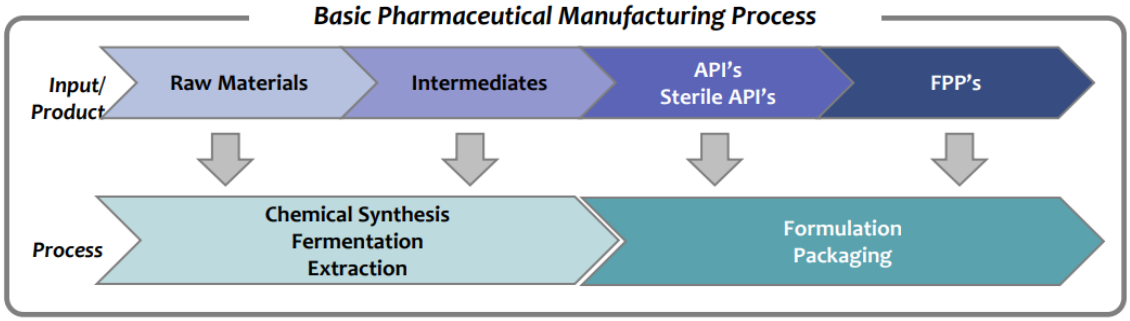
Sector Overview – Pharmaceuticals Sector

1. Introduction

1.1 Core Business /Principle activities



1. ***Raw Materials:*** Substrates or elements – biologics, chemicals etc. – that are used as the base for intermediates and API's.
2. ***Intermediate:*** A material produced during steps of the processing of an API that must undergo further molecular change or purification before it becomes an API.
3. ***Active Pharmaceutical Ingredient (API):*** Biologically active compound(s) in a drug formulation that imparts the desired therapeutic effect. Active pharmaceutical ingredients are usually first obtained in the crude state (if there is no biological activity they might be considered "intermediates") and subsequent production operations convert the crude material to the final API that meets pharmacopoeial and/or similar requirements. APIs are sometimes also referred to as 'bulk drugs.'

1. ***Chemical Synthesis:*** The construction of complex chemical compounds from simpler ones.
2. ***Fermentation:*** The production and separation of medicinal chemicals such as antibiotics and vitamins from micro-organisms.
3. ***Extraction:*** The manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials or animal tissues.
4. ***Formulation and Packaging:*** The formulation of bulk pharmaceuticals into various dosage forms such as tablets, capsules, injectable solutions, ointments etc., that can be taken by the patient.

- ***International Non-Proprietary Name (INN):*** Name for the active ingredient in a medicine that is decided by an expert committee and is understood internationally (e.g., paracetamol is the INN or generic name while Panadol and Tylenol are brand names). All generic drugs have a brand name as well as a non-proprietary name, but all drugs having a non-proprietary name (generic name) may not be generic drugs.
- ***Patented Drug:*** A medicinal preparation that is typically protected by a trademark and whose contents are incompletely disclosed; any drug that is proprietary. Other pharmaceutical companies may not sell this substance without permission from the innovator company until it goes 'off-patent' (i.e., patent expires).
- ***Generic Drug:*** Drugs that are intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.

- ***Import Substitution: :*** Promoting domestic production of imported goods to foster industrialization.
- ***Product Rationalization:*** The reorganization, and often reduction, in the number of products within a portfolio in order to increase operating efficiency.

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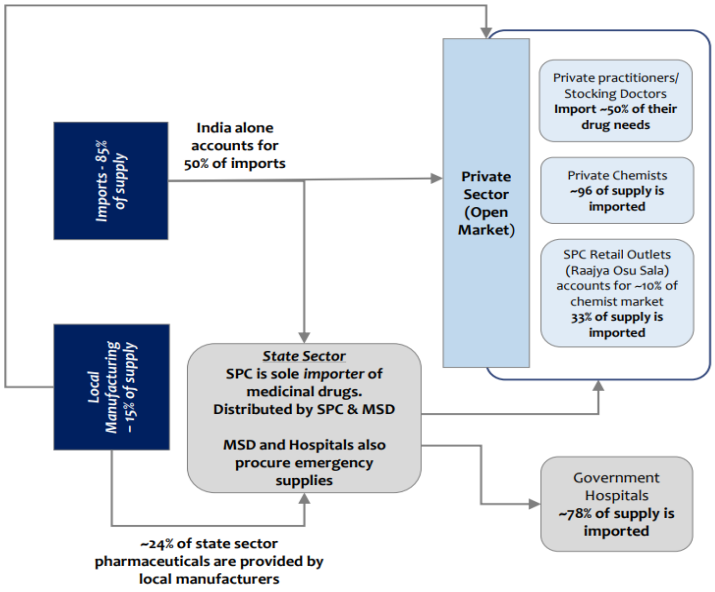
Source: Stax Research Report – August 2020

Flow of Pharma Supplies in Sri Lanka



Source: Stax Research Report – August 2020

1.2 Institutions operating under the sector

Manufacturer	Size (FTE Range)	Quality Certifications			
		GMP (NMRA)	cGMP— WHO	GMP— EU	PIC/S
1. Aithra Pharmaceuticals (Pvt) Ltd	Small (0- 49)	✓			
2. Astron Limited	Large (200+)	✓	✓		
3. C. D. De Fonseka & Sons (Pvt) Ltd.	Small (0- 49)	✓			
4. Celogen Lanka (Pvt) Ltd.	Medium (50- 199)	✓	✓	✓	
5. CIC Life Sciences (Pvt) Ltd.	Medium (50- 199)	✓			
6. Diyatha Pharmaceutical and Healthcare (Pvt) Ltd.	Medium (50- 199)	✓			
7. Emergen Life Sciences (Pvt) Ltd.	Medium (50- 199)	✓			
8. Flexus Pharma (Pvt) Ltd.	Small (0- 49)	✓			
9. Gamma Pharmaceuticals (Pvt) Ltd.	Medium (50- 199)	✓	✓		
10. Glaxo Wellcome Ceylon Ltd.	Large (200+)	✓			✓
11. Himata (Pvt) Ltd.	Small (0- 49)	✓			
12. Interpharm (Pvt) Ltd.	Medium (50- 199)	✓	✓		
13. Lina Manufacturing (Pvt) Ltd.	Medium (50- 199)	✓	✓		✓
14. Medicom (Pvt) Ltd.	Small (0- 49)	✓			
15. Morison PLC	Large (200+)	✓		✓	
16. Navesta Pharmaceuticals (Pvt.) Ltd.	Large (200+)	✓		✓	✓
17. SPMC	Large (200+)	✓	✓		
18. Unical Ceylon Ltd.	Small (0- 49)	✓			
19. Universal Lifeline Ceylon (Pvt) Ltd.	Small (0- 49)	✓	✓		
20. ACE Healthcare (Pvt) Ltd.	Medium (50- 199)	✓	✓	✓	

Source: Stax Research Report – August 2020

2. Production and Consumption

2.1. Annual Domestic Production –

Local manufacturers currently produce 8.5 billion units of medicines per year. However, many large players say they are currently not operating at full capacity and can expand their supply to the market

2.2. Annual Domestic Consumption –

2.3. Amount to be imported annually –

Chemists account for 64% of overall imports:

Almost all drugs (96%) sold by chemists in the local market are imported. Over 180 private local firms are registered importers with the NMRA. These include local conglomerates such as Hemas Group, Browns Group, and Sunshine Holdings who distribute drugs from MNCs as well as smaller regional manufacturers.

Government hospitals account for 33% of overall imports:

Though the Sri Lankan health system is decentralized, the countrywide requirement of drugs and medical supplies are purchased centrally by the SPC – both imports and local drugs – and distributed by the MSD. Pharmaceuticals are purchased on a system of worldwide tenders and quotations. The quarterly drug requirement, based on estimated demand, is distributed to Regional MSDs located in 26 health districts.

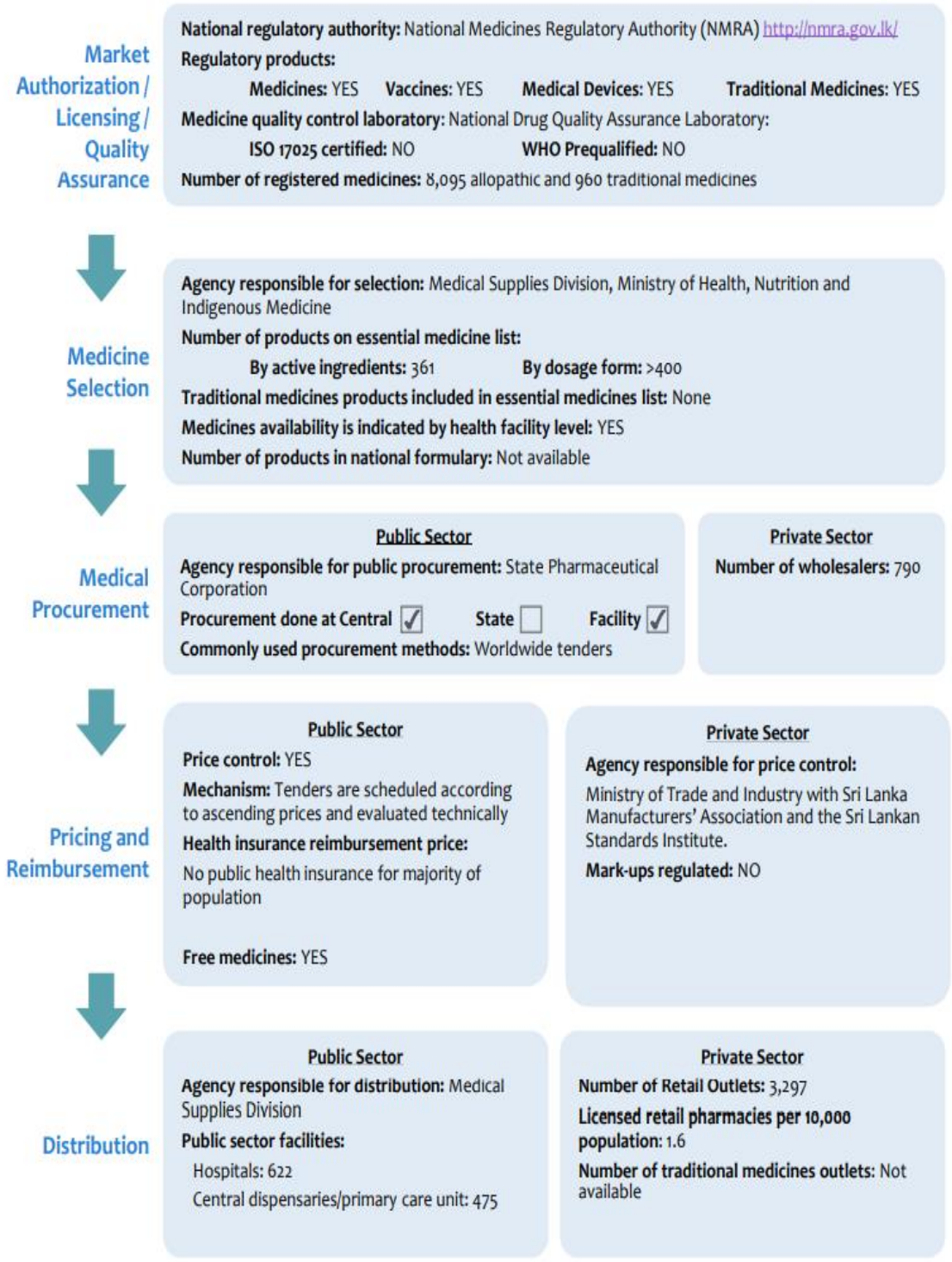
Doctors with a private clinics account for 3% of imports:

Approximately 50% of drugs issued by doctors at private dispensaries/clinics are imported.

2.4. Market share

Imports – 83.6%

Locally produced – 16.4%



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2.5. Product types

150 locally manufactured brands listed in the NMRA. Most of these brands have different forms—capsules, tablets, syrups etc. —which, make up 300 types and dosages of drugs that are manufactured in Sri Lanka.

- **Required raw materials needed to be imported**

Local manufacturers are 100 percent import-dependent for API

3. Turnover

3.1. Export earnings – USD 7.5 million

3.2. Export destinations - USA, Malaysia, Egypt, UAE, Venezuela and Pakistan

4. Government Policy on Sector

- The National Medicines Regulatory Authority (NMRA) ACT, No. 5 OF 2015, repealed the Cosmetics, Devices & Drugs (CDD) Act of 1980. The NMRA Act is the legislative framework that provides the legal authority to regulate and control the manufacture, importation, sale, storage and distribution of CDDs (including nutraceuticals and devices).
- The National Medicines Regulatory Authority (NMRA) is the institution in which the Ministry of Health has vested the authority to implement the provisions of the Act, ensuring that Pharmaceuticals and Medical Devices are made available to the public efficiently and effectively to meet the required standards of quality, and that they are within the existing legislative framework with respect to the production, marketing and dispensing of these items.
- Quality is checked by the National Medicines Quality Assurance Laboratory (NMQAL), which comes under the authority of the NMRA

Sector Strategies

- Improve access to medicines through quality local production
- Strengthen the national medicine regulatory system
- Create incentives designed to move companies along the value chain
- Develop human resources through relevant education and training

- Encourage cluster development and production of active pharmaceutical ingredients
- Create a research and development platform
- Attract foreign direct investment into the pharmaceutical sector

6.Sector Objectives identified with KPIs

Indicator	2015	2020	2025
Pharmaceutical manufacturers with International GMP compliance (n)	2	5	20
Essential medicines purchased by PFSA from local manufacturers (%)	20	50	60
WHO prequalified products produced locally (n)	0	4	15
New manufacturing companies and local capital invested (n)	0	5	11
Joint ventures with international GMP compliant companies (n)	3	8	15
API manufacturers (n)	0	1	3
Export of locally produced medicines by GMP-compliant producers (US$ million)	2	30	80
Phase IV clinical trials and post-marketing studies conducted In Ethiopia (n)	0	10	30
Phase II and III clinical trials conducted In Ethiopia (n)	0	3	10
Bioequivalence studies conducted by Bioequivalence Centre (n)	0	10	25
Studies on bio-availability of essential medicines (n)	0	18	30
Locally developed traditional medicines on the market (n)	0	5	20
Natural products with identified active ingredients (n)	0	80	160
Clinical trials conducted on traditional medicines (n)	0	3	20
Incubators (detailed indicators will be developed) (n)	0	1	3
Number of graduates in industrial pharmacy and regulatory sciences	0	200	1500
Courses established In quality assurance/control, GMP, and entrepreneurship (n)	0	10	50

Source: Stax Research Report – August 2020

8. SWOT Analysis

Strengths	Weaknesses
▪ domestic market size being large ▪ total governmental health expenditure being high ▪ Competitive Industrial Performance Index (CIP) score being high	▪ Lack of Skilled labor force ▪ absence of accredited certification body ▪ In pharma, the supply chain is highly complex and more regulated than in other industries.

Opportunities	Threats
▪ Reaching the global Market	▪ USD Crisis ▪ Global Market crisis ▪ Freight issues ▪ Hap hazard policy changes ▪ Rising unprecedented Electricity tariffs ▪ Tax policy changes

10. Challenge(s) the sector is facing due to Government rules and regulations.

For local manufacturing to grow, it is vital to create an environment conducive to foreign investments. This specifically includes the need to grant waivers on capital investment and expenditure by pharmaceutical companies—to encourage them to expand and upgrade technology.

The promotion of local drug production and its long-term development potential will be hampered by challenging regulatory and operating environment conditions.

SL has to study failures from the past and invest into the areas necessary to lay the groundwork for attracting FDI, and for creating favorable conditions for technology transfers.

11. Global Market Value– USD 142 trillion

12. CAGR - 5.39%