PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce & Industry, Govt. of India)

REGULATORY & MARKET PROFILE OF SRI LANKA

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	South Asia
2	Country	Sri Lanka
3	Capital	Colombo
4	Population	22,576,592 (July 2018 est.)
5	Population growth rate (%)	0.73% (2018 est.)
6	GDP (purchasing power parity)	$ 275.8 billion (2017 est.)
7	GDP - real growth rate (%)	3.3% (2017 est.)
8	GDP - per capita (PPP)	$ 12,900 (2017 est.)
9	Epidemiology	CVS diseases, Diabetes, Hepatitis, Asthma HIV
10	Population below poverty line	6.7%(As per 2012, No update)
11	Age structure (%)	0-14 years: 23.75%
		15-24 years: 14.6%
		25-54 years: 41.6%
		55-64 years: 10.22%
		65 years $ above:9.98%
Source: CIA World Fact Book updated to July 2018		

SRI LANKA- PHARMA MARKET REPORT

Introduction:

Though there is rising demand for Pharmaceuticals especially of chronic nature due, slow progress of Govt health care programs and Local currency's devaluation imports of Pharma is slightly behind the demand supply ratio.

Pharmaceutical expenditure during 2017 is estimated at $ 642 million with a growth of 5%. This expected to touch $664 Million with a growth of 3.3% in 2018.

Strengths

- Robust pharmaceutical market growth.
- Sri Lanka has a national health service, and consultation and treatment are provided free at all public hospitals.
- Government's commitment to improving access to healthcare.

Opportunities

- Sri Lanka depends total on imports for their requirement of Bulk Drugs
- Local industry is yet o catch up with the needs of the country

Latest updates

- In October 2018, the Sri Lanka Chamber of Pharmaceutical Industry (SLCPI) said that despite persistent appeals, the government has failed to address the urgent issue of a fair and proper pricing mechanism for pharmaceutical products in light of the depreciating Sri Lankan rupee against the US dollar.

- In addition, SLCPI highlighted that eleven imported medicines are being or have already been withdrawn from the Sri Lankan market due to the absence of a pricing formula and the drug price ceilings introduced in 2016.

- In September 2018, oDoc(e-health Platform) introduced an online medical consultation platform that enables subscribers and their family to have unlimited medical consultations with experienced GPs and specialists, an innovation that will facilitate access to healthcare services and prescriptions.

Industry Forecast:

Sri Lanka's pharmaceutical market likely to expand over the coming years. The country's growing and ageing population will act as key drivers of market growth. Additionally, there is a latent and growing demand for the treatment of chronic diseases, which will be supported by government efforts to upgrade healthcare services. Government's pro-generic medicines policies, as well as low per-capita spending on medicines, will be an added advantage to generic producers like India.

In 2017, pharmaceutical expenditure in Sri Lanka (hospital and pharmacy medicine sales at consumer prices) reached a value of USD642 mn, and this is estimated to touch $ 664 million in 2018.

By 2022, the market is expected to reach a value of USD787 mn, posting a five-year compound annual growth rate (CAGR) of 4.1 % .

The decision by the health ministry, in July 2018, to reduce the price of nearly 25 medicines used to treat diabetes, respiratory disorders and other chronic diseases will support the development of the country's pharmaceutical and healthcare industry together with increasing the population's access to affordable medicines.

Earlier, the Sri Lanka's health minister reduced the price of 48 essential drugs in 2016 providing greater accessibility to the patients. Prices of 272 drugs from various brands were reduced. Most of the medicines were for chronic illnesses that requires long-term treatment.

Around 85% of pharmaceutical products are imported and the exchange rate impacts significantly on pricing. While capping prices has increased the affordability of certain drugs, the risk of making imports unsustainable has become a major concern for the industry, in light of the depreciation of the Sri Lankan rupee.

Market

A proper distinction between Prescription and over the counter products market is difficult to make due to lax enforcement of Drug rules. Estimated Patented market is only 15-18% of the total $ 642 mn market. The rest consists of generics and over the counter products.

The government in its 2014 budget announced incentives to promote local pharmaceutical industry through an imposition of import duties on pharmaceutical products and making the import of certain Ayurvedic medicines liable to VAT. However, at the same time, the government announced plans to purchase medicines directly from the government of Bangladesh, excluding pharmaceutical companies from mediation in these deals. This highlights the government's focus on the provision of affordable generics.

The combination of drug price caps, import restriction of drugs that are produced locally and a procurement system skewed towards local producers poses as a disincentives to our exporters. The promotion of local drug production will continue to attract some level of interest by foreign investors, given the market's long-term development potential. However, given the country's limited commercial rewards, multinational firms have little incentive to invest and develop a large manufacturing presence in Sri Lanka.

Ongoing improvements in healthcare access in Sri Lanka will be more beneficial to generic drug sales than their patented peers. Section 38 of the National Medicine Drug, Devices & Cosmetic Authority Bill passed in March 2015 necessitates that doctors prescribe medicines according to their international non-proprietary name. Pharmacists are also required to inform patients if generic equivalents to a medicine prescribed are available and to present the cost of each product to facilitate the patient's decision.

Sri Lanka's regulatory environment will remain unfavourable for foreign pharmaceutical firms. While the affordability of medicines was a key focus of the country's National Medicinal Drug, Devices and Cosmetic Authority bill (passed in March 2015), it also has provisions that disadvantage companies importing products into the country. Section 116 (2) of the national medicine policy states that the Manufacturing Regional Division can advise the authorities to restrict the import of products which are sufficiently supplied by local manufacturers. This has prompted the authorities to make ambitious plans to leverage the bill to reduce the types of medicines imported into Sri Lanka from approximately 10,000 to 500.

Only 50% of a patients and 10% of hospitalized patients buy medicines out of their pocket expenses and he rest is met from Public expenditure and/or insurance.

Pharmaceutical Trade:

Despite ongoing government efforts to boost local pharmaceutical manufacturing capacity, Experts opine, Sri Lanka will continue to rely on imports to meet its domestic demand for medicines. Currently 90% of its Pharmaceutical needs are imported. In fact, the local drug industry remains underdeveloped and pharmaceutical foreign investment in the country may remain subdued in the near term. Thus, Sri Lanka is likely to observe an increase in drug imports over the next five years, especially to meet the demand for more advanced treatments.

In 2017, pharmaceutical imports reached a value of USD445 mn, and this is expected to have touched $ 460 mn in 2018. By 2022, pharmaceutical imports are expected to USD545mn observing a compound annual growth rate of 4.1%.

Major sources of drug imports according to 2017 data include India (49% of total drug imports), Pakistan (8%), the US (3%), Switzerland (3%), France (4%), the UK (3%), and Bangladesh (4%).

In June 2014, a subsidiary of India's Cipla acquired a 60% stake in a new company in Sri Lanka to market Cipla's products locally. India is the largest importing partner of Sri Lanka with almost 50% of its needs being met by imports from India.

Efforts of Govt to Increase Local production

In January 2018, Pharma Zone, a Malaysian-capital company approved by the Sri Lankan Board of Investment, and the State Pharmaceuticals Manufacturing Corporation of Sri Lanka(SPMC) agreed to build the country's first exclusive pharmaceutical manufacturing zone (PMZ) in the Welipenna area of the Kalutara district. Envisaged to be in operation by 2019, this PMZ will provide local pharmaceutical manufacturers with the land and infrastructure required to establish manufacturing and production operations.

The government goal is to meet 60% of the domestic demand for pharmaceutical products by locally made drugs by 2020. Currently, 2bn units are being produced locally, equating to about 12% of the market, according to the National Chamber of Pharmaceutical Manufacturers of Sri Lanka (NCPM); thus, the government goal is ambitious.

Statistics:

India's exports to Sri Lanka:

Category	2015-16	2016-17	2017-18	GR%	contbn%
BULK DRUGS AND DRUG INTERMEDIATES	10.93	10.05	12.55	24.86	6.07
DRUG FORMULATIONS AND BIOLOGICALS	180.78	187.19	179.36	-4.18	86.75
AYUSH	0.93	1.54	1.42	-7.59	0.69
Herbal Products	0.62	0.63	1.10	74.59	0.53
Surgicals	7.02	8.72	8.10	-7.06	3.92
Vaccines	4.72	9.12	4.23	-53.59	2.05
Total	205.02	217.24	206.76	-4.82	100.00

Imports of Sri Lanka

Sri Lanka's 's Top ten formulation Importing partners $ Million						
Rank	Country	2015	2016	2017	Gr%	Share%
1	India	204.93	219.20	208.79	-4.75	47.57
2	Pakistan	28.21	29.06	33.13	13.98	7.55
3	France	15.46	16.92	18.35	8.50	4.18
4	Bangladesh	11.69	13.51	16.51	22.22	3.76
5	USA	20.10	25.54	16.25	-36.38	3.70
6	Switzerland	11.71	24.32	14.30	-41.19	3.26
7	Russian Federation		3.05	13.92	355.67	3.17
8	United Kingdom	13.49	13.96	12.83	-8.07	2.92
9	Indonesia	9.60	10.59	11.47	8.28	2.61
10	Denmark	8.62	10.74	10.73	-0.05	2.44
	World	401.47	456.70	438.87	-3.90	100.00
Source:UN comtrade						

REGISTRATION AND LICENSING REQUIREMENTS

➢	Regulatory Authority	:	**National Medicines Regulatory Authority (NMRA)**
➢	Website of regulatory Authority	:	http://nmra.gov.lk/
➢	Fees for Drug Registration	:	1250 USD (Process fee- 750USD, Certificate of Registration- 400 USD & Import License Fee- 100USD)
➢	Normal time taken for registration	:	03 Months
➢	Registration Requirement [Dossier Format]	:	Non-CTD
➢	Whether plant inspection is mandatory	:	No
➢	Requirement of Local agent/ Subsidiary		Subsidiary is not Required. Authorised local importer can file the registration.
➢	Registration Validity		05 Yrs

National Medicines Regulatory Authority (NMRA)

The National Medicines Regulatory Authority (NMRA) is the institution in which the Ministry of Health has vested the authority to ensure that the Pharmaceuticals and Medical Devices available to the public meet the required standards of quality and are within the existing legislative framework with respect to the production, marketing and dispensing of these items.

Overview of the Organization:

Vision

To achieve a healthier nation by ensuring the provision of safe, quality and efficacious Pharmaceutical products and safe & quality cosmetic products.

Mission

To regulate and control the manufacture, importation, sale, storage and distribution of Cosmetics, Devices and Drugs (including nutraceuticals and borderline devices) efficiently and effectively whilst ensuring rational usage.

NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015, which repeals the Cosmetics, Devices & Drugs (CDD) Act 1980 is the legislative framework which provides the legal authority to regulate Cosmetics, Devices & Drugs in Sri Lanka. National Medicines Regulatory Authority (NMRA) is responsible for implementation of the provisions of the Act.

Objectives

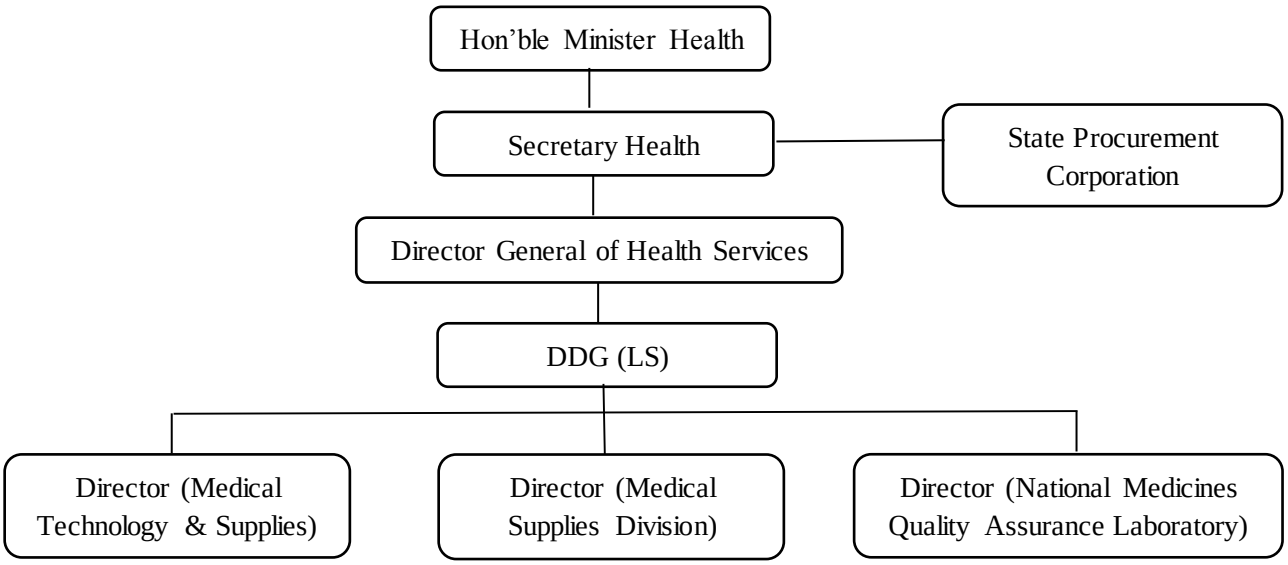
- To ensure that all Pharmaceuticals available in Sri Lanka are of safe, efficacious and acceptable quality
- To ensure all Cosmetics available in Sri Lanka are of safe and acceptable quality
- To ensure uninterrupted availability of Drugs, Cosmetics and Medicinal Devices
- To ensure rational usage

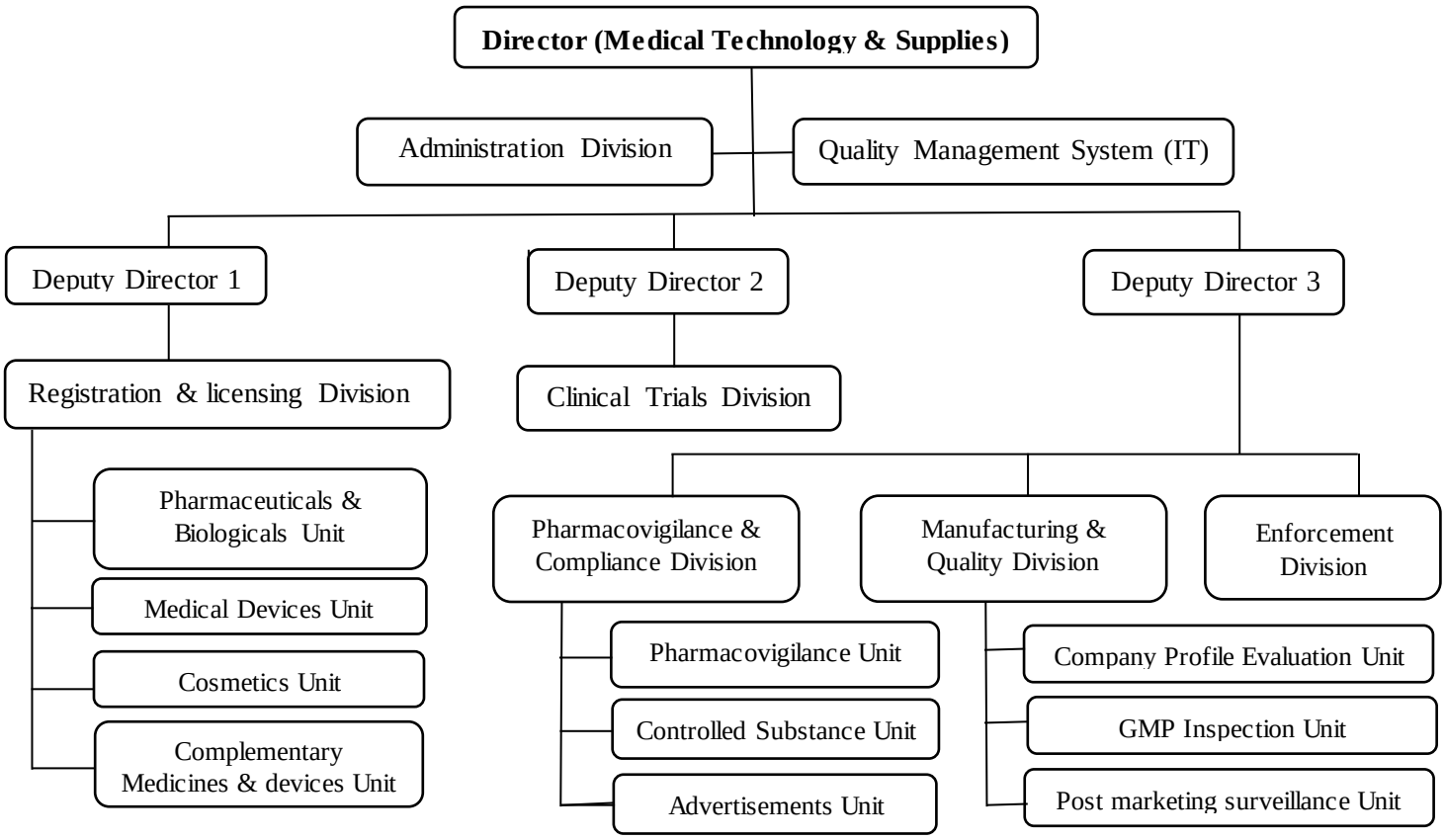
Functions:

- Regulation of Cosmetics, Medical Devices and Medicinal Drugs used in Sri Lanka through a market authorization scheme and a post marketing surveillance system.
- Inspection of manufacturing premises for compliance of Good Manufacturing Practices.
- Inspection and licensing of retail and wholesale establishments of pharmaceuticals and vehicles used to transport pharmaceuticals.
- Monitoring of suspected adverse drug reactions.
- Recalling of Cosmetics, Medical Devices and Medicinal Drugs from the market on safety grounds.
- Control of advertisement on medicinal drugs.
- Control of Narcotics, Psychotropic substances, and Precursors used as medicines, industrial chemicals or used for other scientific purposes.

Organogram:

According to the Act, Director General of Health Services (DGHS) is the Cosmetics, Devices and Drugs Authority. For the purposes of implementation, the delegated Authority to the Director Medical Technology & Supplies (D/MT&S).





Director General of Health Services (DGHS): DGHS is the "Drug Authority" of the country responsible for farming Drugs Therapeutic Committees. Functions of the committee would be to monitor supply, distribution and consumption of drugs at national, provincial and institutional levels.

Director (Medical Technology & Supplies)- (D/MT&S): Issuing of certificate of registration of drugs and licenses to import, distribute, sell and manufacture drugs under regulations of the Act, are implemented by (D/MT&S).

Director (National Medicines Quality Assurance Laboratory- NMQAL): The primary function of NMQAL is to conduct laboratory tests necessary for determining compliance with product safety and quality requirements.

Medical Supplies Division: MSD of the Ministry of Health Nutrition and Indigenous medicine is responsible for the consolidation of annual requirements of drugs for the institutions under the Central Ministry and Provincial Councils.

State Pharmaceutical Corporation: Sole procurement agency for pharmaceutical and surgical consumable items required by government health institutions.

Drugs Registration Procedure

The manufacturer should submit registration applications to the Office of the Director of MT&S through the local agent along with samples for quality testing. The Drug Evaluation Sub-Committee (DESC) comprises specialists in medical and pharmaceutical fields and, with the administrative sector of the Ministry of Health, makes recommendations on the registration of drugs. Quality, safety and efficacy are the main criteria for registration.

The DESC makes use of the WHO's GMP certification scheme - regarding the quality of pharmaceutical products moving in international commerce - when assessing GMP standards and the registration status of a product in its country of manufacture. The Director of MT&S's approval (or rejection) of the product's registration is based on the recommendations of the DESC.

Currently Sri Lanka does not inspect foreign manufacturing sites and evaluates them by their international repute.

Sri Lanka uses several developed states - such as the US, Canada and the UK - as reference regulatory authorities for its pharmaceutical matters, but not without consulting internal investigations.

Pricing structure is approximately 64% above the landing price. The breakup of 64% normally follows the pattern as below.

- Port Duty 4%
- Importer Margin 25%
- Whole saler 8-9%
- Retailer 16.5%.

Since 2014 Sri Lanka requires BE data for ***antimicrobials, antiepileptic drugs and narrow therapeutic index drugs*** as per a circular issued by the NMRA. However, NMRA, has not given a definition that it uses for narrow therapeutic index drugs but the drugs that are generally considered to have a narrow therapeutic index as given in standard text books are considered under this category during their regulatory decisions on "case by case basis".

Imported Drugs:

Approval of the manufacturer

The first step of registering drugs from a new manufacturer (whose drugs are not registered with the DRA previously) is to submit the company information by the **Authorized Local Importer** representing the manufacturer. If the company profile is found to be satisfactory, registration applications will be accepted by CDDA.

Steps involved

- Submission of information about the company
- Receiving of company profile by a Pharmacist

- Assigning a serial number to the application.
- Issuing of a letter to the applicant indicating the serial number.
- Evaluation of company profile in the order of the serial number by a Pharmacist.
- Check the evaluation report by Chief Pharmacist.
- Submission of report to Director for a decision.
- Communication of decision to applicant (Approval / rejection / require more information.

Registration of drugs

The authorized local importer representing the manufacturer of a respective drug has to submit an application with drug samples to the Cosmetics Devices and Drugs Authority (CDDA) for the registration of the drug. This application should be according to the format given in the Schedule IV, Form A of CDD Regulations (Format is enclosed). A sample license should be obtained from the CDDA in order to facilitate customs clearance when importing these into the country.

Once the registration dossier is handed over to the CDDA, it will be entered in a register allocating a serial number to the application. An acknowledgement letter is issued to the importer with the **serial number** which will be the reference number for the application. Importer should pay processing fee for each application.

All applications (except new chemical entities) will have to go through the pharmaceutical evaluation first.
New chemical entities first go to the Drug Evaluation Sub Committee (DESC) of the CDDA. Then the dossiers subjected to a pharmacological evaluation. If the committee decides that it should be registered in this country, then it is taken for thorough pharmaceutical evaluation.

Pharmaceutical quality of products is assessed through pharmaceutical data evaluated and information on factors determining quality (starting materials/ formulation, manufacturing process, intermediate & finished product controls, packaging, stability, bioequivalence data) are carefully considered.

If the pharmaceutical evaluation of the application is satisfactory, it will be submitted to the DESC. The DESC comprises consultants from various specialties and a decision is taken at the DESC meeting accordingly. If registration is recommended, DESC decides on the Schedule under which it should be registered (i.e. I, IIA, 11B, or 111). The local agent will be informed of the decision (whether rejected or approved).

If it is approved, the Certificate of Registration will be issued by the Director Medical Technology and Supplies who is the Chairman of the DESC. Rejections will be informed giving reasons for the decision. Registration is usually valid for 5 years. Under special circumstances (e.g. when the drug is a new chemical entity, the manufacturer is new to this country) a provisional registration will be issued for one year.

Every importer should employ a registered pharmacist and should possess a whole sale license from CDDRA in order to carry out the business. He should also get separate import license on annual basis for each product from the CDDA

Steps involved

- Import of registration samples
  - Submission of application to import registration samples.
  - Payment of sample import licence fee to the cashier of the Ministry of Health.
  - Produce receipt at the CDDA.
  - Issue the licence indicating the quantity permitted.
- Submission of registration application
  - Submission of registration application and samples to the CDDA.
  - Check for completeness by a Pharmacist.
  - If the application is incomplete, return the application with a letter indicating deficiencies.
  - Issue letter for payment of processing fee provided the application is complete.
  - Produce payment receipt to CDDA after paying the processing fee.
  - Official acceptance of application by a Pharmacist.
  - Assigning of serial number to the application
  - Issuing acknowledgement letter to applicant indicating serial number and date of submission
- Evaluation process
  - Applications are evaluated according to Serial Numbers except under special circumstances.
  - Priority is given for Re-registrations and Locally manufactured products (keeping to the order of serial numbers).
  - Applications for New Chemical Entities (NCE) are submitted to the Drug Evaluation Sub-committee at the monthly meeting.
  - At the DESC meeting NCE applications are referred to Consultants for evaluation (mainly Efficacy & Safety).
  - Evaluation reports are discussed at the DESC and a decision is taken by the DESC as to whether the NCE is acceptable to Sri Lanka.
  - If more information is required that is also informed to the company.
  - Samples are sent to NCL for quality testing
  - All generic and branded generics are evaluated according to serial numbers
  - Recommendation for final decision is given by the DESC.
  - Decision of the DESC is communicated to the applicant
  - After approval a Certificate of Registration will be issued on payment of the prescribed fee

Renewal:

The holder of certificate may make an application to the Authority, for renewal of such registration or the licence six months prior to the date of expiry of such registration or the licence. After complete evaluation of application and sample analysis, if requested may renew the registration or the licence for a further period of not less than one year and not exceeding five years.

Application Form for Certificate of Registration of a Drug by an Importer

Form B — Regulation 5(4)

SCHEDULE IV

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

(To be filled in triplicate by applicant)

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

Signed :.....,

Address :.....,

Designation of applicant :.....

For official Use only

Application No. :..... Dated :.....

Decision : Registered/Not registered. Dated :.....

Registration No :..... Dated :.....

Fees paid :..... Receipt No :.....

Date :..... Signature :.....

Authority

Form A **Regulation 5(3)**

SCHEDULE IV

INFORMATION REQUIRED FOR REGISTRATION OF A DRUG.

1. Name of applicant.....

2. Address.....

3. Status of applicant:

   Manufacturer ……..

   Importer .....

   If applicant is Importer, the name and address of the Manufacturer must be given.

4. Name of the drug.....

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

   (2) Official or approved name indicating the official body that has given the name

   (whether B.P., U.S.P. etc.).

5. Dosage form of the drug. e.g. tablet, syrup, injection.

6. Composition.-
   All ingredients, active and inactive, should be listed by their official or approved names and should include their exact quantities as per unit dose or if it is not practical, as percentage of the total formulation.

7. Main pharmacological group and ATC-class (if known) to which the drug belongs:
   (e.g.diuretic etc. C 03 C A 01).

8. A certificate from the health authorities of the country in which it is produced, confirming that the drug is in use there and the period of use and if not, reasons for not marketing it in the country of origin (**Free Sale Certificate**, Certificate according to the W.H.O. Certification Scheme on Pharmaceutical Products moving in International Commerce –the recommended format should be used).

9. Published reports on controlled clinical trials.-establishing the therapeutic efficacy of the drug. (Uncontrolled studies would be accepted only if controlled clinical trials are not necessary to prove efficacy). In the case of combination drugs, evidence must be provided to justify the inclusion of all the active constituents in the formulation.

10. Summary of toxicity tests and tests for teratogenicity indicating the safety of the drug.

11. Data sheet giving the following information:

A) Pharmacology

Pharmacological actions
Mechanism of action (if known)

Relevant Pharmacokinetic data
Bioequivalence/Bioavailability data (when necessary)

B) Clinical Information

Indications
Contraindications
Precautions
Warnings
Adverse effects
Drug interactions
Dosage regimen
Average dose and dose range for adults and children
Dosing interval
Average duration of treatment
Dosage in special situations e.g. renal, hepatic and cardiac insufficiency

Over dosage:

Brief clinical description of symptoms
Treatment of over dosage
Post-marketing surveillance data for new drugs (new chemical entities)

C) Pharmaceutical Information

a. Dosage form and strength.

Separate applications have to be submitted for different strengths of the same product/dosage form.

b. Description of the product.

Description of the physical characteristics of the product. This should include Where applicable:- shape, size, superficial markings for identification purposes, colour, odour, taste, consistency, type of tablet coating (e.g. sugar-coated, film-coated, enteric coated, delayed release, etc.).

When describing liquids, state clearly whether it is in the form of a solution, suspension, emulsion, etc.

c. Packing and Package sizes.

State here briefly the types of immediate container or packing and the pack sizes e.g.
Tablets - bottles of 100's, 500's, blister pack - 50's etc.

d. Manufacturing formula.

Names, quantities and reference to quality standards of all ingredients including those which will disappear during the manufacturing process (i.e. water, alcohol used for granulation etc.).

If the quality standard of an ingredient is not included in one of the official pharmacopoeias, the manufacturers own specification and test method must be submitted.

For injectable preparations total content in each unit container should be given.

Overage.
Where an overage is included, state name of the ingredient and amount. State also the reason for including overage, i.e. whether overage is to cover loss of potency on storage, to permit withdrawal and administration of labelled volumes, required doses, etc. supporting data for inclusion of overage should be enclosed.

e. Manufacture of Product.

If desired, information required under this heading can be enclosed in a sealed envelope marked "Confidential".

Complete Manufacturing Master Formula.

Give the actual batch manufacturing master formula with names and quantities of all ingredients (active and inactive) Substances which are removed in the course of manufacture should be included.

Manufacturing process.
A description of all stages involved in the manufacture of the dosage form is required,

eg. Manufacture of tablets:
Stage 1 : Mix ingredients
Stage 2 : Moist granulation
Stage 3 : Fluid bed drying at 60 C
Stage 4 : Rotary punching

In the full description of the manufacturing process (to be enclosed separately) there should be sufficient details to cover the essential points of each stage of manufacture, such as steps in the comminution of ingredients, method of mixing, order of incorporation of ingredients, fluid media used in moist granulation, drying process, clarification process, formation of final dosage form etc. including methodology, equipment, operating parameters (e.g. temperature, pH adjustments, processing time, sterilization conditions) used in each stage of manufacture. For sterile products, description should include preparation and sterilization of components (i.e. containers, closures etc.).

Validation of important manufacturing operations.
Important production processes have to be validated and the relevant reports submitted.
Validation is defined as "the obtaining and documenting of evidence to demonstrate that a method can be relied upon to produce the intended result within defined limits". Validation should be able to prove that a process yields e.g. homogeneous tablets, capsules or suppositories, or sterile drugs.

Packaging operations.

A description of the packaging of the product into the final containers (immediate and outer) with information on any special precautions taken,

e.g.:
Stage 1 : bulk cream filled into 10 g jars by automatic dispensers.

Stage 2 : automatic weight check
Stage 3 : automatic labelling
Stage 4 : manual transfer to cardboard boxes and sealed.

In details enclosed separately, describe the steps, equipment, flow and precautions for each of the packaging operations.

f. Quality Control.

This section must give a complete account of the tests which will be carried out routinely on each batch of product and its ingredients and must state the specifications with which any sample (ingredient or finished product) would be expected to comply.)

Name(s) and address(es) of person(s)/organization(s) performing quality control tests, if not done by the manufacturer's own quality control department must be given.

Quality control of starting materials (active and inactive).

Specifications and test methods are required for each ingredient used in the manufacture of the product.

Where an ingredient is subject of a current pharmacopoeia it is sufficient to make appropriate references. Copies of relevant monographs need not be attached.

Where specifications are those of the manufacturer's supplier's or any other source, full details of specifications and test methods must be submitted. Source of specifications and test methods must be indicated.

Test methods should be in sufficient detail so as to be reproducible in tests carried out by another laboratory.

If any specification or test is omitted or modified in any way from the original documents, such omissions/modifications must be clearly stated with reasons. This includes additional tests, variations and changes in test conditions, reagents etc.

Modifications, additions, substitute tests, etc. must be described in detail.

Indicate clearly whether the ingredients are bought to a purchase specification with a certificate of analysis, or tested by the manufacturer (or his behalf) for compliance of specification.

Control of intermediate products - in-process control.

Specifications and test methods for in-process control must be submitted especially in cases where such control is of importance to quality parameters that cannot be checked in the final product.
A detailed description is particularly important when the finished product contains low dose of active ingredient or if the product is sterile.

Control of procedures in filling, labelling and packaging operations must be described.

Control of the finished product.

The quality specifications of the finished product must be submitted. These should include the appropriate tests and requirements concerning the pharmaceutical properties of the dosage form such as uniformity of mass, content uniformity, disintegration. In addition the following tests should be considered: Particle size, dissolution rate, pH etc.

If bioavailability/bioequivalence studies for tablets and capsules are not performed, at least dissolution tests must be performed on tablets/capsules contained in the USP XXII even though the product is subject to a monograph which does not specify a dissolution test.

The specification should also cover:

- Identification of active ingredient(s)
- Quantitative determination of active ingredient(s) and preservatives.
- Tests for impurities
- Tests for degradation products

If a product is subject of a monograph in a current pharmacopoeia, it is expected to comply with the specification for that product as well as the general requirements of the general monograph for the dosage form.

Availability/Release rate of active ingredients (in-vitro tests):

Evidence of dissolution rates is particularly important for the following:

Where the drug is of sufficient potency and importance to warrant such investigation.

Where the therapeutic dose of the drug is close to its toxic dose.

Where solubility or other physicochemical properties of the drug indicate that any change in formulation, or source of ingredient might alter the therapeutic efficacy or safety of the drug.

Where specific excipients, coating and other ingredients may affect or alter the dosage form performance e.g. dissolution, disintegration, drug release rate, etc. special formulations e.g. controlled release tablets, depot injections, etc.

g. Information concerning shelf-life, stability and storage conditions.

State proposed shelf-life of the product with recommended storage conditions (Temperature, humidity, light, oxygen etc.)
The recommended storage conditions must be included on the label.

If the product is to be reconstituted before use, the shelf-life/expiry period of the original product as well as the reconstituted product should be stated.

The manufacturer must provide evidence to the effect that the product retains acceptable strength and pharmaceutical quality throughout its shelf-life.

Describe stability studies performed and completed on the product, outlining study protocols, conditions and parameters, characteristics/degradation products monitored, results and conclusion of studies.

Results must be presented in an illustrative form, tables or graphs. Batch number, type of container and storage conditions have to be stated in the reports.

The stability studies must be carried out on the product packed in the container in which it is going to be marketed (sales container).

If the stability studies are carried out on product not packed in the sales container, evidence must be given that the container used is equivalent to the sales container.

In view of the fact that sufficiently long experience of storage of new products has often not been accumulated when an application is made, the results of accelerated tests may be accepted for a preliminary shelf-life. Stability of the product must be followed up at suitable frequency in relation to its shelf-life, on a suitable number of regularly produced batches.

The manufacturer must outline his programme for further stability studies (frequency, number of batches, storage conditions etc.).

Analytical methods used in stability studies must be given, supplemented with documentation of their ability to detect possible changes.

Changes in composition, the manufacturing process or the container or packaging material may necessitate renewed stability studies and revised shelf-life.

h. Packaging materials.

The manufacturer should supply data on the material from which the container and the closure are produced. For plastics, the name of the material, name of manufacturer, chemical structure and physico-chemical properties must be submitted.

Detailed information is required about the technical construction of non-standardized containers, e.g. aerosol containers, spray packs, syringes etc.

Quality specifications of the container and closure must be submitted.

12. List of countries in which the drug (the applicant's formulation/product) is approved or registered for sale.
13. .Fully packed samples of the drug in the form that it will be offered for sale should also be sent, to enable analysis of the product with Certificate of Analysis of the product.
14. A sample of the label(s) used on the container should be supplied.
15. Product information leaflet (PIL).
16. All data should be submitted in English, organized as this schedule IV, with an index in a hard file cover. (A copy should be kept with the applicant.)
17. All pages should be numbered (starting from the last page).
18. A blank sheet should be pasted on the inner side cover to be used as a minutes sheet.

Format of Evaluation of Report by NMRA can be find at
http://nmra.gov.lk/images/stories/new/pdf/applications/new_evaluation_check_list.pdf

Application Form for Licence to import drugs

Form A

Regulation 12(1)

SCHEDULE V

APPLICATION FOR LICENCE TO IMPORT DRUGS

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

Signed :.....

Address :.....

Date :.....

Designation of applicant :.....

Application Form for Renewal of Registration of a Drug for Import / Manufacture

Form E

Regulation 7(3)

SCHEDULE IV

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

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

Registration :.....

Expiry date of last registration :.....

Signed :.....

Address :.....

Date :.....

Designation of applicant :.....

Registration and Licensing of Medicines (fees) Regulations

Republic of Sri Lanka revised the price structure of registration and licensing of medicines vide Registration and Licensing of Medicines (fees) Regulations, No. 02 of 2017 and are effective from 14.06.2017.

(i) Processing fee

	Type		Fee (USD)
(a)	New Molecule Entity (A chemical moiety which has not been previously registered in Sri Lanka, including a new salt, an ester or complex of a previously approved Chemical moiety)	**Part 1** - Initial decision on application (process or decline)	500.00
		Part 2 - Evaluation (if accepted)	1,500.00
(b)	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)		1,000.00
(c)	New Product (any new product of a already registered medicine in Sri Lanka.)		(Foreign) 750.00
			(Local) 500.00
(d)	New Combination Product (A new combination product is a formulation of two or more medicines in a single dosage form which has not been previously registered in Sri Lanka.)		1,500.00
(e)	Therapeutic Biological and Biotechnological Products	**Part 1** - Initial decision on application (process or decline)	1,000.00
		Part 2 - Evaluation (if accepted)	2,000.00
(f)	Application for registration renewal after 5 years		(Foreign) 750.00
			(Local) 500.00
(g)	Application for Manufacturing Plant (MP) approval		(Foreign) 2,000.00

(ii) Fee for Additional Data Evaluation

Type of Evaluation	Fee (USD)
Additional data Evaluation	500.00
Additional data for Manufacturing Plant (MP) Evaluation	500.00

(iii) Fee for certificates:

Type of Registration Certificate	Fee (USD)
Certificate of Registration for 5 years Foreign Manufacturer	**400.00**
Certificate of Registration for 5 years Local Manufacturer	200.00
Provisional Registration for 1 year for Foreign Manufacturer (will be for a maximum of 2 years)	200.00
Provisional Registration for 1 year for Local Manufacturer(will be for a maximum of 2 years)	100.00
Duplicate Copy of Registration Certificate	250.00
Amendment of Registration Certificate	100.00

(iv) Fee for License

Types of Licenses	Fee (USD)
Sample Import License	100.00
Import License	**100.00**
Manufacturing License	100.00
Amendment of License	100.00

(v) Fee for Good Manufacturing Practice Inspection (GMP) – Foreign

Country	Fee (USD)
SAARC Countries	15,000.00
Other Countries	20,000.00

(vi) Fees for analysis of Medicines:

	Analysis		Fee (USD)
a	Biological test		250.00
b	Microbiological test		250.00
c	Assay Test (Chemical, Microbiological, Biological)		250.00
d	Limit test (HPLC)		250.00
e	Dissolution test		250.00
f	Three tests or less than three tests	I) If all three tests are in categories (a), (b), (c), (d) & (e) specified above	750.00
		(II) Otherwise	500.00
g	Four tests or more than four tests	(I) If three or more than three tests are in categories (a), (b), (c), (d) & (e) specified above	1,500.00
		(II) Otherwise	1000.00
h	Single test	Test other than the categories (a), (b, (c), (d) & (e) specified above	175.00

List of Pharmaceutical Manufacturers Association:

01	State Pharmaceuticals Manufacturers Cooperation (SPMC)	http://www.spmclanka.lk/index.php
02	Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI)	www.slcpi.org/