulatory Council for the opium issued to licenced Ayurveda Practitioners.

(3) The Commissioner-General of Ayurveda shall maintain a register to record every request for opium made under the provisions of these regulations, particulars of which to be included in that register shall be determined by the Regulatory Council.

(4) when making a request under sub-regulation (1), information relating to the types of products and amounts of products for which opium is intended to be used and any other relevant particulars shall be provided to the Regulatory Council during specific period of time as determined by the Council.

105. (1) The Commissioner-General of Ayurveda shall, notify the Ayurveda Practitioner who makes a request under regulation 104 in writing of such acceptance or rejection of the request within a period of 60 days from the date of receipt of the request.

(2) Appeal Board, after considering the explanations placed before it shall-

- (a) allow the appeal and direct the Commissioner-General to issue the applicant opium; or
- (b) disallow the appeal.

(3) The decision of the Appeal Board shall be final.

106. (1) Applying opium to the medicine in the course of its production shall be carried out under the supervision of an Ayurveda Community Medical Officer nominated by the Commissioner-General.

(2) The Ayurveda Community Medical Officer shall place his signature on the production reports.

107. No person shall cultivate Cannabis, keep them in possession or store, manufacture Ayurveda product using them or export such Ayurveda product or transport Cannabis without obtaining a licence issued for the purpose by the Commissioner-General assigning specific authority for each such purpose.

108. (1) The Commissioner-General shall be responsible for the issuance of licences as specified in Schedule IV hereto, to registered Ayurveda Practitioners to obtain Cannabis from the Department of Ayurveda and keep them in possession in amounts required for enforcement of the purposes of this Code.

(2) The Commissioner-General shall, on recommendations of the Regulatory Council issue licence to-

- (a) Government entities;
- (b) Semi-government entities; and
- (c) private entities,

upon making a request therefor, to cultivate, receive, keep in possession, store, sell, supply, distribute or transport Cannabis for the purpose of manufacturing Ayurveda products, or export Ayurveda articles, substances or drugs and Ayurveda products manufactured by using Cannabis.

109. The Commissioner-General, upon recommendations of the Regulatory Council, shall decide on the category of registered Ayurveda Practitioners qualified for the receipt of Cannabis and the amount of Cannabis to be issued to them in terms of directives of the Commissioner-General.

110. (1) A registered Ayurveda Practitioner shall submit a written request in the form specified by the Commissioner-General to receive Cannabis for production of drugs for the purpose of treating patients.

(2) Such request shall be accompanied by the particulars of drugs and Ayurveda products intended to be made using Cannabis, together with a processing fee as may be determined by the Commissioner-General, from time to time.

(3) The Commissioner-General shall maintain a comprehensive document on every request received for obtaining Cannabis and the types of drugs and Ayurveda products intended to be made using Cannabis and the required amounts and all other relevant particulars which are included in that request.

- (4) (a) The Regulatory Council may accept the said request within a specific period of time taking into consideration reports submitted and all other relevant information provided or reject the request.
- (b) Where the request is accepted by the Regulatory Council, that fact shall be informed to the applicant in writing.

111. (1) Where the Regulatory Council rejects the request, such rejection, shall be informed to the applicant with reasons therefor within a period of thirty days and the applicant reserves the right to submit an appeal within thirty days of receipt of such rejection.

(2) An appeal under sub regulation (1) shall be submitted to the Commissioner-General in a format specified by the Commissioner-General and, when an oral explanation is required for the purpose, the applicant or his representative shall appear before the Regulatory Council and give such explanation. A Sub-Committee consisting of at least three members of the Regulatory Council may be appointed if an investigation is required to be conducted on the said appeal and the Commissioner-General may conditions subject to which such investigation shall be carried out.

(3) An applicant aggrieved by the decision of the Regulatory Council shall appeal to the Appeal Board referred to in Part X to this Code.

(4) When any specific condition or several conditions specified by the Commissioner-General under sub-regulation (2) is or are violated in the course of any investigation carried out under sub-regulation (2) or any other investigation carried out after giving approval for such registration, the Commissioner-General reserves the right to temporarily suspend the registration and blacklist the applicant upon recommendation of the Regulatory Council.

112. (1) A Government, semi-government or private entity that wishes to cultivate Cannabis or to receive, keep in possession, store, distribute or transport Cannabis, used in the manufacture of Ayurveda articles, substances or drugs and Ayurveda products for both exportation and local sales shall apply to the Regulatory Council to obtain licences for the relevant purpose.

(2) The application shall be by way of a project proposal with a feasibility report, which shall be submitted by way of an Expression of Interest to the Regulatory Council at an open bidding opportunity provided by the Regulatory Council.

(3) The Regulatory Council shall, prior to making its decision shall refer the project proposal and feasibility report to the Medicinal Plants Evaluation Committee for evaluation and if necessary, to any other relevant authority to obtain their recommendations.

(4) The Regulatory Council may, where necessary, require the applicant to furnish further particulars and information on the project proposal prior to issuance of licence.

113. (1) For the purpose of Expression of Interest (EOI) under regulation 112 (2), every prospective applicant shall-

- (a) be a legal person;
- (b) submit only one application in the Form I as specified in Schedule II hereto;
- (c) be an operator of a valid registered local drug manufactory or an institution run under the supervision of a Ayurveda Practitioner registered with the Ayurveda Medical Council;

(2) A duly completed application shall be submitted within the required time period stipulated in the application.

(3) All relevant documents shall be submitted as attachments to the application.

(1) The project proposal and the feasibility study shall be submitted along with the application.

(2) Every application shall be accompanied with an affidavit stating the applicant's willingness to start and continue the project mentioned in the EOI and shall be accompanied by audited financial statements of the applicant for two consecutive years.

(3) Any correction made to the application shall be hand written using blue ink and countersigned by the applicant.

114. (1) The Regulatory Council shall, after considering the application referred to it under regulation 113, issue a temporary licence for a period of six (6) months upon payment of a refundable deposit specified in the Schedule III hereto for the purpose of arranging necessary infrastructure for the project. No person shall commence work of the project under a temporary licence.

(2) The Refundable deposit shall only be refunded-

- (a) in local currency, at the equivalent convertible rate of US Dollars prevailing on the date on which the application was submitted;

- (b) where the applicant does not continue with the project after laps of six months upon deducting 10% of such refundable deposit;
- (c) where the work on the project has caused any damaged to the environment or any other similar damage upon deducting a percentage of the deposit sufficient to make good the loss as determined by the Regulatory Council on a valuation report submitted by a committee appointed for the purpose by such Council;
- (d) upon the receipt of the permanent licence and making the deposit referred to under sub regulation (2) of regulation 115.

(3) A holder of a temporary licence who does not apply for a permanent licence may sell the project property. However, a temporary licence shall not be transferrable under any circumstance.

115. (1) A holder of a temporary licence shall obtain a permanent licence prior to the commencement of operations of the Cannabis project.

(2) Upon the receipt of recommendations of the Medicinal Plants Evaluation Committee on the temporary licence and having evaluated them, the Regulatory Council shall issue the permanent licence to the applicant who shall be referred to as “the Cannabis licensee” for the purposes of this Code, on the payment of a fee specified in Schedule III hereto and the deposit specified in Schedule III hereto.

(3) A Cannabis licensee shall commence operations of the project from the date of issuance of such permanent licence and shall provide a detailed report to the Regulatory Council, of the operations carried out in every month on or before the thirtieth day of next month. In case of export of such declared articles, substances, drugs or Ayurveda products made using Cannabis, documents related to each shipment shall be submitted for prior approval and a no-objection document shall be obtained from the Commissioner-General in report thereof.

(4) Every cannabis licensee shall, prior to exportation of a cannabis consignment, ensure the receipt of payment by way of-

- (a) cash in advance Telegraph Transfer (TT); or
- (b) an irrevocable Letter of Credit (LC).

(5) In respect of all exported declared articles, substances, drugs or Ayurveda products made using Cannabis, the exporter shall submit fund-receiving documents from a commercial bank in Sri Lanka within three months of a shipment or before the next shipment, whichever occurs first.

(6) All bills shall be quantitatively related to market value of the consignment to be expected and undervaluation or overvaluation or violation of import and export regulations shall be grounds for cancellation of licence issued under sub-regulation (2).

(7) A temporary licence or a permanent licence may be canceled without assigning reasons therefor, where the information provided as required above is found to be false.

(8) A written notice of any change in the information relating to the project shall be forthwith be given to the Regulatory Council.

(9) Inspection of the premises, manufactories, fields, cultivation, harvest or stores relating to the Cannabis project by an authorized officer or officers, shall be allowed at any time of the day.

(10) A Cannabis licensee shall, when carrying out a Cannabis project-

- (a) employ proper supervision, adequate care and safety measures in recommended manner during cultivation, production, storage, transportation, marketing and export operations. All measures and techniques in respect thereof shall be provided by the Cannabis licensee;
- (b) establish a formal procedure for the maintenance of an isolated zone for the project;
- (c) construct fences and boundary walls with strict security to cover the entire area used for the project;
- (d) arrange security personnel to patrol near boundary fences and walls, which shall have surveillance posts established covering the entire area of the cannabis project and armed guards shall be deployed for continuous duty;
- (e) establish and maintain an uninterrupted lighting system powered by solar energy or alternative energy or from the national grid;
- (f) auto changeover generators which produce more than 25% of the total required capacity, be additionally installed to maintain a continuous lighting system;
- (g) light up the premises in a manner that every person entering the premises can be identified;
- (h) have armed guards for continuous patrolling of the project area day and night at least once per hour and a record of the same shall be maintained;
- (i) be equipped with electronic surveillance camera system and a fully secured surveillance room shall be established for surveillance, covering all areas of the relevant premises;
- (j) establish a formal procedure for vehicles and personnel access control and its continuity shall be maintained;
- (k) have a formal system for intrusion control and identification of intruders;
- (l) have warning signal monitoring stations and emergency response team in the relevant area to ensure internal and external security of the premises;
- (m) pack cannabis products hygienically and shall be packaged using approved containment methods;
- (n) deploy armed personnel when transporting raw materials or products containing Cannabis;
- (o) use one or more high security sealing methods in the packaging, transportation, sale and exportation of raw materials or products containing Cannabis; and
- (p) keep records of attendance of all employees employed in each premises, accurately and continuously.

116. Every Cannabis Licence issued under the Code shall be –

- (a) substantially in the Form Specified in Schedule IV hereto;

- (b) subject to such terms and conditions specified therein and to the provisions of any other written law to the extent permitted for purposes of this Code;
- (c) valid only in respect of the specified purpose, for which it has been issued; and
- (d) valid for a period of one year and may be renewed on application made ninety days prior to the expiry of the term of licence.

117. (1) A Cannabis Licence issued under this Code shall be renewable on an application made in that behalf to the Regulatory Council in the Form I as specified in the Schedule II hereto within a period of ninety days prior to the expiry of the term of such licence.

(2) A Cannabis Licence shall be renewed by the Regulatory Council, only if it is satisfied that the Licenced Ayurveda Practitioner or the Cannabis licensee has adhered to the provisions of the Act and any other written law this Code and such terms and conditions specified in the licence.

118. (1) Upon the receipt of an application for renewal of a licence under sub-regulation (1) of regulation 117, the Regulatory Council shall, within thirty days of the receipt of such application, either-

- (a) refer the application to the Committee of Officials for the Evaluation of Medicinal Plants or to any other authority for recommendation; or
- (b) reject the application assigning reasons therefor.

(2) The Regulatory Council shall, where it deems necessary may require the applicant to furnish further information relating to a matter or matters specified in the recommendations.

(3) Upon the receipt of such recommendations and on considering such recommendations and information furnished by the applicant and, on being satisfied that all terms and conditions of the licence have been complied with, the Regulatory Council shall -

- (a) renew such licence for a period of one year on payment of the relevant fee as specified in the Schedule III hereto; or
- (b) for reasons to be recorded by the Regulatory Council, refuse to renew the licence.

119. Where the Regulatory Council has refused to renew such licence, the Regulatory Council shall-

- (a) strike off the name of such Licenced Ayurveda Practitioner or the Cannabis licensee from the relevant register;
- (b) take such measures as the Regulatory Council deems appropriate to ensure the items that have been already manufactured but not issued to the market and the items that are still in the process of being manufactured and the cannabis fields, crops, and harvest to be handed over to the Commissioner-General.

120. When the Cannabis licence is cancelled the Licenced Ayurveda Practitioner or the Cannabis licensee as the case may be shall immediately surrender the possession of Cannabis fields, harvest, remaining stocks and Ayurveda products to the Commissioner-General and the Commissioner-General shall on receipt of such information seize and seal such premises.

121. (1) Under this Code, every Ayurveda Practitioner who holds a Cannabis licence shall submit to the Commissioner-General an annual report prepared in the format specified by the Commissioner-General on the utility of the relevant amount of Cannabis for specified purposes under his supervision and also submit an audited financial report and the extent of his responsibility regarding same.

(2) A register of the names of all Ayurveda Practitioners who holds a Cannabis licence shall be maintained by the Commissioner-General based on their respective activity and such register shall be updated regularly.

122. Any Ayurveda Practitioner or Cannabis licensee or any other person who violates any provision of any written law, other than to the extent permitted by the provisions of this Part for the purposes of this Code or any terms and conditions specified by the Regulatory Council pertaining to Cannabis licence shall be guilty of an offence punishable under the Act or such other law, as the case may be and shall be dealt with accordingly.

123. (1) A Cannabis Licencee shall dispose only the residuals of cannabis, which shall be sold to any other industry registered with the Ministry of Industries under an agreement entered into that effect and security parameters determined by the Regulatory Council in respect thereof.

(2) The Cannabis licensee shall maintain a register of every stock of residual Cannabis.

124. (1) Where the Commissioner-General of Ayurveda is of the opinion that-

- (a) a Licenced Ayurveda Practitioner or the Cannabis licensee has neglected compliance with any term or condition under which any Cannabis licence has been issued;
- (b) manufacturing activities performed by using opium have been terminated;
- (c) opium issued has not been properly used in the manufacture of the registered product products;
- (d) a holder of a licence issued under this Part has neglected adherence to any of the term or conditions imposed by the Regulatory Council; or
- (e) a holder of a licence issued under this Part has violated any provision of the Act or this Code or any rule or guideline made thereunder;

the Commissioner-General of Ayurveda shall temporarily suspend the relevant licence, submit relevant information to the Regulatory Council and make arrangements to issue a notice of suspension on the Cannabis Licencee upon recommendations of the Regulatory Council. If the matter needs to be further investigated, the Regulatory Council may appoint a committee consisting of at least three members of the Regulatory Council for the purpose.

(2) Upon such suspension the orders issued by the Regulatory Council shall be followed in respect of whom the notice of suspension has been issued.

(3) The said notice of suspension shall include the reasons for such suspension and require the Cannabis Licencee to show cause in writing within fourteen days of the issuance of that notice as to why such licence shall not be cancelled.

(4) When Cannabis Licencee neglects the submission of the explanations as required under sub-regulation (3) within the period stipulated for the purpose or upon consideration of the explanations so submitted, the decision of the Regulatory Council shall be notified immediately to such Cannabis Licencee.

(5) If, for any reason, a licence is to be canceled based on the decision of the Regulatory Council, it is the responsibility of the person who held such licence to obey rules of such suspension or invalidation and disobeying them shall be a violation of the provisions of this Code.

(6) (a) A Cannabis licensee shall complete the work pertinent to each licence before the expiry of the period of validity of the licence.

(b) If any amount of Cannabis remains unused prior to the date of expiry of the period of validity of that licence, they shall duly be handed over to the issuing authority.

125. (1) A Cannabis deposit shall be maintained under conditions stipulated under this Code and under direct supervision of the Commissioner-General of Ayurveda. All its activities shall be regulated subject to a procedure to be formulated by the Regulatory Council.

(2) The said procedure shall contain clear criteria pertaining to the maintenance of a Cannabis deposit, requirements to be satisfied, guidelines to be followed, conditions to be stipulated and sources of receipt of Cannabis to that deposit and methodologies of distribution.

(3) Issuing authority shall maintain a disposal store for storing Cannabis handed over for disposal in terms of this Code. All the activities of the disposal store shall be regulated subject to a procedure formulated by the Regulatory Council.

126. (1) Guidelines on encouraging research on products made of herbal Cannabis and their intelligent use based on the results obtained upon using such products may be considered by the Commissioner-General of Ayurveda with recommendations of the Regulatory Council.

(2) The Commissioner-General of Ayurveda may permit, upon recommendations of the Regulatory Council and subject to conditions stipulated under this Code, export, store, keep in possession or sell any constituent of or any derivative extracted from, herbal Cannabis.

127. (1) Action may be taken on any medicine containing Cannabis in terms of the provisions in Poisons, Opium and Dangerous Drugs Ordinance only if the breach of the provisions of this Code relating to the production of such medicine is proved with evidence.

(2) Any premises registered by the Regulatory Council for cultivation, storage, transportation, and export of Cannabis production of any medicine by the use of them, and storing of such medicines and sale of such medicine under this Code may, at any time, be inspected by the Regulatory Council or the Commissioner-General or an officer authorized by the Commissioner-General.

(3) Where any officer authorized for the purposes of any other written law enters any premises registered under this Code, an officer authorized by the Commissioner-General shall accompany such officer.

PART X

APPEALS BOARD

128. (1) The Minister shall establish such number of Appeals Boards (hereinafter referred to as the ‘Appeals Board’) to hear and determine the appeals of any person aggrieved by a decision of the Regulatory Council relating to any matter of under this Code.

(2) An Appeals Board appointed under subsection (1) shall be subject specific and shall be comprised of-

- (a) a retired judge of the Court of Appeal who shall serve as the Chairman of the Appeals Board;
- (b) two persons who possess expertise and experience in the subject matter of the appeal;

(3) Every member of an Appeals Board shall sign Terms of Reference prior to hearing of an appeal assigned to it. An Appeals Board appointed under this Part may hear and determine such number of appeals assigned to it.

(4) Every appointment to an Appeals Board shall be subject to such terms and conditions.

(5) Rules shall be made in respect of the conduct of business of an Appeals Boards.

(6) Members of an Appeals Board shall be paid such allowance as may be determined by the Minister in consultation with the Minister assigned the subject of Finance.

129. An Appeals Board shall have power-

- (a) to hear and determin the appeals of persons who are aggrieved by a decision of the Regulatory Council.
- (b) to call expert opinion and order the appellant or any other party to furnish further information and particulars, as may be required by such Appeals Board.

Part XI

GENERAL PROVISIONS

130. (1) Transportation of every consignment of –

- (a) raw cannabis or opium;
- (b) declared article, substance, drug or an Ayurveda product made using cannabis or opium;
- (c) declared medicinal plants as determined by the Regulatory Council;
- (d) minerals, animal matter, goods; or
- (e) poisons or any dangerous drug as determined by the Regulatory Council,

shall be carried out under the authority of a permit obtained from the Commissioner-General for that purpose.

(2) The volume of a consignment referred to in sub-regulation (1) above, shall be determined by the Commissioner-General in accordance with guidelines issued for the purpose by the Regulatory Council.

(3) purchasing of -

- (a) raw cannabis or opium;
- (b) any declared article, substance, drug or an Ayurveda product made using cannabis or opium;
- (c) declared medicinal plants as determined by the Regulatory Council;
- (d) minerals, animal matter, goods; or
- (e) poisons or any dangerous drugs as determined by the Regulatory Council,

shall be carried out under the authority of a permit obtained from the Commissioner-General for that purpose.

(4) Advertising, promotion or propaganda, directly or indirectly, of any-

- (a) declared article, substance, drug or an Ayurveda product;
- (b) activity; or
- (c) place of business,

under this Code, in any print or electronic media including social media shall be carried out under the authority of a permit obtained from the Commissioner-General in accordance with guidelines issued for the purpose by the Regulatory Council.

(5) Fee for a permit issued under sub regulations (1), (3) and (4) above, shall be determined by the Commissioner-General.

(6) Any regulation by or a licence or permit issued to a government institution under this Code shall be free of charge.

131. Any advertisement, promotion or propaganda made in relation to a matter referred to in paragraph (a) of sub regulation (4) shall not –

- (a) contain any safety claim or therapeutic claim;
- (b) use human beings or animals as models;
- (c) contain any image offensive to the standard of morality or decency prevailing in the Sri Lanka society;
- (d) have any visual or audio presentation of any Ayurveda practitioner, which gives the impression of professional or scientific advice, recommendation or endorsement; or
- (e) contain any other material as determined by the Regulatory Council.

132. (1) A general insurance cover with a coverage at least for the third party shall be obtained in respect of every-

- (a) pharmacy;
- (b) manufactory;
- (c) store;
- (d) sales outlet;
- (e) vehicle engaged in distribution; or
- (f) field of declared medicinal plants,

specified under these regulations.

(2) A special insurance cover as determined by the Regulatory Council shall be obtained in respect of every Cannabis Project specified under these regulations.

PART XII

TRANSITIONAL PROVISIONS

133. (1) The Ayurveda Pharmacies Regulations of 1973, published in *Gazette* Extraordinary No.229/3 of September 6, 1973 are hereby rescinded.

(2) Notwithstanding the repeal of the above regulations, every act or deed previously done thereunder shall be deemed to be valid and in force.

(3) Every Ayurveda pharmacy registered under the above regulations, shall require to be re-registered under the provisions of these regulations, within a period of six months from the appointed date or on the expiry of the licence issued in respect thereof, whichever occurs first.

134. (1) For the avoidance of doubt, it is hereby declared that the provisions of these regulations shall-

- (a) not affect processing of any application submitted for the purpose of obtaining any registration, licence or permit under the Act, which has been made prior to the appointed date;
- (b) not affect the validity of any registration made or licence or permit issued under the Act prior to the appointed date;
- (c) not derogate the powers of the Department of Ayurveda or Commissioner-General, to charge, levy or recover any fee or any expense due on the appointed date in respect of a matter carried out under these regulations; or
- (d) not affect any action or suit pending before a court of law or any decision of a court of law given prior to the appointment date.

(2) Every registration made or licence, or permit issued under the Act prior to the appointed date shall remain valid for their respective periods of validity.

135. For the purposes of these regulations –

“Act” means the Ayurveda Act, No. 31 of 1961;

“Ayurveda” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“an Ayurveda product” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“Ayurveda Community Medical Officer” means a medical officer appointed by the Department of Ayurveda to provide primary health care to the public;

“an underlined drug” means a drug that shall not be substituted;

“Cannabis” means all varieties of Cannabis including Cannabis Sativa L

“Commissioner-General of Ayurveda” means the Commissioner-General of Ayurveda appointed under section 3 of the Ayurveda Act, No. 31 of 1961;

“Department of Ayurveda” means the Department of Ayurveda established under section 2 of the Ayurveda Act, No. 31 of 1961;

“District Secretary” means the District Secretary referred to in the Transfer of Powers (Divisional Secretaries) Act, No. 58 of 1992;

“Environmental Impact Assessment (EIA)” means an environmental impact assessment carried out under Part IVC of the National Environmental Act, No. 47 of 1980;

“Initial Environmental Examination (IEE)” means an initial environmental examination carried out under Part IVC of the National Environmental Act, No. 47 of 1980;

“Environmental Protection Licence (EPL) means an Environmental Protection licence obtained under Part IVA of the National Environmental Act, No. 47 of 1980;

“herbal” means any naturally derived plant or mineral or animal substance or part or extract used for medicinal value;

“Herbal Gardens for Research and Extension” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“Minister” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“medicinal plants” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“Provincial Commissioner of Ayurveda” means the Provincial Commissioner of Ayurveda for the respective Province appointed under section 32 of the Provincial Council Act No.42 of 1987;

“*rasa* medicine” means any medicine produced by using minerals in accordance with the Ayurveda Pharmacopeia for therapeutic purposes;

“registered Ayurveda Practitioner” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“registered pharmacy” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“registered store” shall have the same meaning as assigned to it in section 89 of the Ayurveda Act, No. 31 of 1961;

“residuals of Cannabis” shall mean any part of the Cannabis plant devoid of any kind of active ingredients or compounds.

“State University” includes a university established under the Universities Act, No. 16 of 1978 or by an Act of Parliament.

Schedule I

[Regu. 2]

Part I

DECLARED MEDICINAL PLANTS

Medicinal plants include any Siddha, Unani, *Deshiya Chikithsa* (Traditional) or indigenous medicines, which shall be similar to following medicinal plants used in other countries.

ශාක ඖෂධ නාමලේඛනය / List of Herbal Medicines / மூலிகை மருந்துகளின் பட்டியல்;

අංක/ No./ இல	සිංහල නම/ Sinhala name/ சிங்களப்பெயர்	தேமළு නම/ Tamil name / தமிழ்ப்பெயர்	ඉංග්‍රීසි නම/ English name / ஆங்கிலப்பெயர்	විද්‍යාත්මක නාමය/ Scientific name / அறிவியற்பெயர்
1	අංකෙන්ද	விடுகனலை/முட்டநாரி	Claw Flowered Laurel	<i>Acronychia Pedunculata</i>
2	අක්කපාන	ருணக்கள்ளி/சொடக்கு	cathedral bells	<i>Kalanchoe pinnata</i>
3	අක්කරපට්ට			
4	අක්මැල්ල		Toothache Plant	<i>Acmella oleracea</i>
5	අක්ෂොට	நாட்டு அகரெட்டு	Candle Nut Tree	<i>Aleurites moluccanus</i>
6	අගිලේ	செம்புளிச்சான்		<i>Erythroxylum indicum</i>
		செம்மணத்தி		<i>Erythroxylum sideroxyloides</i>
7	අට්ටිකිකා	அத்தி	Cluster fig	<i>Ficus racemosa</i>
8	අඬනතිරිය	கிலுகிலுப்பை	Rattleweed	<i>Crotalaria atusia</i>
				<i>Crotalaria cuneifolia</i>
9	අත්තන	கருவாமித்தை	Thorn Apple	<i>Datura metel</i>
				<i>Brugmansia suaveolens</i>
		வெள்ளை வளமத்தை		<i>Brugmansia chlorantha</i>
10	අතසි	ஆளிவிதை	Flaxseed.	<i>Linum usitatissimum</i>
11	අතිවිඩයම්	அதிவிடயம்	Aconites,	<i>Aconitum heterophyllum</i>
12	අන්දර	விடத்தலை	Sickle Bush	<i>Acacia cinerea</i>
				<i>Acacia dalea</i>
13	අන්නාසි	அன்னாசி	pineapple	<i>Ananas comosus</i>
14	අනෝදා	வட்டத்துத்தி	country mallow	<i>Abutilon indicum</i>
15	අබ	கடுகு	black mustard	<i>Brassica nigra</i>
16	අබ්බි	அபின்	opium poppy	<i>Papaver somniferum</i>
17	අමු	வரகு	kodo millet	<i>Paspalum scrobiculatum</i>
18	අමුකිකරා	அமுக்கரா	Indian Winter cherry	<i>Withania somnifera</i>

අංක/ No./ இல	සිංහල නම/ <i>Sinhala name/</i> <i>சிங்களப்பெயர்</i>	தேමළ නම/ <i>Tamil</i> <i>name / தமிழ்ப்பெயர்</i>	ඉංග්‍රීසි නම/ <i>English name</i> <i>/ ஆங்கிலப்பெயர்</i>	විද්‍යාත්මක නාමය/ <i>Scientific</i> <i>name / அறிவியற்பெயர்</i>
19	අයිසගුල්			
20	අරත්ත	பேரரத்தை	Lesser galangal Snap Ginger	<i>Alpinia calcarata</i>
21	අරලිය	அலரி	temple tree	<i>Plumeria apiculata</i>
				<i>Plumeria bahamensis</i>
				<i>Plumeria obtusa</i>
22	අරළු	சடுக்காய்	Chebolic Myrobalan	<i>Buceras chebula</i>
				<i>Bucida comintana Blanco</i>
				<i>Terminalia chebula</i>
23	අරළුපිටි			
24	අවරිය (නිල්)	அவுரி	Indigo Blue	<i>Anil tinctoria</i>
				<i>Anil tinctoria</i>
				<i>Indigofera tinctoria</i>
25	අශෝක	அசோகமரம்	Asoka Tree	<i>Jonesia asoca</i>
				<i>Jonesia confusa</i>
				<i>Saraca asoca</i>
26	අෂ්ටවර්ගය			
27	අස්වැන්න	பெரும்புலர்த்தி	Alyce Clover	<i>Alysicarpus cylindricus</i>
				<i>Alysicarpus diversifolius</i>
				<i>Alysicarpus vaginalis</i>
28	අසමෝදගම්	ஓமம்		<i>Brachyapium involucraturum</i>
				<i>Stoibrax involucraturum</i>
				<i>Trachyspermum involucraturum</i>
29	අනු	நுணர்	Noni	<i>Morinda angustifolia</i>
				<i>Morinda aspera</i>
				<i>Morinda citrifolia</i>
30	අඩතෝඩා	ஆடாதோடை	Malabar nut	<i>Adeloda serrata</i>
				<i>Adhatoda adhatoda</i>
				<i>Justicia adhathoda</i>
31	අරට්ටේරිය	வெங்காரை	orange jasmine	<i>Chalcas cammuneng</i>
				<i>Chalcas intermedia</i>
				<i>Murraya paniculata</i>
32	අරටඹ	மா	Sri Lankan mango	<i>Buchanania zeylanica Blume</i>
				<i>Mangifera zeylanica</i>
33	අරුත්තෝර	வண்டுக்கொல்லி	ringworm bush	<i>Cassia alataL</i>
				<i>Cassia alata</i>
				<i>Cassia alata</i>
34	අරුත්තොඩ	தேள்கொடுக்கு	Indian Heliotrope	<i>Eliopia riparia</i>
				<i>Eliopia serrata</i>

අංක/ No./ இல	සිංහල නම/ Sinhala name/ சிங்களப்பெயர்	දෙමළ නම/ Tamil name / தமிழ்ப்பெயர்	ඉංග්‍රීසි නම/ English name / ஆங்கிலப்பெயர்	විද්‍යාත්මක නාමය/ Scientific name / அறிவியற்பெயர்
				<i>Heliotropium indicum</i>
35	ඇත්දෙමට	குமிழ்	Comb Tree	<i>Gmelina arborea</i>
				<i>Gmelina arborea</i>
				<i>Gmelina arborea</i>
36	ඇපල්			
37	ඇඹරළලා	அம்பரல்லா	golden apple	<i>Chrysomelon pomiferum</i>
				<i>Cytheraea dulcis</i>
				<i>Spondias dulcis</i>
38	ඇඹුල් ඇඹිලිය	பளியாரை	creeping woodsorrel.	<i>Acetosella corniculata</i>
				<i>Acetosella corniculata</i>
				<i>Oxalis corniculata</i>
39	ඇඹුල් දොඩම්	புளித்தோடை/நாரத்தை	sour orange	<i>Aurantium ×acre</i>
				<i>Citrus aurantium</i>
40	ඇල්	ஆல்		
41	ඇසතු	அரசு	Sacred Fig Tree	<i>Ficus religiosa</i>
42	ඇසළ (ඇහැළ)		Golden Shower Tree	<i>Bactyriolobium fistula</i>
				<i>Cassia bonplandiana</i>
		சரக்கொன்றை		<i>Cassia fistula</i>
43	ඉකිරි	ஆறுமுள்ளி	holly-leaved acanthus	<i>Acanthus doloarin</i>
				<i>Acanthus ebracteatus</i>
				<i>Acanthus ilicifolius</i>
44	ඉඟිනි ඇට	தேற்றா	Clearing Nut Tree	<i>Strychnos heterodoxa</i>
				<i>Strychnos monosperma</i>
				<i>Strychnos potatorum</i>
45	ඉගුරු	இஞ்சி	Ginger	<i>Amomum angustifolium</i>
				<i>Amomum zingiber</i>
				<i>Zingiber officinale</i>
46	චල් ඉගුරු		Cylindric Ginger	<i>Zingiber cylindricum</i>
47	ඉංගුදි	நஞ்சுண்டான்	Desert date'	<i>Balanites aegyptiaca</i>
48	ඉද්ද	குடசப்பாலை	Artic Snow	<i>Echites antidysentericus</i>
				<i>Nerium antidysentericum</i>
				<i>Walidda antidysenterica</i>
49	ඉපිකාන්			
50	ඉදි	நஞ்சு	Ceylon date palm	<i>Phoenix pusilla</i>
51	ඉඹුල්	மலை இலவம்	Silk Cotton Tree	<i>Bombacopsis quinata</i>
				<i>Bombax aculeatum</i>
				<i>Bombax ceiba</i>
52	ඉරමුසු	நன்னாரி	Indian sarsparilla	<i>Hemidesmus indicus</i>

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				<i>Hemidesmus pubescens</i>
				<i>Hemidesmus indicus</i>
53	කළු ඉරමුසු			
54	ඉරිමේදා	வேல்	sweet acacia	<i>Acacia farnesiana</i>
55	ඉරිවේරිය	இருவேலி		<i>Coleus forskalae</i>
				<i>Coleus personatus</i>
				<i>Plectranthus zatarhendi</i>
56	ඉලුක්	நாணல்	Spear Grass	<i>Arundo epigeios</i>
			Cogon Grass	<i>Calamagrostis lagurus</i>
				<i>Imperata cylindrica</i>
57	ඊතණ		Spear grass	<i>Andropogon allionii</i>
				<i>Andropogon austrocaledonicus</i>
				<i>Heteropogon contortus</i>
58	ඊල්ල	பத்தடி	African Tulip Tree,	<i>Bignonia tulipifera</i>
				<i>Spathodea danckelmaniana</i>
				<i>Spathodea campanulata</i>
59	උක්	சுரும்பு	Sugarcane	<i>Saccharum officinarum</i>
60	උගුරුසේස		governor's plum	<i>Flacourtia afra</i>
				<i>Flacourtia balansae</i>
		சுருமுறுக்கி		<i>Flacourtia indica</i>
61	උඩගත බීජ (සාමදාන)	நேத்திர புண்டு	Narrow-Leaf Blepharis	<i>Acanthus integrifolius</i>
				<i>Acanthus repens</i>
				<i>Blepharis integrifolia</i>
62	උඩක්කා/උදක්කා			
63	උළු		black gram	<i>Azuki muogo</i>
				<i>Phaseolus aureus</i>
		உளுந்து		<i>Vigna mungo</i>
64	උළුපියලි		Three flower beggarweed	<i>Aeschynomene triflora</i>
				<i>Desmodium bullamense</i>
		சிறுபுள்ளடி		<i>Desmodium triflorum</i>
65	උදුම්බර		cluster fig	<i>Ficus racemosa</i>
66	උණ	மூங்கில்	bamboo	<i>Bambusa vulgaris</i>
67	උණකපුරු	இலவங்கம்	Camphor Cinnamon	<i>Cinnamomum capparum</i>
68	උණගොඩ	மூங்கில்	bamboo	<i>Bambusa vulgaris</i>
69	උලාඅරිසි/උළුතලේ	வெந்தயம்	Fenugreek	<i>Trigonella foenum</i>
70	එඩරු/එරඳු		Castor bean	<i>Cataputia major</i>
				<i>Cataputia minor</i>

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		ஆமணக்கு		<i>Ricinus communis</i>
71	එනසාල්	ஏலம்	cardamom	<i>Elettaria cardemomum</i>
72	එල්වඵ		Sour cherry	<i>Prunus cerasus</i>
73	එලඉඹුල්		red silk-cotton tree	<i>Bombacopsis quinata</i>
				<i>Bombax aculeatum</i>
		இலவ மரம்		<i>Bombax ceiba</i>
74	එලපිට්ටක්කා	கீழ்காய் நெல்லி	Stone Breaker	<i>Diasperus debilis</i>
				<i>Phyllanthus boninsimae</i>
				<i>Phyllanthus debilis</i>
75	එරඳු	முள்முருக்கு	Variegated Coral Tree	<i>Chirocalyx candolleanus</i>
				<i>Chirocalyx divaricatus</i>
				<i>Erythrina variegata</i>
76	එලඳු		Eggplant	<i>Melongena esculenta</i>
				<i>Melongena incurva</i>
		சுத்தரி		<i>Solanum melongena</i>
77	එලබින්කඹුරු	அடப்பங்கொடி	Beach Morning Glory,	<i>Ipomoea pes-caprae</i>
78	එකාචේරිය	பாம்புக்களா	Indian Snakeroot	<i>Ophioxylon album</i>
				<i>Ophioxylon obversum</i>
				<i>Rauvolfia serpentina</i>
79	ඔලිඳ	குன்றிமணி	rosary pea	<i>Abrus precatorius</i>
80	ඔලිච්චි		olive tree	<i>Olea europaea</i>
81	ඔල්ලු/ඔලු	அல்லி/வெள்ளாம்பல்	pink water-lily	<i>Castalia pubescens</i>
				<i>Nymphaea devoniensis</i>
				<i>Nymphaea pubescens</i>
82	කසද්දට			
83	කංසා	கஞ்சா	Hemp Marihuana Marijuana Soft hemp True hemp	<i>Cannabis sativa</i>
				<i>Cannabis indica</i>
				<i>Cannabis ruderalis</i>
				<i>Cannabis hybrids</i>
84	කන්කේල	வால்மிளகு	Java pepper	<i>Piper cubeba</i>
85	කකුළුසුඟ	கர்கடகசிஞ்சி	zebrawood	<i>Pistacia integerrima</i>
86	කට්ඵල		bayberry	<i>Myrica nagi</i>
87	කටරොඹු/කටරොඳු		blue pea	<i>Clitoria albiflora</i>
				<i>Clitoria bracteata</i>
		சன்னிக்கொடி		<i>Clitoria ternatea</i>

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88	කටුකරඬු	செம்முள்ளி	hophead Philippine violet	<i>Barleria macrostachya</i>
				<i>Barleria monostachya</i>
				<i>Barleria lupulina</i>
89	කටුකරෝසන	சடுகுடிராகினி	Picrorhiza	<i>Picrorhiza scrophulariiflora</i>
90	කටුපෙඳ		Spiny Naiad.	<i>Najas marina</i>
91	කටුවැල්බටු	கண்டங்கத்தி	Thorny night shade,	<i>Solanum arabicum</i>
				<i>Solanum armatum</i>
				<i>Solanum virginianum</i>
92	කතුරුමුරුංගා	அசத்தி	Scarlet Wistaria Tree	<i>Aeschynomene grandiflora</i>
				<i>Agati grandiflora</i>
				<i>Sesbania grandiflora</i>
93	කනේරු	அரளி	Oleander	<i>Nerion oleandrum</i>
				<i>Nerium carneum</i>
				<i>Nerium oleander</i>
94	කප්පරවල්ලිය	சுற்புரவல்லி	Indian borage	<i>Coleus amboinicus</i>
				<i>Coleus aromaticus</i>
				<i>Plectranthus amboinicus</i>
95	කපු	சுந்தூரம்	tree cotton	<i>Camphor Cinnamon</i>
				<i>Gossypium anomalum</i>
				<i>Gossypium arboreum</i>
96	කපුකිනිස්ස		musk mallow	<i>Abelmoschus abelmoschus</i>
		வெண்டி		<i>Abelmoschus betulifolia</i>
				<i>Abelmoschus moschatus</i>
97	කපුරු		camphor	<i>Camphor Cinnamon</i>
98	කබරස	மலைத்தாமரை		<i>Smilax ceylanica Oken</i>
				<i>Smilax collina Kunth</i>
99	කම්පිල්ල	கடில	kumkum tree	<i>Mallotus philippensis</i>
100	කරඳ		Indian beech	<i>Cajum pinnatum</i>
				<i>Cytisus pinnatus</i>
		புங்கு		<i>Pongamia pinnata</i>
101	කරපිංච	சுறிவேப்பிலை	curry leaf	<i>Bergera koenigii</i>
				<i>Camunium koenigii</i>
				<i>Murraya koenigii</i>
102	කරඹ	சிறுசுளாய்	Conkerberry	<i>Antura edulis</i>
				<i>Antura hadiensis</i>
				<i>Carissa spinarum</i>
103	කරල්සැබෝ	நாயுருவி	Devil's horsewhip	<i>Achyranthes acuminata</i>
				<i>Achyranthes aspera</i>

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				<i>Achyranthes aspera</i>
104	කරවිල	பாகல்	Bitter gourd,	<i>Cucumis argyi</i>
				<i>Cucumis intermedius</i>
				<i>Momordica charantia</i>
105	කරාඬු	கராம்பு	Clove	<i>Caryophyllus aromaticus</i>
				<i>Caryophyllus hortensis</i>
				<i>Syzygium aromaticum</i>
106	කලාපුරු	கோரை	Coco Grass	<i>Chlorocyperus rotundus</i>
				<i>Chlorocyperus salaamensis</i>
				<i>Cyperus rotundus</i>
107	කප්කැමීමේරිය	மணல் தக்காளி	American Black Nightshade	<i>Solanum amarantoides</i>
				<i>Solanum americanum</i>
				<i>Solanum americanum</i>
108	කළුපුරු	கருஞ்சீரகம்	Black cumin	<i>Nigella sativa</i>
109	කළුවා			
110	කසඹිලියා	பெரும் காஞ்சொறி	Hawaii Woodnettle	<i>Boehmeria interrupta</i>
				<i>Boehmeria javanica</i>
				<i>Laportea interrupta</i>
111	කසේරුක/කසේරු		greater club rush	<i>Scirpus grossus</i>
112	කහ/අත්ත		turmeric	<i>Amomum curcuma</i>
				<i>Curcuma brog</i>
		மஞ்சள்		<i>Curcuma longa</i>
113	කහට/වගඵලේ		wild guava	<i>Barringtonia arborea</i>
				<i>Careya orbiculata</i>
				<i>Careya arborea</i>
114	කාකෝලි		Hardy Ginger	<i>Roscoeia purpurea</i>
115	කාමරංගා		star fruit	<i>Averrhoa acutangula</i>
		தாமரத்தை		<i>Averrhoa pentandra</i>
				<i>Averrhoa carambola</i>
116	කාලමේස	சிறியாள்நஞ்சை	green chiretta	<i>Andrographis paniculata</i>
117	කාලදානා			
118	කැකිරි	தும்மட்டி	Muskmelon	<i>Bryonia collosa</i>
				<i>Bryonia collosa</i>
				<i>Cucumis melo</i>
119	කැකුණ	நாட்டு அகரோட்டு	the candlenut	<i>Aleurites ambinux</i>
				<i>Aleurites angustifolius</i>
				<i>Aleurites moluccana</i>
120	කැහිපිත්තන්	பொன் முசுமடை	Indian moon-seed	<i>Clypea burmanni</i>

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				<i>Cocculus burmanni</i> .
				<i>Cyclea peltata</i>
121	කැල	பலாசு	flame-of-the-forest	<i>Butea monosperma</i>
122	කිචාරං	கருணைக்கிழங்கு	Elephant Foot Yam	<i>Amorphophallus campanulatus</i>
				<i>Amorphophallus campanulatus</i>
				<i>Amorphophallus paeoniifolius</i>
123	කිතුල්	சித்துள்	jaggery palm	<i>Caryota urens</i>
124	කිණිහිරි	காட்டு பருத்தி	Buttercup Tree,	<i>Bombax gossypium</i>
				<i>Bombax religiosum</i>
				<i>Cochlospermum religiosum</i>
125	කිරිඅගුණ	குறிஞ்சா	Green Milkweed Climber	<i>Apocynum tiliifolium</i>
				<i>Asclepias viridiflora</i>
				<i>Wattakaka volubilis</i>
126	කිරිබදු	நிலப்பூசணி	Railway Creeper	<i>Apopleumon bignonioides</i>
				<i>Batatas bignonioides</i>
				<i>Ipomoea mauritiana</i>
127	කිකිරිදිය		false daisy	<i>Abasoloa taboada</i>
				<i>Acmella lanceolata</i>
		கரிசிலாங்கண்ணி		<i>Eclipta prostrata</i>
128	කංකුමප්පු			
129	කකුරුමාන්	மதுக்காரை	Emetic nut	<i>Randia dumetorum</i>
130	කඩුමිරිස		orange climber.	<i>Cranzia aculeata</i>
				<i>Cranzia asiatica</i>
				<i>Toddalia asiatica</i>
131	කන්දුරුකිකන්		'Indian frankincense	<i>Boswellia serrata</i>
132	කප්පමේනිය	குப்பைமேனி	Indian mercury	<i>Acalypha canescens</i>
				<i>Acalypha caroliniana</i>
				<i>Acalypha indica</i>
133	කඹුක්		arjun tree	<i>Myrobalanus cuneata</i>
				<i>Pentaptera angustifolia</i>
		மருது		<i>Terminalia arjuna</i>
134	කඹුරු	கழற்சி	Grey Nicker	<i>Bonduc canadense</i>
				<i>Bonduc minus</i>
				<i>Caesalpinia bonduc</i>
135	කුරුඳු		Ceylon cinnamon	<i>Camphora mauritiana</i>
				<i>Camphorina cinnamomum</i>
		கறுவா		<i>Cinnamomum verum</i>
136	කුශතණ	தர்ப்பை	halfa grass	<i>Desmostachya Bipinnata</i>
137	කුර	அறக்கீரை	slender amaranth	<i>Albersia caudata</i>

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				<i>Albersia gracilis</i>
				<i>Amaranthus viridis</i>
138	කෙකටිය		Wavy-edged Aponogeton	<i>Aponogeton echinatus</i>
				<i>Spathium crispum</i>
				<i>Aponogeton crispus</i>
139	කෘමිශස්ත			
140	කෙළිඳ	குடசப்பாலை	Tellicherry bark	<i>Holarrhena antidysenterica</i>
141	කෙළිඳහාල්		Tellicherry bark	<i>Holarrhena antidysenterica</i>
142	කෙසෙල්	வாழை	bananas	<i>Musa paradisiaca</i>
143	කොකුම්පොතු		red mango	<i>Trigonocarpus littoralis</i>
				<i>Kokoona zeylanica</i>
144	කොට්ටම්	கோஸ்டம்	Costus root. It	<i>Saussurea lappa</i>
145	කොට්ටම්බා		Sea Almond	<i>Badamia commersonii</i>
				<i>Buceras catappa</i>
				<i>Terminalia catappa</i>
146	කොට්ඨිලා		Hairy Fig	<i>Covellia assamica</i>
				<i>Covellia courtallensis</i>
		பேயத்தி		<i>Ficus hispida</i>
147	කොත්තමල්ලි	கொத்துமல்லி	coriander	<i>Coriandrum sativum</i>
148	කොතලහිඹුටු		Salacia	<i>Salacia reticulata</i>
149	කෝවක්කා	கொவ்வை	Ivy Gourd	<i>Bryonia acerifolia</i>
				<i>Bryonia alceifolia</i>
				<i>Coccinia grandis</i>
150	කොහිල		Spiny Lasia	<i>Dracontium spinosum</i>
				<i>Lasia aculeata</i>
		கொகில		<i>Lasia spinosa</i>
151	කොහොම්	வேம்பு	neem	<i>Antelaea azadirachta</i>
				<i>Antelaea canescens</i>
				<i>Azadirachta indica</i>
152	කොබෝලීල	வெள்ளை மந்தாரை	white orchid-tree	<i>Bauhinia linnaei</i>
				<i>Casparia acuminata</i>
				<i>Bauhinia acuminata</i>
153	කොරාසානි			
154	කොල්ලම්	கதிர்பச்சை	Indian patchouli	<i>Pogostemon heyneanus</i>
155	කොල්ලු	கொள்ளு	horse gram	<i>Dolichos uniflorus</i>
				<i>Glycine uniflora</i>
				<i>Macrotyloma uniflorum</i>
156	කොළොම්	மஞ்சக் கடம்பு	Yellow teak	<i>Haldina cordifolia</i>
				<i>Nauclea cordifolia</i>

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				<i>Haldina cordifolia</i>
157	කෝන්තාලම්	கடம்பம்	Common Putat	<i>Barringtonia racemosa</i>
158	කෝමාරිකා	கற்றாளை	Medicinal Aloe	<i>Aloe barbadensis</i>
				<i>Aloe barbadensis</i>
				<i>Aloe vera</i>
159	කේවක/විෂදුලි		Spreading Sneez Weed	<i>Artemisia minima</i>
				<i>Artemisia orbicularis</i>
		மரிக்கொழுந்து		<i>Centipeda minima</i>
160	කිමීර කාකෝලි		white Himalayan lily	<i>Lilium polyphyllum</i>
161	ගංඝුරිය		portia tree	<i>Bupariti altissima</i>
				<i>Bupariti populnea</i>
		புவரசு		<i>Thespesia populnea</i>
162	ගජතිප්පිලි	ஆனைத்திப்பலி		<i>Scindapsus officinalis</i>
163	ගම්මාලු/අසන	வேங்கை	Malabar kino	<i>Lingoum marsupium</i>
				<i>Pterocarpus marsupius</i>
				<i>Pterocarpus marsupium</i>
164	ගම්මිරිස්	மிளகு	black pepper,	<i>Muldera multinervis</i>
				<i>Piper aromaticum</i>
				<i>Piper nigrum</i>
165	ගල්කුර	பிண்ணாக்கக் கீரை	the chocolateweed	<i>Geruma subtriloba</i>
				<i>Hibiscus donii</i>
				<i>Melochia corchorifolia</i>
166	ගලිස්			<i>Gardenia crameri</i>
167	ගස්කැප්පෙට්ටිය	தெப்படி		<i>Croton laccifer</i>
168	ගස්පෙනෙල	பணலை	three-leaf soapberry,	<i>Sapindus abstergens</i>
				<i>Sapindus acutus</i>
				<i>Sapindus trifoliata</i>
169	ගැටනෙවුල්	பிராய்	Siamese rough bush	<i>Achymus pallens</i>
				<i>Achymus patens</i>
				<i>Streblus asper</i>
170	ගිරිතිල්ල	சமுத்திரப்பாலை	Elephant creeper	<i>Argyreia populifolia</i>
				<i>Argyreia populifolia</i>
				<i>Argyreia populiolia</i>
171	ගුගුල්	குக்குலு	Indian bdellium-tree	<i>Commiphora wightii</i>
172	ගුරුන්ද		stinkwood	<i>Celtis cinnamomea</i>
				<i>Celtis crenatoserrata</i>
				<i>Celtis timorensis</i>
173	ගොංකැකිරි	மொசுமொசுக்கை	Madras pea pumpkin	<i>Bryonia cordifolia</i>
				<i>Bryonia gracilis</i>

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				<i>Mukia maderaspatana</i>
174	ගොටුකොළ	வல்லாரை	Asiatic pennywort	<i>Centella asiatica</i>
				<i>Centella boninensis</i>
				<i>Centella asiatica</i>
175	ගොඩකදුරු	எட்டி	poison nut,	<i>Strychnos nux-vomica</i>
				<i>Strychnos ovalifolia Stokes</i>
				<i>Strychnos nux-vomica</i>
176	ගොඩමානෙල්	விசமுங்கில்	Wild Onion Milk and Wine Lily	<i>Amaryllis insignis</i>
				<i>Amaryllis littoralis</i>
				<i>Crinum latifolium</i>
177	චාලේමුගු		Janli Almond	<i>Hydnocarpus wightianus</i>
178	චීන අල		China Root	<i>Cacalia bulbosa</i>
				<i>Cacalia maculata</i>
				<i>Gynura pseudo-china</i>
179	ජවාමාංස	ஜடாமாஞ்சில்	spikenard	<i>Nardostachys jatamansi</i>
180	ජයපාල		purging croton	<i>Alchornea vaniotii</i>
				<i>Alchornea vaniotii</i>
		நேர்வாளம்		<i>Croton tiglium</i>
181	ජලවේතස			
182	ජීවක	ஜீவகம்	Jeevak	<i>Microstylis wallichii</i>
				<i>Malaxis acuminata</i>
183	ජීවන්ති	பாலைக்கொடி	Cork Swallow-Wort	<i>Leptadenia reticulata</i>
184	කණහාල්	தினை	Foxtail millet	<i>Alopecurus caudatus</i>
				<i>Chaetochloa germanica</i>
				<i>Setaria italica</i>
185	කඹල		Fukien tea tree	<i>Carmona heterophylla</i>
		குராங்கு வெற்றிலை		<i>Carmona microphylla</i>
				<i>Carmona retusa</i>
186	කල්	பனை	Palmyra Palm	<i>Borassus flabelliformis</i>
				<i>Borassus sundaicus</i>
				<i>Borassus flabellifer</i>
187	කල		Sesame	<i>Anthadenia sesamoides</i>
				<i>Sesamum africanum</i>
		எள்		<i>Sesamum indicum</i>
188	කලිස්		Himalayan silver fir	<i>Abies webbiana</i>
189	කැල්		Wild petunia	<i>Convolvulus obscurus</i>
		சிறுதாளி		<i>Ipomoea obscura</i>
190	තිත්තලවු		bottle gourd	<i>Lagenaria siceraria</i>

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191	තිත්ත වැටකොළ	பேய்பீர்க்கு	Bitter Sponge Gourd	<i>Luffa echinata</i>
192	තිත්තවැල්			
193	තිප්පිලි	திப்பலி	Long pepper	<i>Chavica longa</i>
				<i>Chavica roxburghii</i>
				<i>Piper longum</i>
194	තිප්පිලි මුල්	திப்பலி வேர்	Long pepper	<i>Chavica longa</i>
				<i>Chavica roxburghii</i>
				<i>Piper longum</i>
195	තිබ්බෙටු		turkey berry,	<i>Solanum acanthifolium</i>
				<i>Solanum amoenum</i>
		சுண்டை		<i>Solanum torvum</i>
196	තිබ්බි		Malabar Ebony,	<i>Diospyros biflora</i>
				<i>Diospyros citrifolia</i>
				<i>Diospyros malabarica</i>
197	තිරුස්ත්වාලු	சிவதை	turpeth	<i>Operculina turpethum</i>
198	තිරිඳු	கோதுமை	Common wheat	<i>Triticum aestivum</i>
199	තිලපුෂ්පි/ඩිජිටාලිස්	நரிப்புகையிலை	purple foxglove	<i>Digitalis purpurea</i>
200	තුන්පත් කුරුඳු		Winged Naringi.	<i>Anisifolium alatum</i>
		குருந்து		<i>Hesperethusa alata</i>
				<i>Pleiospermium alatum</i>
201	තුඹ		Ceylon slitwort	<i>Leucasia zeylanica</i>
				<i>Phlomis gracilis</i>
		முடிதும்பை		<i>Leucas zeylanica</i>
202	තුඹ කරවිල	மெழுகுப்பாகல்	spiny gourd	<i>Momordica dioeca</i>
				<i>Momordica hamiltoniana</i>
				<i>Momordica dioica</i>
203	තුචරලා		Indian Valerian	<i>Valeriana harmsii</i>
				<i>Valeriana hygrobia</i>
				<i>Valleriana jatamansi</i>
204	තෙඹු	கோட்டம்	Crepe Ginger	<i>Amomum arboreum</i>
				<i>Amomum hirsutum</i>
				<i>Costus speciosus</i>
205	තෙලකීරිය		Milky Mangrove	<i>Commia cochinchinensis</i>
		அகதி		<i>Excoecaria affinis</i>
				<i>Excoecaria agallocha</i>
206	තේක්ක	தேக்கு	teak	<i>Tectona grandis</i>
207	තේජපත්‍ර	தாளிசபத்திரி	Indian bay leaf	<i>Cinnamomum tamala</i>
208	තොටිල	பாலையுடைச்சி	Midnight Horror	<i>Arthrophyllum ceylanicum</i>
				<i>Arthrophyllum reticulatum</i>

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				<i>Oroxylum indicum</i>
209	ක්‍රායමාණා	கம்பந்திரை	Indian Gentian	<i>Gentian kurroa</i>
210	දදකීරිය	அம்மான்பச்சரிசி	Hairy Spurge	<i>Euphorbia Hirta</i>
211	දළුක්	சதுரக்கள்ளி	antique spurge	<i>Euphorbia antiquorum</i>
				<i>Euphorbia arborescens</i>
				<i>Euphorbia antiquorum</i>
212	දාරුහරිද්‍රා		Indian barberry	<i>Berberis aristata</i>
213	වෙනිවැල්	மரமஞ்சள்	False Calumba	<i>Coscinium maingayi</i>
				<i>Coscinium miosepalum</i>
				<i>Coscinium fenestratum</i>
214	දැත්ත	பொடுதலை	Turkey Tangle Fogfruit	<i>Phyla nodiflora</i>
215	දැව			
216	දියපරඩැල්			
217	දැසමන්	சாதிமல்லிகை	Spanish Jasmine	<i>Jasminum grandiflorum</i>
218	දියමිත්ත	வட்டத்திருப்பி	Velvet Leaf	<i>Cissampelos acuminata</i>
				<i>Cissampelos argentea</i>
				<i>Cissampelos pareira</i>
219	දියමිදෙල්ල		powder-puff tree	<i>Barringtonia apiculata</i>
				<i>Barringtonia caffra</i>
		கடம்பம்		<i>Barringtonia racemosa</i>
220	දියලබු	சுரக்காய்	Bottle Gourd	<i>Adenopus abyssinicus</i>
				<i>Cucumis bicirrrha</i>
				<i>Lagenaria siceraria</i>
221	දියහබරල		hastate-leaved pondweed	<i>Calcarunia hastata</i>
				<i>Carigola hastata</i>
		கருங்குவாயை		<i>Monochoria hastata</i>
222	දුම්මැල්ල	புடோல்	Snake Gourd	<i>Trichosanthes cucumerina</i>
223	දිවුල්	விளா	wood-apple	<i>Anisifolium curvispina</i>
				<i>Anisifolium limonia</i>
				<i>Limonia acidissima</i>
224	දුහුඳු		black oil plant	<i>Alsodeia glabra</i>
		வாளாளுவை		<i>Catha paniculata</i>
				<i>Celastrus paniculatus</i>
225	දෙමට		Asian Bushbeech	<i>Bignonia discolor</i>
		குமிழ்		<i>Bignonia moluccana</i>
				<i>Gmelina asiatica</i>
226	දෙළුම්		pomegranate	<i>Granatum punicum</i>
		மாதுளை		<i>Punica florida</i>
				<i>Punica granatum</i>

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227	දෙහි	எலுமிச்சை	West Indian lime,	<i>Citrus × acida</i>
				<i>Citrus × aurantiifolia</i>
				<i>Citrus aurantifolia</i>
228	දේවදාර	தேவதாறு	deodar cedar	<i>Cedrus Deodara</i>
229	දෙවිදුරු			
230	දොඹ	புன்னை	Alexandrian laurel balltree	<i>Balsamaria inophyllum</i>
				<i>Calophyllum apetalum</i>
				<i>Calophyllum inophyllum</i>
231	දේවිදාලි	பேய்ப்பீர்க்க	Bristly Luffa	<i>Luffa echinata</i>
232	ධන්වයාස			<i>Fagonia cretica</i>
233	නවනන්දි	கொம்புக்கள்ளி	Indian tree spurge	<i>Euphorbia tirucalli</i>
234	නස්නාරං		Panama Orange	<i>Citrofortunella madurensis</i>
				<i>Atalantia hindsii</i>
				<i>Citrus madurensis</i>
235	නා	நாகமரம்	Ceylon Ironwood	<i>Calophyllum nagassarium</i>
				<i>Mesua ferrea</i>
				<i>Mesua ferrea</i>
224	නාපිරිත්තා		Wild Hibiscus	<i>Furcaria furcellata</i>
				<i>Furcaria roxburghii</i>
				<i>Hibiscus furcatus</i>
237	නාරං		Loose -skinned orange.	<i>Citrus crenatifolia</i>
238	නික	நொச்சி	Five-leaved Chaste Tree	<i>Agnus-castus negundo</i>
				<i>Vitex agnus-castus</i>
				<i>Vitex negundo</i>
239	නිදිකුම්බ	தொட்டால்சுரங்கி	sensitive plant	<i>Eburnax pudica</i>
				<i>Mimosa pudica</i>
240	නුග	ஆல்	the banyan	<i>Ficus banyana</i>
				<i>Ficus chauvieri</i>
				<i>Ficus benghalensis</i>
241	නෙරිවිෂ			
242	නෙරොච්චි	சிற்றுநெருஞ்சில்	puncture vine	<i>Hedysarum uniflorum</i>
				<i>Tribulus acanthococcus</i>
				<i>Tribulus terrestris</i>
243	නෙල්ලි	நெல்லி	Indian gooseberry	<i>Cicca emblica</i>
				<i>Cicca macrocarpa</i>
				<i>Phyllanthus emblica</i>
244	නෙළුම්	செந்தாமரை	Indian lotus	<i>Nelumbium album</i>
				<i>Nelumbium asiaticum</i>
				<i>Nelumbo nucifera</i>

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245	ජේපාඩගම්	பற்படாகம்	Two-flowered Oldenlandia	<i>Gerontogea corymbosa</i>
				<i>Hedyotis biflora</i>
				<i>Oldenlandia corymbosa</i>
246	පතඟි		sappanwood	<i>Caesalpinia angustifolia</i>
				<i>Caesalpinia sapang</i>
		பதம்கம்		<i>Caesalpinia sappan</i>
247	පඹුරු		Wild Manarine	<i>Atalantia missionis</i>
				<i>Chilocalyx elliptica</i>
				<i>Pamburus missionis</i>
248	පරිප්පු	துவரை	Pigeon pea,	<i>Cajanus thora</i>
				<i>Cajanus bicolor</i>
				<i>Cajanus cajan</i>
249	පරුෂක		phalsa	<i>Grewia asiatica</i>
250	පලොල්	பாதிரி	Messenger of Spring	<i>Bignonia chelonoides</i>
				<i>Bignonia gratis</i>
				<i>Stereospermum suaveolens</i>
251	පැඟිරිමාන්	சித்திரனெல்லா	Citronella Grass	<i>Andropogon citrosus</i>
				<i>Andropogon confertiflorus</i>
				<i>Cymbopogon nardus</i>
252	පිල	அவுரி	Purple Tephrosia	<i>Cracca purpurea</i>
				<i>Galega purpurea</i>
				<i>Tephrosia purpurea</i>
253	පිතකරෝසන			
254	පුපුල	குப்பிளாய்		<i>Cacalia zeylanica</i>
				<i>Eupatorium zeylanicum</i>
				<i>Vernonia zeylanica</i>
255	පුළිල		South Indian Fig	<i>Ficus caulobotrya</i>
				<i>Ficus infectoria</i>
		கல்-ஆல்		<i>Ficus tsjahela</i>
256	පුවක්	கமுகு	Areca-nut	<i>Areca catechu</i>
				<i>Areca catechu</i>
				<i>Areca catechu</i>
257	පුස්වැල්	யானைக்கொழிஞ்சி	Sea-bean	<i>Adenanthera gogo Blanco</i>
				<i>Entada cirrhosa</i>
				<i>Entada pusaetha</i>
258	පුහුල්	நீற்றுப்புசனி	ash-pumpkin	<i>Benincasa cerifera</i>
				<i>Benincasa cylindrica</i>
				<i>Benincasa hispida</i>
259	පෙනෙල		Balloon Vine	<i>Cardiospermum acuminatum</i>

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		முடக்கத்தான்		<i>Cardiospermum corycodes</i>
				<i>Cardiospermum halicacabum</i>
260	පෙරුමිකායම්	பெருங்காயம்	assa-foetida	<i>Ferula assa-foetida</i>
261	පේර	கொய்யா	Guava	<i>Guajava pumila</i>
262	පොල්	தேங்காய்	coconut	<i>Cocos nucifera</i>
263	පොල්පලා	தேங்காய்பூசீரை	mountain knotgrass	<i>Achyranthes lanata</i>
				<i>Achyranthes lanata</i>
				<i>Aerva lanata</i>
264	ප්‍රසාරණි	முதியார் கூந்தல்	skunkvine	<i>Apocynum foetidum</i>
				<i>Gentiana scandens</i>
				<i>Paederia foetida</i>
265	ප්‍රියංගු	காட்டுக்குமிழ்	Beauty berry	<i>Callicarpa macrophylla</i>
266	බබිචුල	கருவேல்	Egyptian Thorn Babul tree	<i>Acacia arabica</i>
				<i>Acacia nilotica</i>
				<i>Acacia nilotica</i>
267	බ්‍රාන්චි	பிரமி	water hyssop	<i>Bacopa monnieri</i>
268	බට		Reed bamboo	<i>Bambusa stridula</i> Moon
		இருள்		<i>Beesha stridula</i> Munro
				<i>Ochlandra stridula</i>
269	බාකුච්චි	கார்போக அரிசி	Purple Fleabane	<i>Psoralea corylifolia</i>
270	බදාම්	வாதுமை	The almond	<i>Prunus amygdalus</i> Baill
271	බැවිල	பழம்பாசி	common wireweed	<i>Sida resamosa</i>
				<i>Sida arrudiana</i>
				<i>Sida acuta</i>
272	බිංඳුරු			
273	බිංකොහොඹ	நிலவேம்பு	Ground bitter	<i>Ebermaiera pulchella</i>
				<i>Melia pumila</i> Moon
				<i>Munronia pinnata</i>
274	බිංකල්	நிலப்பனை	golden eye-grass	<i>Curculigo brevifolia</i>
				<i>Curculigo densa</i>
				<i>Curculigo orchioides</i>
275	බිංනුග	நஞ்சறுப்பான்	Indian-Ipecacuanha	<i>Tylophora indica</i>
276	බුරුල්ල		Bandicoot Berry Common Tree-Vine	<i>Aquilicia ottilis</i>
				<i>Aquilicia sambucina</i>
				<i>Leea indica</i>
277	බුලත්	வெற்றிலை	Betel	<i>Piper betle</i>
278	බුඵ	தானீறி	Bedda nut tree	<i>Buceras bellirica</i>
				<i>Myrobalanus bellirica</i>

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				<i>Terminalia bellirica</i>
279	බෙලි	வில்வம்	bael	<i>Aegle marmelos</i>
				<i>Belou marmelos</i>
				<i>Aegle marmelos</i>
280	බේදනම්			
281	බෝල		Myrrh	<i>Commiphora myrrha</i>
282	මදුවිය	ஆனைக் குண்டுமணி	Red Bead Tree	<i>Adenanthera gersenii</i>
				<i>Adenanthera polita</i>
				<i>Adenanthera pavonina</i>
283	මදනකාම		Portwine Magnolia	<i>Liriopsis fuscata</i>
				<i>Magnolia annonifolia</i>
				<i>Magnolia fuscata</i>
284	ගොටුකොළ	வல்லாரை	Asiatic pennywort	<i>Centella asiatica</i>
				<i>Centella boninensis</i>
				<i>Centella asiatica</i>
285	මදුරුතලා	துளசி	holy basil	<i>Geniosporum tenuiflorum</i>
				<i>Lumnitzera tenuiflora</i>
				<i>Ocimum tenuiflorum</i>
286	මලින		Fire Flame Bush	<i>Acistoma coccineum</i>
				<i>Grislea punctata</i>
				<i>Woodfordia fruticosa</i>
287	මයිල	ஆத்தி	the bidi leaf tree	<i>Bauhinia parviflora</i>
				<i>Bauhinia racemosa</i>
				<i>Buhinia racemosa</i>
288	මස්බැද්ද	சிறுகுறிஞ்சா	Australian cowplant	<i>Gymnema sylvestre</i>
289	මස්වැන්න		Dragon's Scale Fern	<i>Drymoglossum heterophyllum</i>
290	මසන්		Common jujube	<i>Paliurus mairei</i>
		இலந்தை		<i>Rhamnus jujuba</i>
291	මහදුරු	பெருஞ்சீரகம்	common fennel	<i>Foeniculum vulgare</i>
292	මහරි	வாகை	East Indian walnut	<i>Albizia lebbek</i>
293	මාදං	நாவல்	Java Plum,	<i>Syzygium cumini</i>
294	මාසක්කා			
295	මානෙල්	ஆம்பல்	blue lotus	<i>Nymphaea nouchali</i>
296	මැඩහතු	உத்தமபாகாணி	the trellis-vine	<i>Pergularia daemia</i>
297	මිංචි	புதினா	mint	<i>Mentha piperita</i>
298	මිදි			<i>Remna latifolia</i>
299	මුද්දරස්පලම්	திராட்சை	Common grape vine	<i>Vitis vinifera</i>
300	මිගස්	இலுப்பை	butter tree	<i>Madhuca longifolia</i>
301	මුං ඇට	பயறு	green gram	<i>Vigna radiata</i>

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302	මුවැන්න			
303	මුකුණුවැන්න	පොන්නාங்கාணி	sessile joyweed	<i>Alternanthera sessilis</i>
304	මුඩමන	කොට්ටාය්කරන්නෙ	East Indian globe thistle	<i>Sphaeranthus indicus</i>
305	මුරාමංසි			
306	මුරුගා	ධුරුඝක	drumstick tree	<i>Moringa oleifera</i>
307	මුරුවා	පෙරුඝුකුරිච්ඡා	Rajmahal Hemp	<i>Marsdenia tenacissima</i>
308	මුවකිරිය			
309	මුනමල්	මසිඞ්	bullet wood	<i>Mimusops elengi</i>
310	මොණරකුඩුමිඩිය	නෙය්ස්සිට්ටි	Little Iron Weed	<i>Vernonia cinerea</i>
311	මොර	සෙම්පුවම්	dragon's eye	<i>Dimocarpus longan</i>
312	යක්බේරිය	කිලුකිලුට්ටා	the blue rattlepod	<i>Crotalaria verrucosa</i>
313	යකවනස්ස	රණපේරි	Christmas candlestick	<i>Leonotis nepetiifolia</i>
314	යකිනාරං	පේයුතුරුත්තු	Ceylon Atalantia	<i>Atalantia ceylanica</i>
315	යව	බාර්ලිකොත්තම	Barley	<i>Hordeum vulgare</i>
316	යවාස	කාච්ඡොරි	camelthorn	<i>Alhagi Camelorum</i>
317	ධන්වයාස	තුලකනාරි	Virgin's Mantle	<i>Fagonia cretica</i>
318	රට ඉඳි	පේරිත්ත	Date Palm	<i>Phoenix dactylifera</i>
319	රටතෝර	බණ්ණකොල්ලි	candle bush	<i>Cassia alata</i>
320	රණවරා	ආවාර	Tanner's Cassia	<i>Cassia auriculata</i>
321	රත්කිහිරිය		Red Cutch	<i>Acacia chundra</i>
322	රත්තිවුල්	සෙඝ්කොට්ටිවෙලි	Scarlett Leadwort	<i>Plumbago indica</i>
323	රත්මල්		scarlet jungle flame	<i>Ixora coccinea</i>
324	රත්තලුන්	සෙච්ඡත්තනම්	red sandalwood	<i>Pterocarpus santalinus</i>
325	රතුලූනු	බෙඝ්කායම්	Red Onion	<i>Allium cepa</i>
326	රත්කිරිගොකටු	පිරිමත්තණ්ඩු	Mexican poppy	<i>Argemone mexicana</i>
327	ලූනලු			
328	විල්ලුනු			
329	වල්පසකිඳ			<i>Zanonia indica</i>
330	රඹුක්	සෙඝ්කරුම්පු	hardy sugar cane	<i>Saccharum arundinaceum</i>
331	රම්මනිස්ස	නාය්වෙභෙ	Asian spiderflower	<i>Cleome viscosa</i>
332	රසකිඳ	ඒත්තිල්	heart-leaved moonseed	<i>Tinospora cordifolia</i>
333	රාජමාළ	තුට්ටාට්ටා	black-eye pea	<i>Vigna unguiculata</i>
334	රුක්ඳලුණ	අලුතිච්ඡිල්	sage-leaved alangium	<i>Alangium salviifolium</i>
335	රුක්ඳත්තන	ඉඞ්ලිපොට්ටා	Indian Pulai	<i>Alstonia scholaris</i>
336	රුක්මල් (ප්‍රියංගු)		Malaboda tree	<i>Horsfieldia iryagedhi</i>
337	රුඳන්ති	මරිඝ්කොට්ටු	Rosin weed	<i>Cressa cretica</i>
338	රුඳන්තික		Rosin weed	<i>Cressa cretica.</i>
339	රුමස්ති			

අංක/ No./ இல	සිංහල නම/ <i>Sinhala name/</i> <i>சிங்களப்பெயர்</i>	දෙමළ නම/ <i>Tamil</i> <i>name / தமிழ்ப்பெயர்</i>	ඉංග්‍රීසි නම/ <i>English name</i> <i>/ ஆங்கிலப்பெயர்</i>	විද්‍යාත්මක නාමය/ <i>Scientific</i> <i>name / அறிவியற்பெயர்</i>
378	සාරණ	மூக்கிரட்டை	spreading hogweed	<i>Boerhavia diffusa</i>
379	සාලමිටු			
380	සැවැන්දරා	வெட்டிவேர்	vetiver	<i>Vetiveria zizanioides</i>
381	සින්කෝනා	சிங்கோனா	Cinchona	<i>Cinchona officinalis</i>
382	සියඹලා	புளி	Tamarind tree	<i>Tamarindus indica</i>
383	සිරිතේක්කු	சிறுதேக்கு	Blue-flowered Glory Tree	<i>Clerodendrum serratum</i>
384	සිරිල			
385	සිරිවටු			
386	සිවිය		Cubeb	<i>Piper chavya</i>
387	සුදුදුරු	நற்சீரகம்	Cumin	<i>Cuminum cyminum</i>
388	සුදුඳුනු	உள்ளி	Garlic	<i>Allium sativum</i>
389	සුදුහඳුන්	வெண்சந்தனம்	white sandalwood	<i>Santalum ellipticum</i>
				<i>Santalum myrtifolium</i>
				<i>Santalum album</i>
390	සෙංකොට්ටං	சேராங்கொட்டை	marking nut	<i>Semecarpus anacardium</i>
391	සෙනෙහෙකොළ	நிலவாகை	Tinnevelly Senna	<i>Cassia senna</i>
392	සේපාලිකා	பவளமல்லிகை	Night Blooming Jasmine	<i>Nyctanthes arbor-tristis</i>
393	හන	சணல்	brown hemp,	<i>Crotalaria juncea</i>
394	හඬුෂා		common junipe	<i>Juniperus communis</i>
395	හබරල		upright elephant ears,	<i>Alocasia macrorrhizos</i>
396	හරංකහ	புலான் கிழங்கு	white turmeric	<i>Curcuma zedoaria</i>
397	හරේනුක		Lurid Himalayan Monkshood	<i>Aconitum novoluridum</i>
398	හල්	குங்கிலியம்		<i>Vateria copallifera</i>
399	හාතාවාරිය	சாத்தாவாரி	Spiny Asparagus	<i>Asparagus racemosus</i>
400	හික්	ஓதி	Indian ash tree	<i>Lannea coromandelica</i>
401	හිඳුරුපට්ටල්		Incha Palinja Soap bark	<i>Acacia caesia</i>
402	හිඳුරුපියලි		Spiked ginger lily	<i>Hedychium spicatum</i>
403	හීං තිදිකුම්බා		Reinwardt's Tree Plant	<i>Biophytum reinwardtii</i>
404	හීරැස්ස	பிரண்டை	veldt grape	<i>Cissus quadrangularis</i>
405	හොඩල	தானிக்கீரை	Hondala	<i>Adenia hondala</i>
406	හොර			<i>Dipterocarpus zeylanicus</i>
407	පද්මකාශ්ට		Himalayan wild cherry.	<i>Prunus cerasoides</i>

බනිජ ඖෂධ ලැයිස්තුව/ List of Mineral Medicines /கனிம மருந்துகளின் பட்டியல்

අංක/ No./ இல.	සිංහල නම/ Sinhala name / சிங்களப் பெயர்
1	අඳුන්කැට
2	අම්බර
3	අඵහුණු
4	කළු ඊයම්
5	කළු මැටි
6	කසිස්
7	කාන්තපාෂාණ
8	කිරිගරුඩ
9	කිරිමැටි
10	බර්පුර
11	ගල් අඟුරු
12	ගල් නහර
13	ගල් මද
14	ගෙන්දගම්
15	ගොමේද
16	ගොඊපාෂාණම්
17	චන්ද්‍රකාන්ත
18	චපල
19	තඹ
20	තලාතුම්නිරන්
21	දියමන්ති
22	දෝරවැලි
23	නවසාරම්
24	නීලමාණිකා
25	පල්මානික්කම්
26	පලිඟු
27	පුස්කර
28	පුෂ්පරාග
29	පේරෝජක
30	බළල්ලුණු
31	මනෝසීල

අංක/No./ இல.	සිංහල නම/Sinhala name / சிங்களப் பெயர்
32	මාණිකය (රතුකැට)
33	මැටි
34	මුහුදු ලුණු
35	මාද්දාරශාංග
36	යකඩ
37	යබොර
38	යවකර ලුණු
39	රත්රන්
40	රටහුණු
41	රසදිය
42	රාජාවර්ත
43	රිදී
44	රිදීකුත්ථ
45	රෝමක ලුණු
46	ලෝකඩ
47	වැලි
48	විමල
49	වියන්දුඹුලු
50	වීදුරුවැලි
51	වෙඩිලුණු
52	වෛක්‍රාන්ත
53	වෛරොඩි
54	සවිඳ ලුණු
55	සවුක්කරම්
56	සාදිලිංගම්
57	සිංදුර
58	සිවංගුරු
59	සීනක්කාරම්
60	සුදු ඊයම්
61	සුවස ලුණු
62	සූර්යකාන්ත පාෂාණ
63	ස්වජ්ක්ෂාර
64	ශිලාජකු
65	හිරියල්
66	හුණු

Etc.,

සත්ව ඖෂධ නාම ලේඛනය / List of Veterinary Medicines / கால்நடை மருந்துகளின் பட்டியல்

අංක/No./ இல.	සිංහල නම/Sinhala name / சிங்களப் பெயர்
1	ඇට්‍රිකුකුලා
2	ඇතා
3	ඇත් දළ
4	ඉදිබුලා
5	උරුලු සට්ටන්
6	එළගවයා
7	කඟවේණා
8	කස්තුරි
9	කිරි
10	එළකිරි
11	එළකිරි
12	තනකිරි
13	මිකිරි
14	කේජු
15	ගැඩවිලා
16	ගිතෙල්
17	ගෝරෝවන
18	එළගිතෙල්
19	තලගොයා
20	දිමියා
21	දිකිරි
22	දී පෙරලි දිය
23	බිම්මුල්
24	මස්
25	එළ මස්
26	උතුරු මස්
27	කුකුළු බිත්තර
28	ඇට්‍රිකුකුළු බස්නය
29	කළුකිකිලි බස්නය
30	තෝරු බස්නය
31	සස බස්නය
32	මී ඉටි
33	මී ගවයා

අංක/No./ இல.	සිංහල නම/Sinhala name / சிங்களப் பெயர்
34	මී පැණි
35	මී මින්නා
36	මුවා
37	මුත්‍ර
38	මොණරා
39	ගෝමුත්‍ර
40	මෝරු
41	ලාකඩ
42	විෂ
43	සර්ප විෂ
44	වෙඩිරු
45	හංසයා
46	හාවා
47	කවඩි
48	පබළු
49	මුත්‍ර
50	මුත්‍රබේලිකටු
51	මුහුදු පෙණ
52	හක්

Etc.,

Part II

DECLARED ARTICLES, SUBSTANCES AND DRUGS

Articles, substances and drugs include any Siddha, Unani, ***Deshiya Chikithsa*** (Traditional) or indigenous medicines, which shall be similar to following articles, drugs and substances used in other countries.

Articles

Any instrument, apparatus, appliance, software material or any other article, whether use single or in combination including the software necessary for its proper application intended by the manufacture using on human beings.

- Medical technologies (WHO Medical device technical series)
- Custom-made devices
- Assistive devices
- Cosmetic devices
- Personal protective equipment
- ICT Products
- IVDs

Ayurveda Classification

යන්ත්‍ර <i>Blunt instruments (Yantras)</i>	ශස්ත්‍ර <i>Sharp instruments (Sastras)</i>
1. ස්වස්තික යන්ත්‍ර Cruciform instruments (Svastika yantras) 24	1. මණ්ඩලාග්‍ර ශස්ත්‍ර Circular knife (Mandalagra sastra)
2. සන්දංශ යන්ත්‍ර Dissecting forceps or tongs (Sandansha yantras) 2	2. බරපත්‍ර ශස්ත්‍ර Bone saw (Karapatra)
3. තල යන්ත්‍ර Spoon shaped instruments (Tala yantras) 2	3. වෘද්ධිපත්‍ර ශස්ත්‍ර Scalpel (Vrddhipatra)
4. නාඩි යන්ත්‍ර Tubular instruments (Nadi yantras) 20	4. වඛ ශස්ත්‍ර Nail parer (Nakhasastra)
5. ශලාක යන්ත්‍ර Rod like instruments (Shalaka yantras) 28	5. මුද්‍රික ශස්ත්‍ර Ring knife (Mudrika)
	6. උත්පලපත්‍ර ශස්ත්‍ර Lancet (Utpalapatra)
	7. අර්ධධාරා ශස්ත්‍ර Single edged knife (Ardhadhara)
	8. සූචි ශස්ත්‍ර Suturing needle (Suci sastra)
	9. කුසපත්‍ර ශස්ත්‍ර Bistoury (Kusapatra)
	10. අතිමුඛ ශස්ත්‍ර Hawk bill scissors (Atimukha)
	11. සරාරිමුඛ ශස්ත්‍ර (Scissors (Sararimukha)

යන්ත්‍ර <i>Blunt instruments (Yantras)</i>	ශස්ත්‍ර <i>Sharp instruments (Sastras)</i>
	12. අන්තරමුඛ ශස්ත්‍ර curved bistoury (Amataramukha)
	13. ත්‍රිකුර්චක ශස්ත්‍ර Three edged knife (Trikurcaka)
	14. කුතාරිකා ශස්ත්‍ර Chisel (Kutharika)
	15. ව්‍රිහිමුඛ ශස්ත්‍ර Trocar (Vrihimukha)
	16. අරා ශස්ත්‍ර Awl (Ara)
	17. වේතසපත්‍රක ශස්ත්‍ර Scalpel of different type (Vetasapatraka)
	18. බද්දි ශස්ත්‍ර Sharp hook (Badisa)
	19. දන්තශංක ශස්ත්‍ර Tooth scaler (Dantasanku)
	20. ඒෂණි ශස්ත්‍ර Sharp probe (Esani sastra)

Substances and Drugs

- Raw/ crude drugs
- Extracts
- Compound formulations
- Herbo mineral formulations
- *Kasaya*
- *Kvatha*

- *Asava and Arista*
- *Arka / Avaleha / Leha / Paka*
- *Kvatha Chuma*
- *Guggulu*
- *Chuma*
- Granules
- *Ghrita/taila*
- *Lavana ksara*
- *Lepa*
- *Vati and Gutika / Pilla*
- *Netra bindu and Anjana*
- *Parpati*
- *Pisti*
- *Mandura*
- *Rasayoga*
- *Lauha*
- ***Dhoopa / Dhooma***
- *Bhasma*
- Granules
- Extract powders (Powdered extracts)

- Syrup / Suspension
- Fluid extracts
- Oral emulsions
- Herbal oils
- Aromatic waters
- Ointment / cream / lotion

- Capsule
- Caplets
- Tablets
- Pills
- Herbal toothpaste
- Herbal soap
- Herbal injectable forms
- herbal cosmeceuticals
- Herbal inhalers
- Confectioneries
- Dusting powder
- Suppositories/ pessaries
- lozenges
- gargles/ mouth wash/ mouth paint
- medicinal sprays
- plasters Etc.,

Schedule II

Form A

Application for Registration / Renewal of a Manufactory of Ayurveda Article, Substance or Drug

For official use only
File No/ Registration No: -
Money order/ Receipt No: -
Date of issue: -
Signature of subject officer: -

First time registration ☐

Annual registration ☐

(Put the “✓” sign in the appropriate box.)

1. Applicants' details

1.1	Name of applicant: -
1.2	Address: -
1.3	National Identity card/ Passport / Driving license No: -
1.4	Profession: -
1.5	Post at drug manufactory: -
1.6	Telephone No: - Fixed: - Mobile: -
1.7	Email address: -

2. Details of drug company/ Institution

2.1	Name of company/ Institution: -
2.2	Address: -
2.3	Telephone number: -
2.4	Email address: -
2.5	Business registration certificate number: - Date of issue: -
2.6	If registered under Department of ayurveda, Registration certificate no: - Date of issue: -
2.7	Date of establishment of company/Institution: -

3. Details of manufactory (Pharmacy)

3.1	Name of manufactory : -
3.2	Address: -

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3.3	Province: - District: - Divisional secretariate: - Grama Niladhari Division and No: -
3.4	Rate No: -
3.5	Telephone No: -
3.6	Email address: -
3.7	If registered under department of ayurveda, Registration certificate no: - Date of issue: -
3.8	Date of establishment of drug manufactory: -

4. Details of consultant physician

4.1	Full name of physician: -			
4.2	Ayurveda medical council registration No: -		General/Special	
	Date of Registration: -		Date of renewal: -	
4.3	Registration Section:- Number of Special registration (If availa			
4.4	Address: -			
4.5	Telephone no: -	Fixed: -	Mobile: -	
4.6	Email address: -			

5. Details of product

5.1	Name of the product according to ayurveda/ Siddha/Unani/Traditional medicines pharmacopeia: -						
5.2	Trade name of the product: -						
5.3	Nature of product: -						
	Medicine		Diet and nutritional supplementary products		Cosmetic products		Devices
5.4	Therapeutic indications/uses of product: -						
5.5	If you have obtained registration for this product under department of ayurveda: registration number first-time: - Date: - registration number last -time: - Date: -						
5.6	Has any research been done on this product in Sri Lanka after first registration? (yes/no) If yes, briefly describe the results (attach a copy of the report/publication)						

6. If the product is a medicine,

6.1	If the product is medicine, mention the Name of text/page/recipe no: - Please mention whether this medicine obtained from Classical texts/ pharmacopeia/Traditional base											
6.2	Is it a new product, mention the recipe (to be prepared separate document): - Certificate of legal provision in the relevant country: -											
6.3	Dose and dosage: -											
6.4	Route of administration: -											
	External application		Orally		Inhalation		Vasthi		Nasya		others	

7. If the product is exported, give details

Serial No.	category (Raw Materials/ Medicines/ Packaging material/ Preservatives/ Excipients etc.)	Types of Raw Materials/ Medicines/ Packaging material/ Preservatives/ Excipients) to be exported	Countries expected to export	Name and address of the foreign company	Export Quantity (Kg / Unit) last year	Expected export quantity for next year (Kg / units)

8. Details of imported material used in the preparation of production (If available)

8.1	Whether imported materials are used in the preparation of medicine?	Yes/No
8.2	If yes, Name of institution issued license for importation of materials	
8.3	License No: - Date: -	
8.4	Country of import	
8.5	Name of the raw material manufacturer in relevant country	
8.6	Address	
8.7	List of imported raw materials (relevant documents to be submitted)	
8.8	Has any processed products been imported to be used as a raw material in the product?	Yes/No
8.9	If yes, name / names of processed products imported as raw materials	

8.10	Has separate approval obtained from Department of Ayurveda to import such product?	Yes/No
8.11	If yes, the referral letter number Date: -	

9. Details whether raw materials included in this product are restricted by the rules and regulations imposed in Sri Lanka:

Serial No.	Type of ingredients restricted by law	District and Divisional Secretariat where the relevant raw materials are procured	Address of the place of procurement of the relevant raw materials	License number and date of approval for the use of the relevant ingredients	Quantity of raw materials used in above product last year (Kg / Unit)	Quantity expected to be procured in next year (Kg / Unit)

10. Details of preservatives / excipients of the product (If available):

Serial No.	Type of preservatives/ excipients contained in the product	Quantity and percentage per unit to be used for the above product	Amount of material used last year for the above product (Kg / Unit)	Amount expected to be procured in next year (Kg / Unit)

11. Certificate of Consultant Physician

I,(Name) holder of National Identity card No.....of(address) the consultant Ayurvedic medical practitioner of the above named institution/ayurvedic drug manufacturing company hereby certify that I abide by the Registered Ayurvedic Medical Practitioners Rules No. 1 of 2014 made under the Ayurvedic Act No .31 of 1961 and that I am legally responsible for standard of the products and in connection therewith manufactured under my supervision and that I will provide my services full time and that I will be held responsible and will be responsible personally for the correctness of all information disclosed under No. 4 hereto

Signature of ayurveda practitioner: -

Date: -

Official Seal

12. Declaration of Applicant: -

I hereby certify that the information given in the application is true and correct. I am personally responsible and liable for the accuracy of all information furnished herein.

Signature of applicant: -

Date: -

Official Seal

Official use only

Money Order No: -

Receipt No: -

Document submitted date: -

Note :Complete /☐ Incomplete / ☐Forged document / ☐Complaints ☐

Name and signature of person received: -

Note: Completed check-list, document containing all necessary details and product samples, equivalent to market release samples as required, should be handed over along with this application by the consulting Ayurvedic practitioner to the technical division of the Department of ayurveda on specified dates.

Form C

Application for Import and Export Registration / Renewal
Ayurveda Products, Ingredients, Packing Material, Preservatives, Excipients

For official use only
Document No: -
Receipt No: -
Date of issue: -
Signature of subject Officer: -

First time registration ☐ **Import** ☐ **Business Registration for Import/ Export** ☐

Annual registration ☐ **Export** ☐ **Product/ article/ substance/ drug** ☐

1. Details of applicant

1.1	Name of applicant: -		
1.2	Address: -		
1.3	NIC No/Passport No/Driving License No: -		
1.4	Profession: -		
1.5	Post of applicant within relevant institution/Business: -		
1.6	Telephone No: -	Fixed: -	Mobile: -
1.7	Email address: -		

2. Details of consultant physician

2.1	Full name of physician: -		
2.2	Ayurveda medical council registration no: -		General <input type="checkbox"/> Special <input type="checkbox"/>
	Date of Registration: -		Date of renewal: -
2.3	Section of special registration: -		
2.4	Personal address: -		
2.5	Telephone no: -	Fixed: -	Mobile: -
2.6	Email address: -		

3. Import/Export details

(If certified copies are attached, mark “✓” in the relevant box)

3.1	Nature of the Import/Export business	A sole proprietorship	<input type="checkbox"/>
		A joint venture	<input type="checkbox"/>
		A company	<input type="checkbox"/>

3.2	Type of goods expected to be imported	Ayurveda products	<input type="checkbox"/>
		Raw Material	<input type="checkbox"/>
		Packaging	<input type="checkbox"/>
		Preservatives	<input type="checkbox"/>
		Excipients	<input type="checkbox"/>
3.3	Type of goods expected to be exported	Ayurveda products	<input type="checkbox"/>
		Raw Material	<input type="checkbox"/>
		Packaging	<input type="checkbox"/>
		Preservatives	<input type="checkbox"/>
		Excipients	<input type="checkbox"/>
3.4	Have you obtained approval from the Import and Export Control Department for the import/export of the above goods?		Yes/No
3.5	Have you obtained approval from Export Development Board approved for exporting the above goods?		Yes/No
3.6	Have you obtained a Tax Identification No issued by the Inland Revenue Department?		Yes/No
3.7	Have the above goods been registered with the Sri Lanka Customs for import/export?		Yes/No
3.8	Has approval been obtained from Department of Ayurveda for import/export of the above goods?		Yes/No
3.9	Sample Import Permit No. issued by Department of Ayurveda:		
	Date of issue:		

4. Details of the company/ business

4.1	Name of Company/Business: -	
4.2	Address: -	
4.3	Telephone No: -	
4.4	Email address: -	
4.5	Number of Company/Business Registration Certificate: - Date of issue: -	
4.6	Department of Ayurveda Registration Certificate No: - Date of issue: -	
4.7	Date of establishment of Company/Business	

5. Details of the goods to be imported

Serial No.	category (Raw Materials/ Ayurveda products/ Packaging/ Preservatives/ excipients etc.)	Types of raw materials/ Ayurveda products / packaging/ preservatives/ excipients expected to be imported	Country expected to be import	Name and address of foreign company	Quantity of imports during last year (Kg / Unit)	Expected Quantity of imports next year (Kg / Unit)

6. Details of the goods to be exported

Serial No.	category (Raw Materials/ Ayurveda products / Packaging/ Preservatives/ excipients etc.)	Types of raw materials/ Ayurveda products / packaging/ preservatives/ excipients expected to be imported	Country expected to be export	Name and address of foreign company	Quantity of exports during last year (Kg / Unit)	Expected Quantity of imports next year (Kg / Unit)

7. Certified copies of attachments

(If certified copies are attached put “✓” mark in the relevant column)

7.1	Photocopy of the document approved by the Import and Export Control Department for import/ export of the above goods	
7.2	Photocopy of the document approved by the Export Development Board for export of the above category/categories	
7.3	Photocopy of the document obtaining a Tax Identification Number issued by the Inland Revenue Department	
7.4	Photocopy of the document registered with Sri Lanka Customs for import/export of the above goods	
7.5	Photo copy of the said document if prior approval has been obtained from the Department of Ayurveda for import/export of the above goods	
7.6	Detailed quality assurance report of imported goods	
7.7	Certificate of origin of the imported product	
7.8	Photocopy of Foreign Sales Agreement	
7.9	Photocopy of Company/Business Registration Certificate of the Foreign Company/ Business	
7.10	Photocopy of Sample Import Permit issued by Department of Ayurveda	

8. Declaration of applicant: -

I hereby certify that all information presented herein is true and correct and I am personally responsible and liable for the accuracy of said information.

Signature of applicant: -

Date: -

Official seal of company

Official use only

Money Order No.: -

Receipt No.: -

Document submitted date: -

Note: Complete ☐ / Incomplete ☐ / Forged document ☐ / Complaints ☐

Name and signature of person received: -

Note: Completed check-list, document containing all necessary details and product samples, equivalent to market release samples as required, should be handed over along with this application by the consulting Ayurvedic practitioner to the technical division of the Department of ayurveda on specified dates.

Form D

APPLICATION FOR LICENCE TO IMPORT AN AYURVEDA PRODUCT/ RAW MATERIAL/ PACKING MATERIAL/ PRESERVATIVE/ EXCIPIENT AS SAMPLES FOR TEST/ EXAMINATION/ ANALYSIS/ CLINICAL TRIAL/ DISTRIBUTION AS PHYSICIAN'S SAMPLES

For official use only
Document No: -
Receipt No: -
Date of issue: -
Signature of subject Officer: -

I/ We
of hereby apply for a licence to import from
..... the Ayurveda product/ Raw material/ Packing
material/ Preservative/ Excipient specified below as samples for the test/ examination/ analysis/ clinical trial/ distribution as
physician's samples.

1. Details of applicant

1.1	Name of applicant: -			
1.2	Address: -			
1.3	NIC No/Passport No/Driving License No: -			
1.4	Profession: -			
1.5	Post of applicant within relevant institution/Business: -			
1.6	Telephone No: -	Fixed: -	Mobile: -	
1.7	Email address: -			

2. Details of consultant physician

2.1	Full name of physician: -			
2.2	Ayurveda medical council registration no: -		General <input type="checkbox"/> Special <input type="checkbox"/>	
	Date of Registration: -		Date of renewal: -	
2.3	Section of special registration: -			
2.4	Personal address: -			
2.5	Telephone no: -	Fixed: -	Mobile: -	
2.6	Email address: -			

3. Import details

(If certified copies are attached, mark "✓" in the relevant box)

3.1	Nature of the Import business	A sole proprietorship	<input type="checkbox"/>
		A joint venture	<input type="checkbox"/>
		A company	<input type="checkbox"/>

3.2	Type of goods expected to be imported	Ayurveda products	<input type="checkbox"/>
		Raw Material	<input type="checkbox"/>
		Packaging	<input type="checkbox"/>
		Preservatives	<input type="checkbox"/>
		Excipients	<input type="checkbox"/>
3.3	Have you obtained approval from the Import and Export Control Department for the import/export of the above goods?		Yes/No
3.4	Have the above goods been registered with the Sri Lanka Customs for import/export?		Yes/No

4. Details of the company/ business

4.1	Name of Company/Business: -	
4.2	Address: -	
4.3	Telephone No: -	
4.4	Email address: -	
4.5	Number of Company/Business Registration Certificate: - Date of issue: -	
4.6	Department of Ayurveda Registration Certificate No: - Date of issue: -	
4.7	Date of establishment of Company/Business	

5. Details of the goods to be imported

5.1	Name of Company/Business: -	
5.2	Address: -	
5.3	Telephone No: -	
5.4	Email address: -	
5.5	category (Raw Material/ Ayurveda product/ Packaging/ Preservative/ excipient etc.)	
5.6	Types of raw material/ Ayurveda product / packing material/ preservative/ excipient expected to be imported	
5.7	Generic name of the material/ product	
5.8	Brand name (if any):	
5.9	Dosage form and Strength	
5.10	Quantity:	

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PART I : SEC. (I) - GAZETTE EXTRAORDINARY OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA - 08.04.2024

6. Certified copies of attachments

(If certified copies are attached put “✓” mark in the relevant column)

6.1	Photocopy of the document approved by the Import and Export Control Department for import/export of the above goods	
6.2	Photocopy of the document registered with Sri Lanka Customs for import/export of the above goods	
6.3	Photo copy of the said document if prior approval has been obtained from the Department of Ayurveda for import of the above goods	

7. Declaration of applicant: -

I hereby certify that all information presented herein is true and correct and I am personally responsible and liable for the accuracy of said information.

Signature of applicant: -

Date: -

Official seal of company

Official use only

Money order No.: -

Receipt No.: -

Document submitted date: -

Note: Complete ☐ / Incomplete ☐ / Forged document ☐ / Complaints ☐

Name and signature of person received: -

Form E

Application for Registration / Renewal of an Ayurvedic Pharmacy

Official use only
File No/ Registration No:
Money Order/ Receipt No: -
Date of Issue: -
Signature of Subject Officer: -

First time registration ☐

Annual registration ☐

(Put the “✓” sign in the appropriate box.)

1. Applicants' details

1.1	Name of applicant: -
1.2	Address: -
1.3	National Identity card/ Passport / Driving license No: -
1.4	Profession: -
1.5	Post at drug manufactory: -
1.6	Telephone No Fixed: - Mobile: -
1.7	Email address: -

2. Details of the company/institute

(Only if the applicant is registered as drug manufacturer)

2.1	Name of Company/Institution: -
2.2	Address: -
2.3	Telephone number: -
2.4	Email address: -
2.5	Business registration certificate number: - Date of issue: -
2.6	If registered under Department of Ayurveda Registration certificate No: - Date of issue: -
2.7	Date of establishment of Company/Institution: -

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3. Details of Ayurveda Pharmacy

3.1	Name: -
3.2	Address: -
3.3	Province: - District: - Divisional Secretariate Division: - Grama Niladhari Division: -
3.4	Rate No.: -
3.5	Telephone No.: -
3.6	Email address: -
3.7	Business registration certificate number :- Date of issue :-
3.8	If registered in the Department of Ayurveda, as a Ayurveda pharmacy Registered certification No. :- Date of Issue :
3.9	Date of establishment of Ayurveda pharmacy:-

4. Details of pharmacist

4.1	Full name of the pharmacist: -		
4.2	Ayurveda medical council registered No: -		
	Date of registration: -		Registration renewal date: -
4.3	Personal address of pharmacist: -		
4.4	Telephone No.: -	Fixed: -	Mobile: -
4.5	Email address: -		

5. Details on marketing division

5.1	Is this building built as per approved regulations? :-	Yes/No
5.2	Number of staff: -	

6. Details of drugs expected to be sold

(If there are more than one type of medicine, produce an Annexure)

Serial No.	Category	Types of drugs expected to be sold	Trade name	Registered under Department of Ayurveda?	Quantity of products in previous year (Kg / unit)	Expected quantity next year (Kg / unit)

7. Certified copies of attachments

(If certified copies are attached, mark ✓ in the box in front of the relevant column)

7.1	certified photocopy of pharmacist's Registration Certificate	
7.2	certified photocopy of Business Registration Certificate (if available only)	
7.3	Route map showing the nearest route from the nearest city to the Pharmacy (Google map)	
7.4	Inspection and Money order receipts for first/annual registration license	

8. Certificate of pharmacist:

As the pharmacist of the above-mentioned institution/pharmacy, I,
..... (Name) holder of National Identity card No
..... of
.....(address) I hereby act in accordance with the criteria of the Ayurvedic Medical Council under the Ayurveda Act, No. 31 of 1961 and sell under my supervision. That the products received are legally responsible for dispensing standardized medicines to the customer in prescribed dosages in accordance with medical prescriptions and provide full-time service, and the accuracy of all the information presented under No. 4 herein. I hereby certify that I am personally responsible and liable for

Signature:

Date:

Official seal:

9. Certificate of the applicant

I hereby certify that the above information is true and correct

Signature:

Date:

Official seal:

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10. Certificate of Grama Seva Niladhari

(Must be certified by the Gram Seva Niladhari of the relevant Grama Seva division to which the premises intended to run the pharmacy)

I confirm that the address (must be the address mentioned under No. 3 in the application form) is correct, and that the address is located in.....
..... Divisional Secretariat Division, Bearing Grama Seva Division No.....
.....

Signature of Grama Niladhari:

Date:

Officer's Name:

Official seal

Sub Signature of Divisional Secretary:

Date:

Official seal

Official use only

Money Order No.: -

Receipt No.: -

Document submitted date: -

Note: Complete ☐ / Incomplete ☐ / Forged document ☐ / Complaints ☐

Name and signature of person received: -

Date: -

Form F

Application for Approval to Register/ Renewal Storage facilities for Ayurveda Products/

Raw materials/ Packaging materials

Official use only
File No/ Registration No: -
Money Order/ Receipt No: -
Date of Issue: -
Signature of subject officer: -

First time registration ☐

Annual registration ☐

(Put the “✓” sign in the appropriate box.)

1. Applicant's details

1.1	Name of applicant: -			
1.2	Address: -			
1.3	National Identity card/ Passport / Driving license No: -			
1.4	Profession: -			
1.5	Applicants position at medicinal store: -			
1.6	Telephone No :-	Fixed: -	Mobile: -	
1.7	Email address: -			

2. Details of Company/Institution

2.1	Name of Company/Institution: -
2.2	Address: -
2.3	Telephone number: -
2.4	Email address: -
2.5	Business registration certificate number: - Date of issue: -
2.6	If registered under Department of Ayurveda Registration certificate No: - Date of issue: -
2.7	Date of establishment of Company/Institution: -

3. Details of medicinal store

3.1	Name of store: -
3.2	Address: -
3.3	Province: - District: - Divisional Secretariate: - Grama Niladhari Division: -
3.4	Rate No: -
3.5	Telephone No: -
3.6	Email address: -
3.7	If registered under Department of Ayurveda Registration certificate No: - Date of issue: -
3.8	Date of establishment of medicinal store: -
3.9	Is this building built as per approved regulations? :- Yes/No
3.10	Number of staff: -

4. Details of Pharmacist

4.1	Full name of Pharmacist: -		
4.2	Ayurveda medical council registration No: -		
	Date of Registration: -	Date of renewal: -	
4.3	Personal address: -		
4.4	Telephone No: -	Fixed: -	Mobile: -
4.5	Email address: -		

5. Details of store keeper/keepers

(If more than one person, attach the following details of all individuals)

5.1	Full name of Store keeper: -		
5.2	Personal address: -		
5.3	National Identity Card/ Passport / Driving License No: -		
5.4	Telephone No: -	Fixed: -	Mobile: -
5.5	Email address: -		

6. Details regarding storage

Serial No.	category (Raw Materials/ Medicines/ Packaging materials/ Preservatives/ Excipients etc.)	Types of raw materials/ Medicines/packaging materials/ preservatives/ excipients stored	Quantity stored last year (Kg / Unit)	Expected quantity to store next year (Kg / Unit)

7. Details regarding Exportation

Serial No.	category (Raw Materials/ Medicines/ Packaging materials/ Preservatives/ Excipients etc.)	Types of Raw Materials/ Medicines/ Packaging materials/ Preservatives/ Excipients to be exported	Country expected for exportation	Name and address of the foreign company	Exported Quantity last year (Kg/ units)	Expected Export Quantity next year (Kg/units)

8. Details regarding Importation

Serial No.	Category (Raw Materials/ Medicines/ Packaging materials/ Preservatives/ Excipients etc)	Raw Materials/ Medicines/ Packaging materials/ Preservatives/ Excipients expecting for importation	Country expected for importation	Name and address of the foreign company	Imported Quantity last year (Kg/ units)	Expected Import Quantity next year (Kg/units)

9. Certified copies of attachments

(If certified copies are attached, mark “✓” in relevant column)

9.1	certified photocopy of pharmacist's Registration Certificate	
9.2	Building plan of the medicinal store(copy of the plan certified by the local council / city council / municipal council)	
9.3	certified photocopy of Business Registration Certificate (if available only)	
9.4	Route map showing the nearest route from the nearest city to the medicinal store (Google maps)	
9.5	Inspection and Money order receipts for first/annual registration license	

10. Certificate of pharmacist

As the pharmacist of the above-mentioned institution/medicinal store, I,
.....(Name) holder of National Identity card No.....of
.....(address) I hereby act in accordance with the criteria of the Ayurvedic Medical Council under the Ayurveda Act, No. 31 of 1961 and sell under my supervision. That the products received are legally responsible for dispensing standardized medicines to the customer in prescribed dosages in accordance with medical prescriptions and provide full-time service, and the accuracy of all the information presented under No. 4 herein. I hereby certify that I am personally responsible and liable for

Signature: -

Date: -

Official seal: -

11. Certificate of applicant

I hereby certify, that the storage facilities are maintained in accordance with all the arrangements recommended by the Department of Ayurveda, that unusable medicines/raw materials/packaging materials are not issued, that they are stored in a separate premises, that all the above storage materials are legally required to be issued to the customer/production, and I am responsible for the accuracy of the above information. I hereby certify that I am personally responsible and liable for.

Signature: -

Date: -

Official seal: -

12. Certificate of Grama Niladhari

(Must be certified by the Gram Seva Niladhari of the relevant Grama Seva division to which the premises intended to run the pharmacy)

I confirm that the address (must be the address mentioned under No. 3 in the application form) is correct, and that the address is located in.....
..... Divisional Secretariat Division, Bearing Grama Seva Division No.....
.....

Signature of Grama Niladhari:

Date:

Officer's Name:

Official seal

Sub Signature of Divisional Secretary:

Date:

Official seal

Official use only

Money Order No: -

Receipt No: -

Documents submitted date: -

Note: Complete ☐ / Incomplete ☐ / Forged document ☐ / Complaints ☐

Name and signature of person received: -

Date: -

Form G

**Application for Registration/ Renewal for Transport/ Distribution
of Ayurveda Medicines, Ayurveda Products, Raw materials, Packing materials**

Official use only
File No/ Registration No: -
Money Order/ Receipt No: -
Date of Issue: -
Signature of Subject Officer: -

First time registration ☐

Annual registration ☐

(Put the “✓”sign in the appropriate box.)

1. Details of the applicant

1.1	Name of applicant: -		
1.2	Address: -		
1.3	National Identity Card/ Passport / Driving license No: -		
1.4	Profession: -		
1.5	Post at Drug manufactory/Cultivated land: -		
1.6	Telephone No	Fixed:-	Mobile:-
1.7	Email address: -		

2. Details of the company/ Institution

2.1	Name of company/Institution: -
2.2	Address: -
2.3	Telephone number: -
2.4	Email address: -
2.5	Business registration certificate number: - Date of issue: -
2.6	If registered in the Department of Ayurveda Registration certificate No: - Date of issue: -
2.7	Date of incorporation of company/Institution: -

3. Details on vehicles expected to be used for transportation purposes

3.1	Number of vehicles expected to be used: -		
3.2	Address where the vehicle is located: -		
3.3	Province: - District: - Divisional Secretariate: - Grama Niladhari Division: - Of vehicle location		
3.4	Type of vehicle	Vehicle number	Colour

4. Driver's details

	Name of driver	Driving license No.	Driver's Personal Address

5. Details on Ayurveda Medicines / Raw materials / Packaging materials to be transported

Serial No.	Category (Ayurvedic Medicines / Raw materials / Packaging materials)	Type of Ayurvedic Medicines / Raw materials / Packaging materials intended to be transported	Trade name	Quantity transported during the last year (Kg / Unit)	Annual quantity expected to be transported (Kg / Unit)

6. Certified copies of attachments

(If certified copies are attached, mark "✓" in the box of the relevant column)

6.1	Certified Photocopies of revenue license certificates of vehicles	
6.2	Certified Photocopies of driving license of drivers to be employed	
6.3	Certified photocopy of business registration certificate	
6.4	Certified Copy of Registration Certificate under Department of Ayurveda (Certificates of registration of drug manufactories/stores/cultivation lands applicable for transportation)	
6.5	Route map showing the expected routes to carry out transport activities (Google maps)	
6.6	Inspection and Money order receipts for first / annual registration license	

7. Declaration of applicant

I hereby certify that the transportation of Ayurveda medicines/raw materials/packaging materials are carried out with the prior approval under the Department of Ayurveda, and that I am personally responsible and liable for the accuracy of all the above details.

Signature:

Date:

Official seal:

Official use only

Money order No.: -

Receipt No.: -

Document submitted date: -

Note: Complete ☐ / Incomplete ☐ / Forged document ☐ / Complaints ☐

Name and signature of person received: -

Date:-

Form H

Application for Registration of Raw Materials that restricted by the rules and regulation imposed in Sri Lanka, for the Ayurveda Production

Official use only
File No./ Registration No: -
Money order/ Receipt No.: -
Date of issue: -
Signature of subject officer: -

First time registration ☐

Name of the raw material

Annual registration ☐

that restricted by

(Put the “✓” sign in the appropriate box.)

the rules and regulation :-

1.Details of applicant

1.1	Name of applicant: -
1.2	Address: -
1.3	NIC No./Passport No./Driving License No.: -
1.4	Profession: -
1.5	Post of applicant at drug manufactory: -
1.6	Telephone No.: - Fixed: - Mobile: -
1.7	Email address: -

2. Details of the company/ Institution

2.1	Name of Institution/Company: -
2.2	Address: -
2.3	Telephone No.: -
2.4	Email: -
2.5	Number and date of company registration: - Date of issue: -

2.6	If registered under Department of Ayurveda, Registration certificate Number: - Date of issue: -
2.7	Date of establishment of the Institution/Company: -

3. Details of drug manufactory

3.1	Name of drug manufactory: -
3.2	Address of drug manufactory: -
3.3	Province: - District: - Divisional secretariate division: - Grama Niladhari Division and No: -
3.4	Rate No.: -
3.5	Telephone No.: -
3.6	Email address: -
3.7	If registered under Department of Ayurveda, Registration Certificate Number: - Date of issue: -
3.8	Date of establishment of the drug manufactory: -

4. Details of consultant physician

4.1	Full name of physician: -
4.2	Ayurveda medical council registration No.: - General/special Date of registration: - Date of renewal: -
4.3	Registration section: - Number of Special registration (If available): -
4.4	Address: -
4.5	Telephone No: - Fixed: - Mobile: -
4.6	Email address: -

5. Details of product

5.1	Name of the product according to ayurveda/ Siddha/Unani/Traditional medicines pharmacopeia: -
5.2	Trade name of the product: -

5.3	Nature of product: -										
	Medicine		Diet and nutritional supplementary products		Cosmetic products		Devices				
5.4	Therapeutic indications/uses of product: -										
5.5	If you have obtained registration for this product under department of ayurveda:										
	registration number first-time: -					Date: -					
	registration number last -time: -					Date: -					
5.6	Has any research been done on this product in Sri Lanka after first registration? (yes/no) If yes, briefly describe the results (attach a copy of the report/publication)										
5.7	If the product is medicine, mention the Name of text/page/recipe No: - Please mention whether this medicine obtained from Classical texts/ pharmacopeia/Traditional base										
5.8	Is it a new product, mention the recipe (to be prepared separate document): - Certificate of legal provision in the relevant country: -										
5.9	Dose and dosage: -										
5.10	Route of administration: -										
	External application		Orally		Inhalation		Vasthi		Nasya		others
5.11	Required amount of the above raw material per unit :-										

6. If the product is exported, give details

Serial No.	category (Raw Materials/ Medicines/ Packaging material/ Preservatives/ Excipients etc.)	Types of Raw Materials/ Medicines/ Packaging material/ Preservatives/ Excipients) to be exported	Countries expected to export	Name and address of the foreign company	Export Quantity (Kg / Unit) last year	Expected export quantity for next year (Kg / units)

7. Details of imported material used in the preparation of production (If available)

7.1	Whether imported materials are used in the preparation of medicine?	Yes/No
7.2	If yes, Name of institution issued license for importation of materials	

7.3	License No.: - Date: -	
7.4	Country of import	
7.5	Name of the raw material manufacturer in relevant country	
7.6	Address	
7.7	List of imported raw materials (relevant documents to be submitted)	
7.8	Has any processed products been imported to be used as a raw material in the product?	Yes/No
7.9	If yes, name / names of processed products imported as raw materials	
7.10	Has separate approval obtained from Department of Ayurveda to import such product?	Yes/No
7.11	If yes, the referral letter number Date: -	

8. Details of raw materials that restricted by the rules and regulations imposed in Sri Lanka:

Serial No.	Type of ingredients restricted by law	District and Divisional Secretariat where the relevant raw materials are procured	Address of the place of procurement of the relevant raw materials	License number and date of approval for the use of the relevant ingredients	Quantity of raw materials used in above product last year (Kg / Unit)	Quantity expected to be procured in next year (Kg / Unit)

9. Certificate of consultant Physician

I,(Name) holder of National Identity Card No.....of(address) the consultant Ayurvedic medical practitioner of the above named institution/ayurvedic drug manufacturing company hereby certify that I abide by the Registered Ayurvedic Medical Practitioners Rules No. 1 of 2014 made under the Ayurvedic Act No .31 of 1961 and that I am legally responsible for standard of the products and in connection therewith manufactured under my supervision and that I will provide my services full time and that I will be held responsible and will be responsible personally for the correctness of all information disclosed under No. 4 hereto

Signature of ayurveda practitioner: -

Date: -

Official seal

10. Declaration of applicant: -

I hereby certify that the information given in the application is true and correct. I am personally responsible and liable for the accuracy of all information furnished herein.

Signature of applicant: -

Date: -

Official seal

Official use only

Money order No.: -

Receipt No.: -

Document submitted date: -

Note :Complete ☐ /Incomplete ☐ / Forged document ☐ / Complaints ☐

Name and signature of person received: -

Form I

Application for Cultivation, manufacture of Ayurveda products, storage, distribution, sale, transportation and exportation of Medicinal cannabis

For Official use only	
File No./ Registration No.: -	
Money order/ Receipt No.: -	
Date of issue: -	
Signature of subject officer: -	

Nature of Business

Local Organization ☐

Foreign Organization ☐

A joint venture ☐

A sole proprietary ☐

Obtaining a temporary license

Obtaining a permanent license

Cultivate ☐

Cultivate ☐

Manufacture ☐

Manufacture ☐

Export ☐

Export ☐

Put the “✓” sign in the appropriate box.)

1. Details of the applicant

1.1	Name of applicant: -	
1.2	Address: -	
1.3	National Identity card/ Passport / Driving license No: -	
1.4	Profession: -	
1.5	Telephone No.: - Fixed Mobile	
1.6	Email address: -	

2. Details of the manufacturing company/business

2.1	Name of company /business	
2.2	Address: -	

2.3	Telephone No.: -	
2.4	Email address: -	
2.5	company/business registration certificate No.: - Date of Issue: -	
2.6	If registered under Department of ayurveda Registration certificate No.: - Date of issue: -	
2.7	Date of establishment of company/Business: -	
2.8	Applicant's position in the company/Business: -	

3. Details of Board of Directors/Partners/Members

(Details of all members/partners should be submitted)

Serial No.	Designation in company	Full name of officer/board member	National Identity Card Number	Specimen Signature

Annexures relating to Nos. 1, 2, 3

(If copies are attached, mark ✓ in relevant column)

01	certified photocopy of Business/Company Registration Certificate	
02	certified photocopy of Registration certificate (If registered under Department of Ayurveda)	
03	Photocopies of National Identity Card/Passport of Applicant/Board of Directors/ Members/ Partners (mention number of attachments)	
04	Bank statements of Near 3 months of local/foreign bank accounts to verify financial capability	
05	Certificate of bank balance of approximately near 3 months in local/foreign bank accounts	
06	Document authorized to sign on behalf of the company	
07	Affidavit confirming authorization to sign on behalf of the company	
08	If the relevant entity is a company, the report containing the authorized board of directors' decision to submit the EOI (Board Resolution)	
09	In case of Sole Proprietorship/Partnership, Affidavit confirming the nature of the business and personal details.	
10	Cash Receipt of Non-Refundable Deposit Fee Credited to bank account of Department of Ayurveda	

4. **Details of Consultant Physician**

4.1	Full name of consultant physician: -	
4.2	If registered under Department of ayurveda Registration certificate No.: - Date of issue: - Date of Renewal: -	Special <input type="checkbox"/> General <input type="checkbox"/>
4.3	Section of special registration: -	
4.4	Personal address: -	
4.5	Telephone No.: - Fixed Mobile	
4.6	Email address: -	

5. **Details of pharmacist**

5.1	Full name of pharmacist: -	
5.2	Ayurveda Medical Council Registration no: - Date of issue: - Date of Renewal: -	
5.3	Personal address: -	
5.4	Telephone No.: - Fixed Mobile	
5.5	Email address: -	

Annexures relating to Nos. 4,5

(If copies are attached, mark ✓ in relevant column)

01	Certified copy of consultant physician's Ayurveda Medical council registration certificate	
02	Certified copy of pharmacist's Ayurveda Medical council registration certificate	

6. **Details on cultivation**

(In case of more than one land, annexures should be submitted for each cultivation land in this format)

6.1	Name of the company/business/individual who acquired the ownership of the cultivation land	
6.2	Address: -	
6.3	Telephone No.: -	
6.4	Email address: -	

6.5	<p>Area under primary cultivation Acres</p> <p>Area under secondary cultivation Acres</p> <p>Total area of cultivation Acres</p> <p>Used for cultivation</p>	
6.6	How the land is surrounded	<p>A border wall <input type="checkbox"/></p> <p>Mesh covers/Cover fencing <input type="checkbox"/></p>
6.7	<p>Province: -</p> <p>District: -</p> <p>Divisional secretariate: -</p> <p>Grama Niladhari Division and No.: -</p> <p>Of cultivation land</p>	
6.8	Nature of ownership of the applicant party in respect of the cultivated land	
6.9	Rate No.: -	
6.10	Date of commencement of cultivation land	
6.11	<p>Name of Agriculture instructor supervising primary cultivation</p> <p>Professional qualification (Mention the degree/s)</p> <p>Personnel Address</p> <p>National Identity card/ Passport / Driving license No: -</p> <p>Telephone No.: - Fixed: -</p> <p>Mobile: -</p> <p>Email address: -</p>	
6.12	<p>Name of Agriculture instructor supervising secondary cultivation</p> <p>Professional qualification (Mention the degree/s)</p> <p>Personnel Address</p> <p>National Identity card/ Passport / Driving license No: -</p> <p>Telephone No.: - Fixed: -</p> <p>Mobile: -</p> <p>Email address: -</p>	

6.13	License number obtained from the Central Environment Authority for maintaining a cultivation land: - Date of issue: -	
6.14	If registered under Department of ayurveda, Registration certificate no: - Date of issue: -	
6.15	Are the proper protective measures recommended by Department of Ayurveda being followed?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Annexures relating to No. 4

(If copies are attached, mark ✓ in relevant column)

01	Copies of documents proving the ownership of the cultivated land	
02	Photocopies of National Identity Card/Passport of cultivation supervising agriculture instructors (Mention number of attachments)	
03	Copy of certificate proving qualifications of primary cultivation supervising agriculture instructor	
04	Copy of certificate proving qualifications of secondary cultivation supervising agriculture instructor	
05	Detailed report on the safety measures used for the cultivated land	
The following annexures must be submitted before granting the permanent license		
06	Photocopy of license obtained from Central Environment Authority	
07	Photocopy of Medicinal Cultivation Registration Certificate of Department of Ayurveda	
08	Police Report of the Police Officer in Charge of the Police area to which the Cultivated Land belongs	
09	Observation report with the counter sign of the divisional secretariate and signature of Grama niladhari which the Cultivated Land belongs.	

7. Details of drug manufactory

7.1	Name of drug manufactory: -	
7.2	Address: -	
7.3	Telephone No: -	
7.4	Email address: -	

7.5	Province: - District: - Divisional secretariate: - Grama Niladhari Division and No.: - Of drug manufactory	
7.6	Applicants' nature of right regarding the drug manufactory and manufacturing land	
7.7	Area of land owned by the drug manufactory	
7.8	How the land is surrounded	A border wall <input type="checkbox"/> Fence with mesh cover <input type="checkbox"/>
7.9	Rate No.: -	
7.10	If registered under department of ayurveda, Registration certificate No: - Date of issue: -	
7.11	Date of establishment of drug manufactory: -	
7.12	Full name of consultant physician: - Personal address: - National Identity card/ Passport No: - Ayurveda medical council registration No. and Date: - Section of special registration: - Last Renewal Date: - Telephone No.: - Fixed Mobile Email address: -	General <input type="checkbox"/> Special <input type="checkbox"/>
7.13	Name of supervising technical officer Personal address: - National Identity card/ Passport No: - Telephone No.: - Fixed Mobile Email address: -	

7.14	License No obtained from Central Environment Authority Date of issue: -	
7.15	Is this drug manufactory built as per recommended safety regulations approved by Department of Ayurveda?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Appendix relating to No. 7

(If copies are attached, mark ✓ in relevant column)

01	Certified copy of Ayurveda Product Registration Certificate under Department of Ayurveda	
02	Certified copies of documents proving ownership of drug manufactory	
03	Copy of Ayurveda medical council registration certificate of the physician supervising the drug manufactory.	
04	Copy of certificate proving qualification of technical officer supervising the drug manufactory.	
05	Photocopies of National Identity Card/Passport of technical officer supervising the drug manufactory. (Mention number of attachments)	
06	Detailed report on the safety measures used for the drug manufactory.	
The following annexures must be submitted before granting the permanent license		
07	Certified copy of license obtained from Central Environment Authority	
08	Police Report of the Police Officer in Charge of the Police area to which the drug manufactory belongs.	
09	Observation report with the counter sign of the divisional secretariate and signature of Grama niladhari which the drug manufactory belongs.	

8. Details of Product

(Products here indicates “Ayurvedic medicines and other cannabis related products”, In case of more than one product, annexures should be submitted for each product in this format)

8.1	Category of product	Medicine <input type="checkbox"/> Diet and nutritional supplementary <input type="checkbox"/> Cosmetic products <input type="checkbox"/> Devices <input type="checkbox"/> Other
8.2	Trade name of the product	
8.3	Text book name of the product	

8.4	Name of text, page, recipe No. (Please mention whether this product is obtained from Classical texts/ pharmacopeia/ Traditional base)	
8.5	Therapeutic indications/uses of product	For Therapeutic purpose <input type="checkbox"/> For rejuvenation purpose <input type="checkbox"/> For Cosmeceutical purpose <input type="checkbox"/> Other
8.6	Dose and dosage	
8.7	Route of administration	Orally <input type="checkbox"/> External application <input type="checkbox"/> Inhalation <input type="checkbox"/> Vasti <input type="checkbox"/> Nasya <input type="checkbox"/> Other
8.8	If you have obtained registration for this product under department of ayurveda before: Registration number first-time: - Date: - Registration number last -time: - Date: -	
8.9	Has any research been done on this product in Sri Lanka after first registration?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8.10	If yes, briefly describe the results	

9. Summary report on products

Serial No.	Category	Text book name of the product	Trade name	Mode of approval			Quantity of products in previous year (Kg / unit)	Expected quantity per next year (Kg / unit)	
				Pharmacopeia					If approved from TCAM, medicine name, number and date
				Ayurveda	Siddha	Unani			

10. Summary report on above product/products containing cannabis species, all subspecies and other ingredients restricted by the rules and regulations imposed in Sri Lanka.

Serial No	Chemical/Scientific Name of Ingredient Restricted by Law	District and Divisional Secretariat where the relevant raw materials are procured	Address of the place of procurement of the relevant raw materials	License number and date of approval for the use of the relevant ingredients	Quantity of raw materials used in above product last year (Kg / Unit)	Quantity expected to be procured in next year (Kg / Unit)

Annexures relating to Nos. 08,09,10

(If copies are attached, mark ✓ in relevant column))

01	If it is a new product, mentioned the recipe	
02	If it is a new product, certificate of approval obtained by TCAM	
03	If registered under Department of ayurveda, copy of the valid certificate	
04	Has any research been done on this product in Sri Lanka after first registration, attach a copy of the report/publication	

11. Details of imported raw materials/packaging/preservatives/excipients used in the manufacturing process of related product

(In case of more than one raw material/packaging/preservatives/excipient, annexures should be submitted for each production in this format. If applicable Only)

11.1	Have any Imported raw materials/packaging/preservatives/excipients been used for the respective product?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11.2	Scientific/Textbook name of the any processed product if it is imported to be used as an ingredient in respective product.	
11.3	Nature of raw material	
11.4	Scientific/Chemical name of raw material	
11.5	Raw material	Common <input type="checkbox"/> Rare <input type="checkbox"/> Endemic <input type="checkbox"/> Threatened with extinction <input type="checkbox"/>
11.6	Are there regulations or ordinances related to the ingredient?	

11.7	Mode of import/export of raw materials	Raw <input type="checkbox"/> Dry <input type="checkbox"/> Extract <input type="checkbox"/> Other.....
11.8	Scientific/Chemical Name of Packaging material/preservative/excipient	
11.9	Trade Name of Packaging material/preservative/excipient	
11.10	The expected quantity to be imported in a year (Kg/unit)	

12. Summary report related to import goods

Serial No.	category (Raw Materials/ Ayurveda products/ Packaging/ Preservatives/ excipients etc.)	Types of raw materials/ Ayurveda products / packaging/ preservatives/ excipients expected to be imported	Country expected to be import	Name and address of foreign company	Quantity of imports during last year (Kg / Unit)	Expected Quantity of imports next year (Kg / Unit)

Annexures relating to Nos. 11,12

(If copies are attached, mark ✓ in relevant column)

01	Registration certificate issued by Department of Ayurveda for importation of each category	
02	Copy of letter approved by Ayurveda Drugs and Products Regulatory Council in regarding the product to be imported.	
03	Certified Copy of Sample Import Permit issued by Department of Ayurveda	
Following documents should be submitted at each Shipment In order to obtain the import license issued by the Department of Ayurveda for each shipment.		
04	Detailed quality assurance report of imported goods	
05	Certificate of origin of the imported product	
06	Approval obtained from Sri Lanka Import and Export Control Department	
07	Pro-forma Invoice issued by the seller	

13. Details of Storage

(In case of more than one storage, annexures should be submitted for each storage in this format)

13.1	Name of storage: -	
13.2	Address: -	

13.3	Telephone No.: -	
13.4	Email address: -	
13.5	Province: - District: - Divisional secretariate: - Grama Niladhari Division: - Of storage	
13.6	Rate No.: -	
13.7	Date of establishment of storage: -	
13.8	Nature of ownership of the applicant party regarding the building and land where the storage is established	
13.9	Area used for storage (Indicate the square ft amount separately)	Raw material Sq. ft Products Sq. ft Packaging Sq. ft Preservatives Sq. ft Excipients Sq. ft
13.10	If registered under Department of ayurveda Registration certificate No.: - Date of issue: -	
13.11	Is this storage built as per recommended rules and regulations approved by Department of Ayurveda?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13.12	Whether the storage is maintained in accordance with the regulations approved by Department of Ayurveda?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13.13	Are quarantine measures followed to secure stored materials within the storage premises?	Yes <input type="checkbox"/> No <input type="checkbox"/>

14. Details of Store Keeper/Keepers

(In case of more than one store keeper, annexures should be submitted for each individual in this format)

14.1	Full name of store keeper	
14.2	Personal address	
14.3	National Identity card/ Passport No/Driving License No: -	
14.4	Telephone No.: - Fixed Mobile	
14.5	Email address: -	

15. Details Regarding Storage

Serial No.	category (Raw Materials/ Medicines/ Packaging materials/ Preservatives/ Excipients etc.)	Types of raw materials/ Medicines/packaging materials/ preservatives/ excipients stored	Quantity stored during last year (Kg / Unit)	Expected quantity expected to store for next year (Kg / Unit)

Annexures relating to Nos. 13,14,15

(If copies are attached, mark ✓ in relevant column)

01	Registration certificate obtained from Department of Ayurveda for the storage of each category	
02	Confirmation document of ownership of the applicant party regarding the building and land where the storage is established	
03	License issued by the Department of Ayurveda for the storage of cannabis species, all subspecies and other ingredients or Ayurvedic products containing such ingredients restricted by law in Sri Lanka	
04	Photocopy of license obtained from Central Environment Authority	
05	Police Report of the Police Officer in Charge of the Police area to which the storage belongs	
06	Observation report with the counter sign of the divisional secretariate and signature of Grama niladhari which the storage belongs	
07	Photocopies of store keeper/s National Identity Card/Passport (Mention number of attachments)	

16. Details on vehicles expected to be used for transportation purposes

16.1	Number of vehicles expected to be used: -			
16.2	(If multiple locations, give separate details of each location) Province: - District: - Divisional secretariate: - Grama Niladhari Division: - Of vehicle location			
16.4	Type of vehicle	Vehicle number	Color	Engine capacity

17. Driver's details

	Name of driver	Driving license No.	Driver's Personal address

18. Details on Ayurveda Medicines / Raw materials / Packaging materials to be transported

Serial No.	Category (Ayurvedic Medicines / Raw materials / Packaging materials)	Type of Ayurvedic Medicines / Raw materials / Packaging materials intended to be transported	Trade name	Quantity transported during the last year (Kg / Unit)	Annual quantity expected to be transported (Kg/ Unit)

Annexures relating to Nos. 16,17,18

(If copies are attached, mark ✓ in relevant column)

01	Registration certificate obtained from Department of Ayurveda for the transportation of each category	
02	License issued by the Department of Ayurveda for the storage of cannabis species, all sub-species and other ingredients or Ayurvedic products containing such ingredients restricted by law in Sri Lanka (Permit should be obtained in each case of transport)	
03	Route map showing the expected routes to carry out transport activities	
04	Certified Photocopies of revenue license certificates of vehicles to be used for transportation of Products/ Medicines / Raw materials / Packaging materials / Preservatives/ Excipients	
05	Photocopies of driving license of drivers (Mention number of attachments)	

19. Details related to exportation

(In case of more than one type, annexures should be submitted for each type of goods in this format)

19.1	Type of goods expected to be imported	products <input type="checkbox"/>
		Raw Material <input type="checkbox"/>
19.2	Nature of the product to be imported	Medicine <input type="checkbox"/>
		Diet and nutritional supplementary <input type="checkbox"/>
		Cosmetic products <input type="checkbox"/>
		Devices <input type="checkbox"/>
		Other

19.3	Trade name of the product to be exported	
19.4	Textbook name of the product be exported	
19.5	Mode of export	Raw <input type="checkbox"/> Dry <input type="checkbox"/> Extract <input type="checkbox"/> Other.....

20. Summary report of the goods to be exported

Serial No.	category (Raw Materials/ Ayurveda products / Packaging/ Preservatives/ excipients etc.)	Types of raw materials/ Ayurveda products / packaging/ preservatives/ excipients expected to be exported	Country expected to be export	Name and address of foreign company	Quantity of exports during last year (Kg / Unit)	Expected Quantity of imports next year (Kg / Unit)

Annexures relating to Nos. 19,20

(If copies are attached, mark ✓ in relevant column)

01	Photocopy of the document approved by the Import and Export Control Department for export of the above good/s	
02	Photocopy of the document approved by the Export Development Board for export of the above good/s	
03	Photocopy of the document obtaining a Tax Identification Number issued by the Inland Revenue Department	
04	Photocopy of the document registered with Sri Lanka Customs for export of the above goods	
05	Photo copy of the said document if prior approval has been obtained from the Department of Ayurveda for export of the above goods	

21. Details about the project proposal to be submitted for feasibility study

21.1	Name of project proposal	
21.2	Details in brief	

Annexure relating to Nos. 21

(If copies are attached, mark ✓ in relevant column)

01	project proposal	
02	Detail report on the human resources expected to be used in the project	
03	Affidavit to act in accordance with labor, women and child protection laws	

Schedule III

Price Schedule

No.	Service	Unit	Value
1	Registration of Local Products / Medicines - Normal Process		
	Registration/Licence fee	LKR	15,000.00
	Renewal fee - Annually*	LKR	5,000.00
	Appeal fee	LKR	7,500.00
2	Registration of Local Products / Medicines – Expedited Process		
	Registration/Licence fee	LKR	30,000.00
	Appeal fee	LKR	10,000.00
3	Registration of Imported Products / Medicines/ Local Business - Normal Process		
	Registration/Licence fee	USD	500
	Renewal fee - Annually*	USD	150
	Appeal fee	USD	200
4	Registration of Imported Products / Medicines/ Local Business – Expedited Process		
	Sample Licence fee	USD	200
	Any change of sample licence	USD	100
	Registration/Licence fee	USD	1,000
	Appeal fee	USD	300
5	Registration of Export Products / Medicines/ Local Business - Normal Process		
	Registration fee	USD	10
	Renewal fee - Annually (each product)*	USD	10
6	Registration of Export products/medicines / Local Business – Expedited Process		
	Registration fee	USD	20
	Renewal fee - Annually (each product)*	USD	20

No.	Service	Unit	Value
7	Registration of Manufacturing premises - (Normal Process)		
	Registration/Licence fee	LKR	50,000.00
	Annual registration*	LKR	25,000.00
	Duplicate certificate fee	LKR	5,000.00
	Drug Stores	LKR	15,000.00
	Drug Stores - Renewal Annually*	LKR	10,000.00
8	Registration of Manufacturing premises - (Expedited Process)		
	Registration/Licence fee	LKR	100,000.00
	Annual registration*	LKR	50,000.00
	Duplicate certificate fee	LKR	5,000.00
	Drug Stores	LKR	30,000.00
	Drug Stores - Renewal Annually*	LKR	20,000.00
9	Approval for media advertisement - Normal Process		
	Paper advertisement	LKR	40,000.00
	Mass media / Social media	LKR	40,000.00
10	Approval for media advertisement - Expedited Process		
	Paper advertisement	LKR	80,000.00
	Mass media / Social media	LKR	80,000.00
11	Transport Certificate - Normal Process		
	Registration fee	LKR	15,000.00
	Duplicate Certificate fee	LKR	5,000.00
	Annual renewal fee*	LKR	10,000.00

No.	Service	Unit	Value
12	Transport Certificate - Expedited Process		
	Registration fee	LKR	30,000.00
	Duplicate Certificate fee	LKR	5,000.00
	Annual renewal fee*	LKR	20,000.00
13	Drug stores (Store with manufacturing unit excluded) - Normal Process		
	Registration/Licence fee	LKR	25,000.00
	Duplicate certificate fee	LKR	5,000.00
	Annual renewal fee*	LKR	15,000.00
14	Drug stores (Store with manufacturing unit excluded) - Expedited Process		
	Registration/Licence fee	LKR	50,000.00
	Duplicate certificate fee	LKR	5,000.00
	Annual renewal fee*	LKR	30,000.00
15	Pharmacy - Normal Process		
	Registration/Licence fee - Retail	LKR	20,000.00
	Duplicate certificate fee	LKR	5,000.00
	Annual renewal fee*	LKR	10,000.00
16	Pharmacy - Expedited Process		
	Registration/Licence fee - Retail	LKR	40,000.00
	Duplicate certificate fee	LKR	5,000.00
	Annual renewal fee*	LKR	20,000.00

No.	Service	Unit	Value
17	Projects related to Cannabis		
	Refundable Deposit	USD	100,000
	Project evaluation fee	USD	1,250
	Temporary licence fee	USD	300
	Permanent licence fee	USD	200
	Renewal fee - Annually - each item*	USD	200
	Appeal fee	USD	250
	Duplicate certificate fee	USD	10
18	Importing raw materials/capsules/packing materials/substance/other product related to Ayurveda value addition		
	Licence fee - each product	LKR	10,000.00
	Fee for No Objection letter - each product	LKR	5,000.00
	Renewal fee Annually - each product.*	LKR	2,000.00
* 10% Penalty fee will be charged for each application delayed every month.			

Schedule IV

ආයුර්වේද නිෂ්පාදනාගාරයක් ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத உற்பத்தி நிலையமாகப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF AN AYURVEDIC MANUFACTURING CENTER

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ස්ථානය ආයුර්වේද ඖෂධ නිෂ්පාදනාගාරයක් ලෙසට ලියාපදිංචි කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் கட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது மருந்து உற்பத்தி நிலையமாகப் பதிவு செய்யப்பட்டுள்ளது என்பதனை உறுதிப்படுத்துகின்றேன்.

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, the place detailed below has been registered as an Ayurveda drug manufacturing center.

මා විසින් හෝ නීති කෘත්‍යායක නිකුත්කළ නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මීස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර ක කාලයක් සඳහා මෙම සහතිකය වලංගු පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ඖෂධ නිෂ්පාදනාගාරයේ නම

மருந்து உற்பத்தி நிலையத்தின் பெயர்

Name of the Drug Manufacturing Center

නිෂ්පාදනාගාරයේ ලිපිනය

மருந்து உற்பத்தி நிலையத்தின் முகவரி

Address of the Drug Manufacturing Center

ඖෂධ නිෂ්පාදනාගාර අයිතිකරුගේ නම

மருந்து உற்பத்தி நிலைய உரிமையாளரின் பெயர்

Name of the proprietor of the Drug Manufacturing Center

පිළියෙල කරනු ලබන ඖෂධ වර්ග

தயாரிக்கப்படும் மருந்துகளின் வகைகள்

Types of drugs being prepared

ඖෂධ නිෂ්පාදනාගාරය පිහිට වූ දිනය

மருந்து உற்பத்தி நிலையம் நிறுவப்பட்ட திகதி

Date of the Establishment of Drug Manufacturing Center

උපදේශක වෛද්‍යවරයාගේ නම සහ ලියාපදිංචි අංකය

ஆலோசனை வைத்தியரின் பெயர் மற்றும் பதிவு இலக்கம்

Name of the Consultant physician and registration No.

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரகம். 20 ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சுவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் ஏவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නව නිෂ්පාදනයක් ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத புதிய உற்பத்தியைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF A NEW AYURVEDA PRODUCT

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ආයුර්වේද නව නිෂ්පාදනයක් ලෙසට ලියාපදිංචි කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப சீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத புதிய உற்பத்தியைப் பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, the place detailed below has been registered as an Ayurveda new product.

මා විසින් හෝ නීති කතෘයක නිතෘනුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර ක කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

මාෂධ නිෂ්පාදනාගාරයේ නම மருந்து உற்பத்தி நிலையத்தின் பெயர் Name of the Drug Manufacturing Center	
නිෂ්පාදනාගාරයේ ලිපිනය மருந்து உற்பத்தி நிலையத்தின் முகவரி Address of the Drug Manufacturing Center	
මාෂධ නිෂ්පාදනාගාර අයිතිකරුගේ නම மருந்து உற்பத்தி நிலைய உரிமையாளரின் பெயர் Name of the proprietor of the Drug Manufacturing Center	
නිෂ්පාදනය කරනු ලබන නව නිෂ්පාදනය தயாரிக்கப்படும் புதிய உற்பத்தி வகைகள் Name of new Ayurveda product	වර්ගය / Catogery/ උපලේඛනය / Schedule
නව නිෂ්පාදනය නිෂ්පාදනය සඳහා අනුමත වූ දිනය புதிய உற்பத்திக்காக அனுமதிக்கப்பட்ட திகதி The date the new product is approved for production	
උපදේශක වෛද්‍යවරයාගේ නම සහ ලියාපදිංචි අංකය ஆலோசனை வைத்தியரின் பெயர் மற்றும் பதிவு இலக்கம் Name of the Consultant Physican and registration No.	

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரசும. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද ඖෂධ සැලකිලි ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத மருந்து விற்பனை நிலையத்தினைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF AN AYURVEDA PHARMACY

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ස්ථානය ආයුර්වේද ඖෂධ සැලකිලි ලියාපදිංචි කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் கட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத புதிய உற்பத்தியைப்பயிப் பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, the place detailed below has been registered as an Ayurveda pharmacy.

මා විසින් හෝ නීති කෘත්‍යයක නිත්‍යනුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර ක කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආයුර්වේද ඖෂධසලේ නම

மருந்து விற்பனை நிலையத்தின் பெயர்

Name of the Ayurveda Pharmacy

ආයුර්වේද ඖෂධසලේ ලිපිනය

மருந்து விற்பனை நிலையத்தின் முகவரி

Address of the Ayurveda Pharmacy

ආයුර්වේද ඖෂධසල අයිතිකරුගේ නම

மருந்து விற்பனை நிலைய உரிமையாளரின் பெயர்

Name of the proprietor of the Ayurveda Pharmacy

අලෙවි කරනු ලබන ඖෂධ කාණ්ඩ

விற்பனை செய்யப்படும் மருந்துகள்

Categories of drugs sold

ආයුර්වේද ඖෂධසල ආරම්භ කළ දිනය

மருந்து விற்பனை நிலையம் ஆரம்பிக்கப்பட்ட திகதி

Date of Establishment of Ayurveda Pharmacy

ආයුර්වේද ඖෂධසල භාරව සිටින වෛෂ්ඨිකවරයාගේ නම සහ ලියාපදිංචි අංකය

மருந்து விற்பனை நிலைய மருந்தாளரின் பெயர் மற்றும் பதிவு இலக்கம்

Name Registration Number of the Pharmacist in charge of the Ayurveda Pharmacy

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.

ஆயுள்வேத திணைக்களம், மஹரசம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி

.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.

சுவனீப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.

N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නිෂ්පාදන ගබඩාවක් ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத மருந்து களஞ்சியமாகப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF AN AYURVEDIC DRUG STORE

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ස්ථානය ආයුර්වේද නිෂ්පාදන ගබඩාවක් ලෙසට ලියාපදිංචි කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப சீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத மருந்து களஞ்சியமாகப் பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, the place detailed below has been registered as an Ayurveda drug store.

මා විසින් හෝ නීති කෘත්‍යයක නිතරනුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර ක කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආයුර්වේද නිෂ්පාදන ගබඩාවේ නම

மருந்து களஞ்சிய நிலையத்தின் பெயர்

Name of Ayurveda drug store

ආයුර්වේද නිෂ්පාදන ගබඩාවේ ලිපිනය

மருந்து களஞ்சிய நிலையத்தின் முகவரி

Address of the Ayurveda drug store

ගබඩාව අයත් සමාගමේ/වාපාරයේ/ අයිතිකරුගේ නම

மருந்து களஞ்சிய உரிமையாளரின் பெயர்

Name of the company/business/proprietor whom the store belongs

ගබඩා කරනු ලබන නිෂ්පාදන කාණ්ඩ

களஞ்சியப்படுத்தப்படும் மருந்துகளின் வகைகள்

Categories of drugs being stored

ආයුර්වේද නිෂ්පාදන ගබඩාව ආරම්භ වූ දිනය

மருந்துக் களஞ்சியம் நிறுவப்பட்ட திகதி

Date of Establishment of Ayurveda drug store

ආයුර්වේද නිෂ්පාදන ගබඩාව භාරව සිටින චෛෂ්ඨිකවරයාගේ නම සහ ලියාපදිංචි අංකය

மருந்துக் களஞ்சிய மருந்தாளரின் பெயர் மற்றும் பதிவு இலக்கம்

Name of the Registration Number of the Pharmacist in charge of the Ayurveda drug store

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.

ஆயுள்வேத திணைக்களம், மஹரகம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி

.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.

சவனப்பு: மேற்கூறப்பட்ட விவரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.

N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නිෂ්පාදන ආනයන ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத உற்பத்தி இறக்குமதியினைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF IMPORTATION OF AYURVEDA PRODUCTS

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන සමාගම/ව්‍යාපාරය/පුද්ගලයාට පහත ආයුර්වේද නිෂ්පාදන ආනයනය සඳහා ලියාපදිංචිය ලබා දෙන බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுர்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத உற்பத்தி இறக்குமதிக்காக பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, that the registration for import of Ayurveda products is granted to the Company/Business/Individuals whose details are below.

මා විසින් හෝ තිබී කාතෘකයක නිත්‍යානුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආයුර්වේද නිෂ්පාදන ආනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම
ஆயுள்வேத உற்பத்தி இறக்குமதி நிறுவனம்/வியாபாரம்/தனிநபரின் பெயர்
Name of Ayurveda Products Importing Company/Business/Individual

ආයුර්වේද නිෂ්පාදන ආනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය
ஆயுள்வேத உற்பத்தி இறக்குமதி நிறுவனம்/வியாபாரம்/தனிநபரின் முகவரி
Address of Ayurveda Products Importing Company/Business/Individual

ආනයනය කරනු ලබන ආයුර්වේද නිෂ්පාදන
இறக்குமதி ஆயுள்வேத மருந்து உற்பத்திகள்
Imported Ayurveda products

ආයුර්වේද නිෂ්පාදනය ආනයන අවශ්‍යතාවය	පර්යේෂණ	නිදර්ශක	අලෙවිය
ஆயுள்வேத உற்பத்தி இறக்குமதி தேவை	ஆராய்ச்சி	மாதிரி	விற்பனை
Import requirement of Ayurveda products	Research	Specimen	Sale

ආයුර්වේද නිෂ්පාදන ගබඩා කරන ස්ථානයේ නම හා ලිපිනය
ஆயுள்வேத மருந்து உற்பத்தி களஞ்சியத்தின் பெயரும் முகவரியும்
Name and address of Ayurveda product store

ආනයන අපනයන පාලන දෙපාර්තමේන්තු ලියාපදිංචි අංකය හා දිනය
இறக்குமதி மற்றும் ஏற்றுமதிச் சட்டுப்பாட்டுத் திணைக்களத்தின் பதிவுச் சான்றிதழ் இலக்கமும் திகதியும்
Number and Date of Import Export Control Department registration

දේශීය ආදායම් දෙපාර්තමේන්තුව මගින් නිකුත් කළ බදු අනන්‍යතා අංකය
தேசிய வருமானத் திணைக்களத்தின் மூலம் வழங்கப்படுகின்ற வரி அடையாள இலக்கம்
Tax Identification Number issued by the Inland Revenue Department

ආයුර්වේද නිෂ්පාදන ආනයනය සඳහා ලබාගත් ශ්‍රී ලංකා රේගුවේ ලියාපදිංචි අංකය
மேற்படி பொருட்கள் இறக்குமதி செய்வதற்காக இலங்கை சுங்கத்தின் பதிவு இலக்கம்
Sri Lanka Customs registration number obtained for import of Ayurveda Products

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹாகம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சுவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නිෂ්පාදන අපනයන ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத உற்பத்தி ஏற்றுமதியினைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF EXPORTATION OF AYURVEDA DRUG PRODUCTS

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන සමාගම/ව්‍යාපාරය/පුද්ගලයාට පහත ආයුර්වේද නිෂ්පාදන අපනයනය සඳහා ලියාපදිංචිය ලබා දෙන බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டனை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப சீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத உற்பத்தி இறக்குமதிக்காக பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, that the registration for Export of Ayurveda products is granted to the Company/Business/Individuals whose details are below.

මා විසින් හෝ නීති කාන්‍යයක නිකානුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර ක කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இறத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

මාම අපනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම
ஆயுள்வேத மருந்து உற்பத்தி ஏற்றுமதி நிறுவனம்/வியாபாரம்/தனிநபரின் பெயர்
Name of Ayurveda Products exporting Company/Business/Individual

මාම අපනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය
ஆயுள்வேத உற்பத்தி ஏற்றுமதி நிறுவனம்/வியாபாரம்/தனிநபரின் முகவரி
Address of Ayurveda Products exporting Company/Business/Individual

අපනයනය කරනු ලබන ආයුර්වේද නිෂ්පාදන
ஏற்றுமதி ஆயுள்வேத உற்பத்திகள்
Exported Ayurveda products

ආයුර්වේද නිෂ්පාදන අපනයන අවශ්‍යතාවය	පර්යේෂණ	නිදර්ශක	අලෙවිය
ஆயுள்வேத உற்பத்தி தேவை	ஆராய்ச்சி	மாதிரி	விற்பனை
Export requirement of Ayurveda products	Research	Specimen	Sale

ආයුර්වේද නිෂ්පාදන ගබඩා කරන ස්ථානයේ නම හා ලිපිනය
ஆயுள்வேத மருந்து உற்பத்தி களஞ்சியத்தின் பெயரும் முகவரியும்
Name and address of Ayurveda product store

ආනයන අපනයන පාලන දෙපාර්තමේන්තුව ලියාපදිංචි අංකය හා දිනය
இறக்குமதி மற்றும் ஏற்றுமதிச் கட்டுப்பாட்டுத் திணைக்களத்தின் பதிவுச் சான்றிதழ் இலக்கமும் திகதியும்
Number and Date of Import Export Control Department registration

දේශීය ආදායම් දෙපාර්තමේන්තුව මගින් නිකුත් කළ බදු අනන්‍යතා අංකය
தேசிய வருமானத் திணைக்களத்தின் மூலம் வழங்கப்படுகின்ற வரி அடையாள இலக்கம்
Tax Identification Number issued by the Inland Revenue Department

ආයුර්වේද නිෂ්පාදන අපනයනය සඳහා ලබාගත් ශ්‍රී ලංකා රේගුවේ ලියාපදිංචි අංකය
மேற்படி பொருட்கள் ஏற்றுமதி செய்வதற்காக இலங்கை சுங்கத்தின் பதிவு இலக்கம்
Sri Lanka Customs registration number obtained for export of Ayurveda Products

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ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටා පාර, නාවික, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரகம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
கவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் ஏவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද අමුද්‍රව්‍ය ආනයන ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத மூலப்பொருட்கள் இறக்குமதியினைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF IMPORTATION OF AYURVEDA RAW MATERIALS

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන සමාගම/ව්‍යාපාරය/පුද්ගලයාට පහත ආයුර්වේද අමුද්‍රව්‍ය ආනයනය සඳහා ලියාපදිංචිය ලබා දෙන බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டனை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப சீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத மூலப்பொருட்கள் இறக்குமதிக்காக பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act, No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, that the registration for import of Ayurveda raw materials is granted to the Company/Business/Individuals whose details are below.

මා විසින් හෝ නීති ක්‍ෂත්‍රයක නිත්‍යනුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මීස මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර ක කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

අමුද්‍රව්‍ය ආනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම
ஆயுள்வேத மூலப்பொருட்கள் இறக்குமதி நிறுவனம்/வியாபாரம்/தனிநபரின் பெயர்
Name of Ayurveda raw materials Importing Company/Business/Individual

අමුද්‍රව්‍ය ආනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය
ஆயுள்வேத மூலப்பொருட்கள் இறக்குமதி நிறுவனம்/வியாபாரம்/தனிநபரின் முகவரி
Address of Ayurveda raw materials Importing Company/Business/Individual

ආනයනය කරනු ලබන අමුද්‍රව්‍ය
இறக்குமதி மூலப்பொருட்கள்
Imported Ayurveda raw materials

අමුද්‍රව්‍ය ආනයන අවශ්‍යතාවය	පර්යේෂණ	නිදර්ශක	අලෙවිය
ஆயுள்வேத மூலப்பொருட்கள் இறக்குமதி தேவை	ஆராய்ச்சி	மாதிரி	விற்பனை
Import requirement of Ayurveda raw materials	Research	Specimen	Sale

අමුද්‍රව්‍ය ගබඩා කරන ස්ථානයේ නම හා ලිපිනය
ஆயுள்வேத மூலப்பொருட்கள் சளஞ்சியத்தின் பெயரும் முகவரியும்
Name and address of Ayurveda raw materials store

ආනයන අපනයන පාලන දෙපාර්තමේන්තුව ලියාපදිංචි අංකය හා දිනය
இறக்குமதி மற்றும் ஏற்றுமதிக்கு கட்டுப்பாட்டுத் திணைக்களத்தின் பதிவுச் சான்றிதழ் இலக்கமும் திகதியும்
Number and Date of Import Export Control Department registration

දේශීය ආදායම් දෙපාර්තමේන්තුව මගින් නිකුත් කළ බදු අනන්‍යතා අංකය
தேசிய வருமானத் திணைக்களத்தின் மூலம் வழங்கப்படுகின்ற வரி அடையாள இலக்கம்
Tax Identification Number issued by the Inland Revenue Department

අමුද්‍රව්‍ය ආනයනය සඳහා ලබාගත් ශ්‍රී ලංකා රේගුවේ ලියාපදිංචි අංකය
மூலப்பொருட்கள் இறக்குமதி செய்வதற்காக இலங்கை சுங்கத்தின் பதிவு இலக்கம்
Sri Lanka Customs registration number obtained for import of Ayurveda raw materials

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ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரசம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சுவனீப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද අමුද්‍රව්‍ය අපනයන ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத மூலப்பொருட்கள் ஏற்றுமதியினைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF EXPORTATION OF RAW MATERIALS

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන සමාගම්/ව්‍යාපාරය/පුද්ගලයාට පහත ආයුර්වේද අමුද්‍රව්‍ය අපනයනය සඳහා ලියාපදිංචිය ලබා දෙන බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் கட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத மூலப்பொருட்கள் ஏற்றுமதிக்காகப் பதிவு செய்யப்பட்டுள்ள என்பதனை உறுதிப்படுத்துகின்றேன்

I am hereby approving that in accordance with the Ayurveda Act, No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, that the registration for export of Ayurveda raw materials is granted to the Company/Business/Individuals whose details are below.

මා විසින් හෝ නීති කතෘයක නිත්‍යානුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

අමුද්‍රව්‍ය අපනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම
ஆயுள்வேத மூலப்பொருட்கள் ஏற்றுமதி நிறுவனம்/வியாபாரம்/தனிநபரின் பெயர்
Name of Ayurveda raw materials exporting Company/Business/Individual

අමුද්‍රව්‍ය අපනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය
ஆயுள்வேத மூலப்பொருட்கள் ஏற்றுமதி நிறுவனம்/வியாபாரம்/தனிநபரின் முகவரி
Address of Ayurveda raw materials exporting Company/Business/Individual

අපනයනය කරනු ලබන අමුද්‍රව්‍ය
ஏற்றுமதி ஆயுள்வேத மூலப்பொருட்கள்
Exported Ayurveda raw materials

අමුද්‍රව්‍ය අපනයන අවශ්‍යතාවය	පර්යේෂණ	නිදර්ශක	අලෙවිය
ஆயுள்வேத மூலப்பொருட்கள் ஏற்றுமதி தேவை	ஆராய்ச்சி	மாதிரி	விற்பனை
export requirement of Ayurveda raw materials	Research	Specimen	Sale

අමුද්‍රව්‍ය ගබඩා කරන ස්ථානයේ නම හා ලිපිනය
ஆயுள்வேத மூலப்பொருட்கள் களஞ்சியத்தின் பெயரும் முகவரியும்
Name and address of Ayurveda raw materials store

අපනයන සංවර්ධන මණ්ඩලයේ ලියාපදිංචි අංකය හා දිනය
இறக்குமதி மற்றும் ஏற்றுமதிக்கு கட்டுப்பாட்டுத் திணைக்களத்தின் பதிவுச் சான்றிதழ் இலக்கமும் திகதியும்
Number and Date of Import and Export Control Department registration

දේශීය ආදායම් දෙපාර්තමේන්තුව මගින් නිකුත් කළ බදු අනන්‍යතා අංකය
தேசிய வருமானத் திணைக்களத்தின் மூலம் வழங்கப்படுகின்ற வரி அடையாள இலக்கம்
Tax Identification Number issued by the Inland Revenue Department

අමුද්‍රව්‍ය අපනයනය සඳහා ලබාගත් ශ්‍රී ලංකා ටේෂුවේ ලියාපදිංචි අංකය
மூலப்பொருட்கள் இறக்குமதி செய்வதற்காக இலங்கை சுங்கத்தின் பதிவு பெறப்பட்டுள்ளதா
Sri Lanka Customs registration number obtained for export of Ayurveda raw materials

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ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரகம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சுவனியப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නිෂ්පාදන ක්‍රියාවලිය සඳහා ඇසුරුම්/සංරක්ෂණ ද්‍රව්‍ය/සහායක ද්‍රව්‍ය
ආනයන ලියාපදිංචි කිරීමේ සහතික පත්‍රය

ஆயுள்வேத உற்பத்திகளிற்கான /மருந்துப் பொதிகள் /பாதுகாப்புத் திரவியங்கள் /துணைத் திரவியங்கள் என்பனவற்றின்
இறக்குமதியினைப் பதிவு செய்வதற்கான விண்ணப்பம்

CERTIFICATE OF IMPORT REGISTRITON OF PACKAGING/PRESERVATIVES/
EXCPIENTS FOR AYURVEDA MANUFACTURING PROCESS

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන සමාගම/ව්‍යාපාරය/පුද්ගලයාට පහත ආයුර්වේද නිෂ්පාදන ක්‍රියාවලියට අවශ්‍ය පහත ඇසුරුම්/සංරක්ෂණ ද්‍රව්‍ය/සහායක ද්‍රව්‍ය ආනයනය සඳහා ලියාපදිංචිය ලබා දෙන බව කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டனை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத மூலப்பொருட்கள் இறக்குமதிக்காக பதிவு செய்வதற்கான நிலையமாகப் பதிவு செய்யப்பட்டுள்ளது என்பதனை உறுதிப்படுத்துகின்றேன்.

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, that the registration for import of packaging/preservatives/excipient materials required for the Ayurveda manufacturing process is granted to the Company/Business/Individuals whose details are below.

මා විසින් හෝ නීති කාන්‍යයක නිත්‍යනුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்துஓ வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම
இறக்குமதி நிறுவனம் /வியாபாரம் /தனிநபரின் பெயர்
Name of Importing Company/Business/Individual

ආනයන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය
இறக்குமதி நிறுவனம் /வியாபாரம் /தனிநபரின் முகவரி
Address of Importing Company/Business/Individual

ආනයනය කරනු ලබන ඇසුරුම්/සංරක්ෂණ ද්‍රව්‍ය/සහායක ද්‍රව්‍ය
இறக்குமதி மருந்துப் பொதிகள் /பாதுகாப்புத் திரவியங்கள் /துணைத் திரவியங்கள்
Imported packaging/preservatives/excipient materials

ආනයන අවශ්‍යතාවය	පර්යේෂණ	නිදර්ශක	නිෂ්පාදනය	අලෙවිය
இறக்குமதி தேவை	ஆராய்ச்சி	மாதிரி	உற்பத்தி	விற்பனை
Import requirement	Research	Specimen	production	Sale

ගබඩා කරන ස්ථානයේ නම හා ලිපිනය
சளஞ்சியத்தின் பெயரும் முகவரியும்
Name and address of store

ආනයන අපනයන පාලන දෙපාර්තමේන්තු ලියාපදිංචි අංකය හා දිනය
இறக்குமதி மற்றும் ஏற்றுமதிச் சட்டுப்பாட்டுத் திணைக்களத்தின் பதிவுச் சான்றிதழ் இலக்கமும் திகதியும்
Number and Date of Import Export Control Department registration

දේශීය ආදායම් දෙපාර්තමේන්තුව මගින් නිකුත් කළ බදු අනන්‍යතා අංකය
தேசிய வருமானத் திணைக்களத்தின் மூலம் வழங்கப்படுகின்ற வரி அடையாள இலக்கம்
Tax Identification Number issued by the Inland Revenue Department

ආනයනය සඳහා ලබාගත් ශ්‍රී ලංකා ඊර්ලවේ ලියාපදිංචි අංකය
மூலப்பொருட்கள் இறக்குமதி செய்வதற்காக இலங்கை சுங்கத்தின் பதிவு இலக்கம்
Sri Lanka Customs registration number obtained for import

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ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரசம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
கவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නිෂ්පාදන ක්‍රියාවලිය සඳහා ඇසුරුම්/සංරක්ෂණ ද්‍රව්‍ය/සහායක ද්‍රව්‍ය අපනයන ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத உற்பத்திகளிற்கான /மருந்துப் பொதிகள் /பாதுகாப்புத் திரவியங்கள் /துணைத் திரவியங்கள் என்பனவற்றின்
ஏற்றுமதியினைப் பதிவு செய்வதற்கான விண்ணப்பம்
CERTIFICATE OF EXPORT REGISTRTION OF PACKAGING/PRESERVATIVES/
EXPCIPIENTS FOR AYURVEDA MANUFACTURING PROCESS

වලංගු කාලය செல்லுபடியாகும் Valid Period	දින සිට தொடக்கம் from	දින දක්වා வரை Up to	සහතික පත්‍රයේ අංකය சான்றிதழின் இலக்கம் Certificate No.
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ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන සමාගම/වාහාරය/පුද්ගලයාට පහත ආයුර්වේද නිෂ්පාදන ක්‍රියාවලියට අවශ්‍ය පහත ඇසුරුම්/සංරක්ෂණ ද්‍රව්‍ය/සහායක ද්‍රව්‍ය අපනයනය සඳහා ලියාපදිංචිය ලබා දෙන බව කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப சீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத உற்பத்திகளிற்கான/மருந்துப் பொதிகள்/பாதுகாப்புத் திரவியங்கள்/துணைத் திரவியங்கள் என்பனவற்றின் ஏற்றுமதிக்காகப் பதிவு செய்வதற்காக நிலையமாகப் பதிவு செய்யப்பட்டுள்ளது என்பதனை உறுதிப்படுத்துகின்றேன்.

I am hereby approving that in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda, that the registration for export of packaging/preservatives/excipient materials required for the Ayurveda manufacturing process is granted to the company/individual whose details are below.

මා විසින් හෝ නීති කතෘයක නිත්‍යානුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මීස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

අපනයන සමාගමේ/වාහාරයේ/පුද්ගලයාගේ නම ஏற்றுமதி நிறுவனம்/வியாபாரம்/தனிநபரின் பெயர் Name of Exporting Company/Business/Individual					
අපනයන සමාගමේ/වාහාරයේ/පුද්ගලයාගේ ලිපිනය ஏற்றுமதி நிறுவனம்/வியாபாரம்/தனிநபரின் முகவரி Address of Exporting Company/Business/Individual					
අපනයනය කරනු ලබන ඇසුරුම්/සංරක්ෂණ ද්‍රව්‍ය/සහායක ද්‍රව්‍ය ஏற்றுமதி மருந்துப் பொதிகள் /பாதுகாப்புத் திரவியங்கள் /துணைத் திரவியங்கள் Exporting packaging/preservatives/excipient materials					
අපනයන අවශ්‍යතාවය ஏற்றுமதி தேவை Import requirement	පර්යේෂණ ஆராய்ச்சி Research	නිදර්ශක மாதிரி Specimen	නිෂ්පාදනය உற்பத்தி production	අලෙවිය விற்பனை Sale
ගබඩා කරන ස්ථානයේ නම හා ලිපිනය சளஞ்சியத்தின் பெயரும் முகவரியும் Name and address of store					
ශ්‍රී ලංකා අපනයන සංවර්ධන මණ්ඩලයේ ලියාපදිංචි අංකය හා දිනය இலங்கை ஏற்றுமதி அபிவிருத்தித் திணைக்களத்தின் பதிவுச் சான்றிதழ் இலக்கமும் திகதியும் Number and Date of Import Export Control Department registration					
දේශීය ආදායම් දෙපාර්තමේන්තුව මගින් නිකුත් කළ බදු අනන්‍යතා අංකය தேசிய வருமானத் திணைக்களத்தின் மூலம் வழங்கப்படுகின்ற வரி அடையாள இலக்கம் Tax Identification Number issued by the Inland Revenue Department					
අපනයනය සඳහා ලබාගත් ශ්‍රී ලංකා රේගුවේ ලියාපදිංචි අංකය மூலப்பொருட்கள் ஏற்றுமதி செய்வதற்காக இலங்கை சுங்கத்தின் பதிவு இலக்கம் Sri Lanka Customs registration number obtained for export					

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාච පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரகம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் ஏவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

LICENCE TO IMPORT AN AYURVEDA PRODUCT AS SAMPLES
FOR TEST/ EXAMINATION/ ANALYSIS/ CLINICAL TRIAL/
DISTRIBUTION AS PHYSICIAN'S SAMPLES

Licence No.:

..... of
..... is/are hereby licenced to import from
..... the Ayurveda product specified below for the purpose
of test/ examination/ analysis/ clinical trial/ distribution as physician's samples.

This licence is subject to conditions prescribed in the Ayurveda Code for Ayurveda medicine and Surgery Regulations, 2024 made under the Ayurveda Act, No. 31 of 1961 and shall be in force during the period stated in this licence, unless it is earlier suspended or cancelled.

Generic name of Ayurveda product :

Brand name (if any) :

Quantity :

Pack size(s) :

Country of the origin :

Name of the Manufacturer :

Contact details of the Manufacturer :

Period of validity of the licence :

Date of issue :

Receipt No. for fees paid and Date :

.....
Commissioner General of Ayurveda

.....of20 Department of Ayurveda, Old Kottawa Road, Navinna,
Maharagama.

N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද නිෂ්පාදන ප්‍රවාහනය ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத உற்பத்திகள் வேறு இடங்களிற்கு எடுத்துச் செல்வதனைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION FOR TRANSPORT OF AYURVEDIC PRODUCTS

වලංගු කාලය
செல்லுபடியாகும்
Valid Period

දින සිට
தொடக்கம்
from

දින දක්වා
வரை
Up to

සහතික පත්‍රයේ අංකය
சான்றிதழின் இலக்கம்
Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ආයුර්වේද නිෂ්පාදන ප්‍රවාහනය සඳහා ලියාපදිංචිය ලබා දෙන බව කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் கட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத உற்பத்திகள் வேறு இடங்களிற்கு எடுத்துச் செல்லப்படுவதற்காக பதிவு செய்யப்பட்டுள்ளது என்பதனை உறுதிப்படுத்துகின்றேன்.

I am hereby approved that the Ayurvedic products listed below have been registered for transportation in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda.

මා විසින් හෝ නීති කතායක නිත්‍යානුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මීස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආයුර්වේද නිෂ්පාදන ප්‍රවාහනය කරන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම
ஆயுள்வேத உற்பத்திகளை வேறு இடங்களிற்கு எடுத்துச் செல்லும் நிறுவனத்தின் /வியாபாரத்தின் /தனி நபரின் பெயர்
Name of Company/ Business/ individual transporting Ayurveda products

ආයුර්වේද නිෂ්පාදන ප්‍රවාහනය කරන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය
ஆயுள்வேத உற்பத்திகளை வேறு இடங்களிற்கு எடுத்துச் செல்லும் நிறுவனத்தின் /வியாபாரத்தின் /தனி நபரின் முகவரி
Address of Company/ Business/ individual transporting Ayurveda products

ප්‍රවාහනය කරනු ලබන ආයුර්වේද නිෂ්පාදන වර්ග
வேறு இடங்களிற்கு எடுத்துச் செல்லப்படும் ஆயுள்வேத உற்பத்திகள்
Types of Ayurveda products transported

අයදුම්කරු සතු ආයුර්වේද දෙපාර්තමේන්තුවෙහි ලියාපදිංචි නිෂ්පාදනාගාර/ගබඩා/මසුසැල් විස්තර
விண்ணப்பதாரியிடம் ஆயுள்வேத திணைக்கள பதிவு இலக்கம் உற்பத்தி நிலையம் /களஞ்சியம் /விற்பனை நிலைய தரவுகள்
Details of manufactures/ stores/ pharmacies registered with the Department of Ayurveda owned by the applicant

අයතනයේ නම நிறுவனத்தின் பெயர் Name of Institute	ලියාපදිංචි අංකය பதிவு இலக்கம் No of Registration	ලිපිනය முகவரி Address
.....
.....

ප්‍රවාහනය සඳහා යොදාගනු ලබන රථය පිළිබඳ විස්තර
வேறு இடங்களிற்கு எடுத்துச் செல்வதற்காகப் பயன்படுத்தப்படும் வாகனம் பற்றிய விபரங்கள்:
Details of the vehicle used for transportation

වර්ගය වාසන වகை Type	ලියාපදිංචි අංකය වාසන இல. No of Registration	වර්ණය நிறம் Colour
.....
.....
.....

.....
ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரகம். 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
கவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද අමුද්‍රව්‍ය ප්‍රවාහනය ලියාපදිංචි කිරීමේ සහතික පත්‍රය
ஆயுள்வேத மூலப்பொருட்கள் வேறு இடங்களிற்கு எடுத்துச் செல்வதனைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION FOR TRANSPORT OF RAW MATERIALS

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ආයුර්වේද අමුද්‍රව්‍ය ප්‍රවාහනය සඳහා ලියාපදිංචිය ලබා දෙන බව කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் சட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப கீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத மூலப்பொருட்கள் வேறு இடங்களிற்கு எடுத்துச் செல்லப்படுவதற்காக பதிவு செய்யப்பட்டுள்ளது என்பதனை உறுதிப்படுத்துகின்றேன்.

I am hereby approved that the Ayurveda raw materials below have been registered for transportation in accordance with the Ayurveda Act No. 31 of 1961 and subject to the orders and instructions issued from time to time by the Department of Ayurveda.

මා විසින් හෝ තීති කෘතයක නිතෘනුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආයුර්වේද අමුද්‍රව්‍ය ප්‍රවාහනය කරන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ නම ஆயுள்வேத மூலப்பொருட்களை வேறு இடங்களிற்கு எடுத்துச் செல்லும் நிறுவனத்தின் /வியாபாரத்தின் /தனி நபரின் பெயர் Name of Company/ Business/ individual transporting Ayurveda raw material		
ආයුර්වේද අමුද්‍රව්‍ය ප්‍රවාහනය කරන සමාගමේ/ව්‍යාපාරයේ/පුද්ගලයාගේ ලිපිනය ஆயுள்வேத மூலப்பொருட்களை வேறு இடங்களிற்கு எடுத்துச் செல்லும் நிறுவனத்தின் /வியாபாரத்தின் /தனி நபரின் முகவரி Address of Company/ Business/ individual transporting Ayurveda raw material		
ප්‍රවාහනය කරනු ලබන ආයුර්වේද අමුද්‍රව්‍ය වර්ග வேறு இடங்களிற்கு எடுத்துச் செல்லப்படும் ஆயுள்வேத மூலப்பொருட்கள் Types of Ayurveda raw material transported		
ආයුර්වේද අමුද්‍රව්‍ය ප්‍රවාහන අවශ්‍යතාවය - ආනයනය/අපනයනය/නිෂ්පාදනයට/ගබඩාකරණයට/දේශීය වෙළෙඳපොළ ஆயுள்வேத மூலப்பொருட்கள் வேறு இடங்களிற்கு எடுத்துச் செல்லும் தேவை ஏற்றுமதி /இறக்குமதி /உற்பத்திக்கு /களஞ்சியத்திற்கு /உள்நாட்டு சந்தை Ayurveda raw material transportation requirement - Import/Export/Production/Storing/Local market		
අයදුම්කරු සහ ආයුර්වේද දෙපාර්තමේන්තුවෙහි ලියාපදිංචි නිෂ්පාදනාගාර/ගබඩා/මුසුසැල් විස්තර விண்ணப்பதாரியிடம் ஆயுள்வேத திணைக்கள பதிவு இலக்கம் உற்பத்தி நிலையம் /களஞ்சியம் /விற்பனை நிலைய தரவுகள் Details of manufactures/ stores/ pharmacies registered with the Department of Ayurveda owned by the applicant		
ආයතනයේ නම/නිර්වචනවත් නම/නම	ලියාපදිංචි අංකය/පතිවු/ලියාපදිංචි අංකය	ලිපිනය/මුසුසැල් Address
ප්‍රවාහනය සඳහා යොදාගනු ලබන රථය පිළිබඳ විස්තර வேறு இடங்களிற்கு எடுத்துச் செல்வதற்காகப் பயன்படுத்தப்படும் வாகனம் பற்றிய விபரங்கள் Details of the vehicle used for transportation		
වර්ගය/වර්ගය වகை Type	ලියාපදිංචි අංකය/වගාකන இல. No of Registration	වර්ණය/நிறம் Colour
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ආයුර්වේද කොමසාරිස් ජනරාල්
ஆயுள்வேத ஆணையாளர் நாயகம்
Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවික, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
ஆயுள்வேத திணைக்களம், மஹரசம். 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
.....of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
சுவனப்பு: மேற்கூறப்பட்ட விபரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
N.B. Any change in the above particulars must be notified within 14 days.

ආයුර්වේද ඖෂධ වගා භූමියක් ලියාපදිංචි කිරීමේ සහතික අංකය
ஆயுள்வேத மருந்துகள் உற்பத்தி விளை நிலத்தைப் பதிவு செய்யும் சான்றிதழ்
CERTIFICATE OF REGISTRATION OF AN AYURVEDA MEDICINAL CULTIVATING LAND

වලංගු කාලය	දින සිට	දින දක්වා	සහතික පත්‍රයේ අංකය
செல்லுபடியாகும்	தொடக்கம்	வரை	சான்றிதழின் இலக்கம்
Valid Period	from	Up to	Certificate No.

ආයුර්වේද දෙපාර්තමේන්තුව විසින් 1961 අංක 31 දරන ආයුර්වේද පනතේ ප්‍රකාරව හා වරින්වර නිකුත් කරනු ලබන නියෝග හා උපදෙස්වලට යටත්ව පහත විස්තර දැක්වෙන ස්ථානය ආයුර්වේද ඖෂධ වගා භූමියක් ලෙසට ලියාපදිංචි කරන ලද බව කරන ලද බව මෙයින් සහතික කරමි.

1961 ஆம் ஆண்டின் 31 ஆம் இலக்க ஆயுள்வேத சட்டத்தின் பிரகாரம் காலத்திற்குக் காலம் வழங்கப்படும் கட்டளை மற்றும் அறிவுறுத்தல்களுக்கு ஏற்ப சீழ்க் குறிப்பிடப்படும் நிலையமானது ஆயுள்வேத மருந்துகள் விளை நிலமாகப் பதிவு செய்யப்பட்டுள்ளது என்பதனை உறுதிப்படுத்துகின்றேன்.

I am hereby approving that accordance with the Ayurveda Act No. 31 of 1961 and subject to orders and instructions issued from time to time by the Department of Ayurveda, that the following details have been registered as an Ayurveda medicinal cultivation land.

මා විසින් හෝ නීති කතායක නිත්‍යානුකූල නියෝගයක් මගින් කලින් අවලංගු නොකරනු ලැබුවහොත් මිස මෙම මෙම සහතික පත්‍රයේ සඳහන් දින සිට වසර කාලයක් සඳහා මෙම සහතිකය වලංගුව පවතී.

என்னால் அல்லது சட்டத்தின் ஏற்பாடுகளின் மூலம் இரத்துச் செய்யப்படாவிட்டால், இச் சான்றிதழ் பத்திரத்தில் குறிப்பிடப்பட்டுள்ள தினத்திலிருந்து வருட காலத்திற்கு இச் சான்றிதழ் செல்லுபடியாகும்.

This certificate shall remain valid for a period of year from the date of this certificate unless revoked earlier by me or by legal order of a legal act.

ආයුර්වේද ඖෂධ වගාව අයිතිකරුගේ නම
 ஆயுள்வேத ஔடத விளை நிலத்தின் உரிமையாளரின் பெயர்
 Name of the owner of Ayurveda medicinal cultivation land

ආයුර්වේද ඖෂධ වගාව අයිතිකරුගේ ලිපිනය
 ஆயுள்வேத ஔடத விளை நிலத்தின் உரிமையாளரின் முகவரி
 Address of the owner of Ayurveda medicinal cultivation land

ආයුර්වේද ඖෂධ වගාවේ නම
 ஆயுள்வேத ஔடத விளை நிலத்தின் பெயர்
 Name of Ayurveda medicinal cultivation land

ආයුර්වේද ඖෂධ වගාව පිහිටි ස්ථානයේ ලිපිනය
 ஆயுள்வேத ஔடத விளை நிலத்தின் முகவரி
 Address of Ayurveda medicinal cultivation land

වගා කරනු ලබන ඖෂධ වර්ග
 விளைவிக்கப்படும் ஔடதங்களின் வகைகள்
 Types of medicines being cultivated

ආයුර්වේද ඖෂධ වගාකර ඇති ඉඩම් ප්‍රමාණය
 ஆயுள்வேத ஔடதங்கள் விளைவிக்கப்பட்ட நிலத்தின் அளவு
 Area of land under cultivation of Ayurveda medicines

ආයුර්වේද ඖෂධ වගාව ආරම්භ කළ දිනය
 ஆயுள்வேத ஔடத வளர்ப்பு ஆரம்பிக்கப்பட்ட திகதி
 Date of commencement of Ayurveda medicinal cultivation land

ආයුර්වේද ඖෂධ වගාව භාරව සිටින කෘෂි උපදේශකවරයාගේ නම සහ ලියාපදිංචි අංකය
 ஆயுள்வேத ஔடதங்கள் விளைச்சலை மேற்பார்வை செய்யும் ஆலோசகரின் பெயர் மற்றும் பதிவு இலக்கம்
 Name and Registration number of agriculture supervisor in charge of Ayurveda medicinal cultivation

.....
 ආයුර්වේද කොමසාරිස් ජනරාල්
 ஆயுள்வேத ஆணையாளர் நாயகம்
 Commissioner General of Ayurveda

20.....මස.....වැනි දින පරණ කොට්ටාව පාර, නාවින්න, මහරගම ආයුර්වේද දෙපාර්තමේන්තුවේදී ය.
 ஆயுள்வேத திணைக்களம், மஹாகம. 20 ஆம் ஆண்டு மாதம் ஆம் திகதி
of20 Department of Ayurveda, Old Kottawa Road, Navinna, Maharagama

සංලක්ෂ්‍යය : ඉහත සඳහන් විස්තර සම්බන්ධයෙන් කිසියම් වෙනසක් ඇති වී නම් ඒ බව දින 14 ක් ඇතුළත දැනුම් දිය යුතුය.
 கவனிப்பு: மேற்கூறப்பட்ட விவரங்களில் மாற்றம் எவையேனும் ஏற்பட்டால், அம்மாற்றத்தினை 14 நாட்களுக்குள் அறிவிக்க வேண்டும்.
 N.B. Any change in the above particulars must be notified within 14 days.

TEMPORARY/ PERMANENT LICENCE
FOR CULTIVATE, MANUFACTURE, PURCHASE, STORAGE, DISTRIBUTION, SALE,
EXPORT OF CANNABIS AND CANNABIS RELATED ARTICLES, SUBSTANCE OR DRUGS
AND AYURVEDA PRODUCTS

Licence No:

..... of
..... is/are hereby temporary/ permanent licenced to operate
cultivation, manufacturing, purchase, storage, distribution, sale, export Cannabis and Cannabis related articles, substance or
drugs and Ayurveda products, from to

This licence is subject to conditions prescribed in the Ayurveda Code for Ayurveda medicine and Surgery Regulations, 2024
made under the Ayurveda Act, No. 31 of 1961 and shall be in force during the period stated in this licence, unless it is earlier
suspended or cancelled.

Type of licence :

Type of Ayurveda product :

Brand name (if any) :

Period of validity of the licence :

Date of issue :

Receipt No. for fees paid and Date :

.....

Commissioner General of Ayurveda

.....of20 Department of Ayurveda, Old Kottawa Road, Navinna,
Maharagama.

N.B. Any change in the above particulars must be notified within 14 days.

Schedule V**SPECIFICATION RELATING TO PACKING, LABELLING AND CONTENTS OF A BROCHURE****Label and Packing Contents of the Brochure**

The container of every medicine imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label bearing the following information in with the National Language Policy requirement.

- (a) The official or generic name.
- (b) If conformity with a pharmacopeial monograph is claimed for a product, relevant labeling requirements given in both general and specific monographs shall be adhered to.
- (c) The brand/ proprietary name (if any): The brand name should not be already registered for another product.
- (d) A statement of the active substance(s) showing quantitative particulars:
 - (i) The quantity of each active ingredient, identified by its appropriate non- proprietary name, in each dosage unit of the medicinal product expressed in terms of weight, volume, capacity or units of activity; or
 - (ii) where there is no dosage unit, the quantity of each active ingredient identified by its appropriate non-proprietary name, in the container of the medical product expressed in terms of weight, volume, capacity, or units of activity or percentage by weight or volume of the total quantity;
- (e) Pack size: the number of doses, contained in the pack with reference to weight, or volume of the contents.
- (f) Excipient(s) known to have undesirable effects and any other similar ingredients specified by the Authority.
- (g) The dosage.
- (h) The route of administration for injectable products.
- (i) Storage temperature and, other special storage precautions if any.
- (j) A special warning that the product must be stored out of reach of children.
- (k) Specific instructions if the product needs to be reconstituted, diluted, or prepared by any other means prior to its use.
- (l) Where applicable, the product is sterile.
- (m) Where applicable, the product is free from bacterial endotoxins or the product is apyrogenic.
- (n) For injectable solutions, not to use if visible particles are present.
- (o) Any other special warnings and precautions that may be necessary for the particular medicinal product.
- (p) The date of manufacture in clear terms (month/ year)
- (q) The date of expiry in clear terms (month/ year)

- (r) The batch or lot number assigned by the manufacturer, and
- (s) The period for which the medicine can be used after the opening of the container or after the reconstitution of the product, if applicable as the case may be.
- (t) Specific precautions relating to disposal of unused quantities of the product, where applicable.
- (u) The name of the manufacturer and address of the manufacturing site.
 - The name and address of the batch releaser shall be used, if different from the drug product manufacturer.
 - Where the product owner is different to the manufacturer, the label shall indicate such face in the following manner: 'manufactured by (name and address of actual manufacturer) for (name of product owner)'.
 - The name and address of the packaging site(s) may be included [if different from the manufacturing/ release site (s)]

Directives of the National Languages Commission

In keeping with the National Languages Policy requirements, the official or generic name shall be displayed in Sinhala, Tamil and English languages.

- For medicines dispensed with an intact outer carton (e.g. a liquid bottle, an ointment tube), displaying the name in local languages on the outer carton is sufficient.
- If the product is taken out from the outer carton for dispensing (e.g. blister strips) or if the product has no outer carton, the primary label should indicate the name in local languages.
- The requirement is not compulsory for injections which require professional healthcare staff for administration.

Exemptions for smaller labels

Primary labels on smaller containers such as a blister strip, an ampoule or vial with a volume of 10 ml or less shall contain the following minimum information:-

- (a) the generic or common name,
- (b) the brand name (where applicable),
- (c) the strength of the drug (where applicable),
- (d) lot or Batch number,
- (e) the date of expiry; and
- (f) the name or logo of the manufacturer or the product owner.

In addition, route of administration shall be indicated for injections. This may be indicated in abbreviations. The storage instructions shall be indicated on strips.

The information exempted on the primary label should be included on the outer carton and/ or the leaflets.

Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack. It is important that the particulars remain available to the user up to the point at which the last does is removed from the blister pack.

General Information provided in the labels should be consistent with the information.