1950-2020 Stability Sustainability Shared Prosperity

Work In Progress

Study Series - Winning Industries

ERD-SS-WI 09/01/2021

Pharmaceutical Manufacture

Real Sector Division - Economic Research Department
Central Bank of Sri Lanka

This study was conducted by Mrs. S Piranavi who is currently serving as an Economist of the Economic Research Department. If you have any comments with regard to this presentation, please email the Real Sector Division on realsector@cbsl.lk.

Industry Background

Pharmaceutical industry includes the manufacture, extraction, processing, purification, and packaging of chemical materials to be used as medications

The ***Vistas of Prosperity and Splendour*** policy framework highlights the aim to increase domestic production of pharmaceuticals

"All drugs and medical consumables that can be produced within the country to international standards, will be produced locally. An adequately equipped WHO-standard quality control laboratory will be established to safeguard the quality of the drugs."

Accordingly, **"Aluth Ratata, Aluth Beheth"** programme was initiated

Rs.130 billion spent to imports pharmaceuticals annually, President reveals plan to save Rs 60 billion

September 12, 2020 at 3:20 AM

Sri Lanka to give Strategic Development Project tax breaks for pharma zone

BY IMESH RANASINGHE | Tuesday November 10, 2020 12:00

Pharma making zone in Hambantota 200 acres for 20 companies in Phase 1

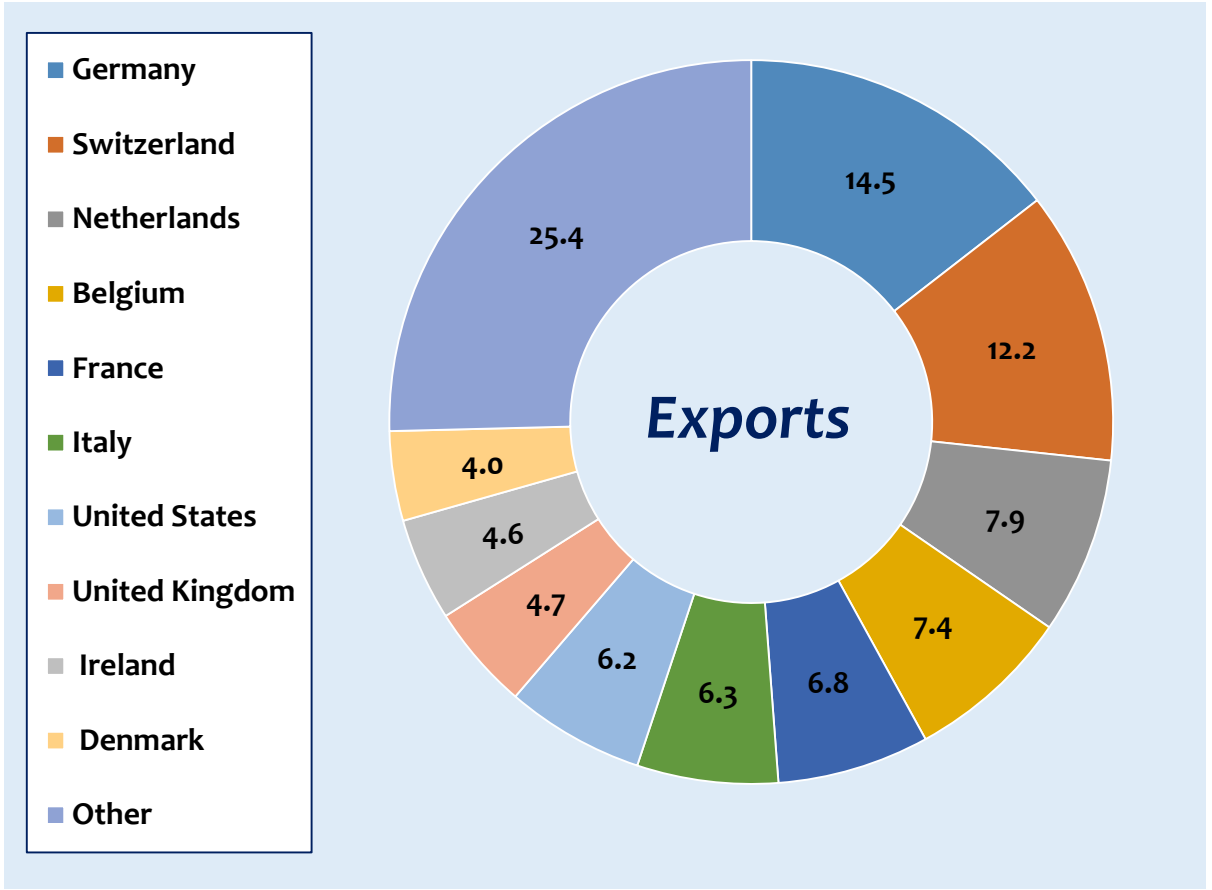
Wednesday, November 11, 2020 - 01:10

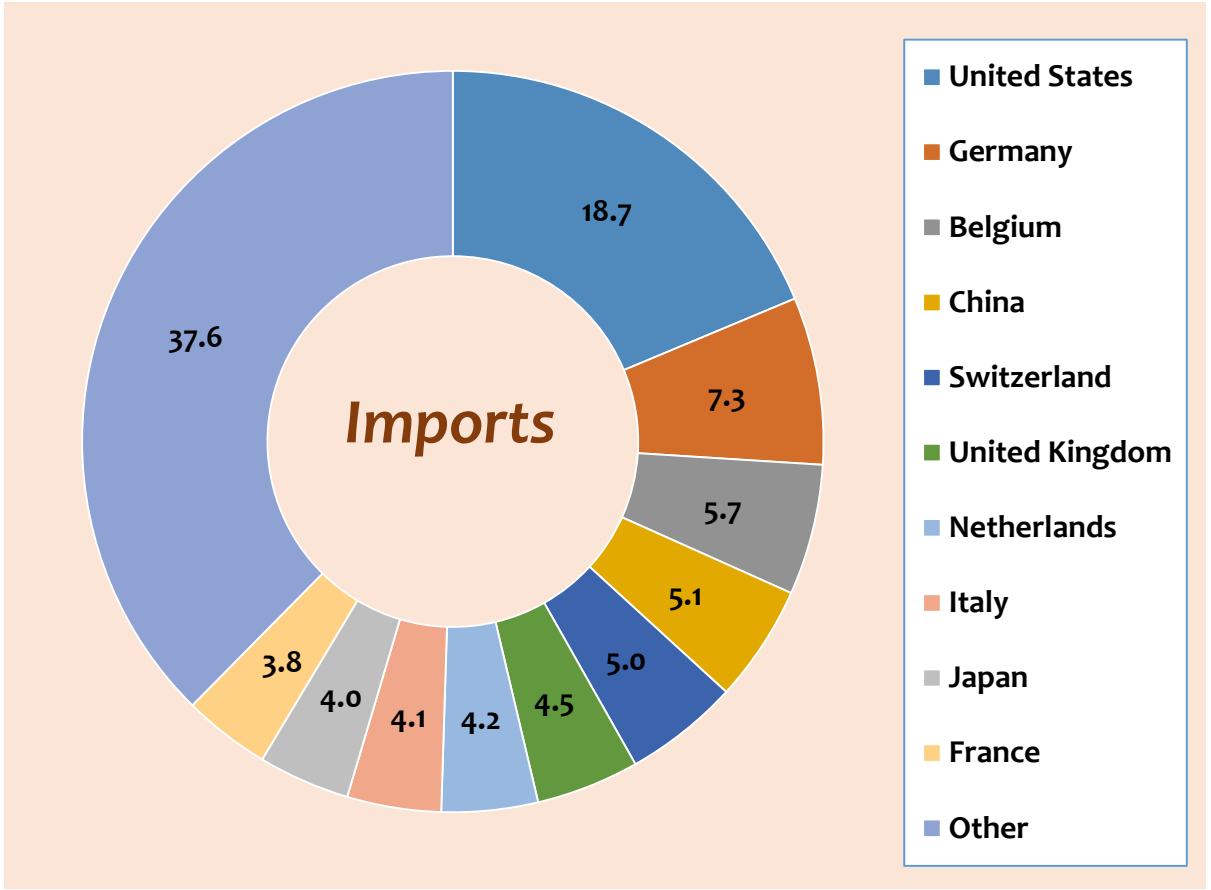
Manufacturing of Medicines

The importation of drugs for free health care in our country alone costs about US $ 550 million annually. I propose to provide bank and financial facilities on Treasury guarantees to increase the production capacity of the State Pharmaceutical Manufacturing Corporation to expand the production of essential pharmaceuticals. I also propose to establish a modern investment zone for local and foreign private investors under the Strategic Development Act.

Industry Status - Global

Top Global Exporters and Importers of Pharmaceutical Products (Percentage of total global export and import value, 2019)

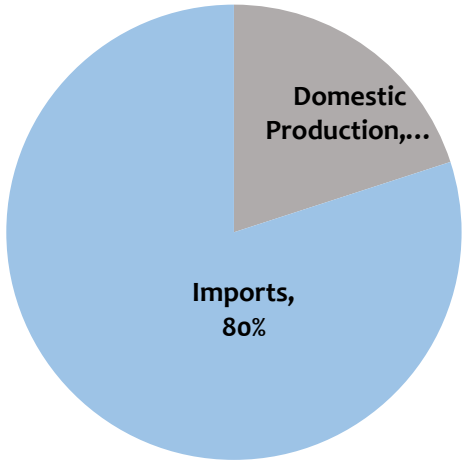




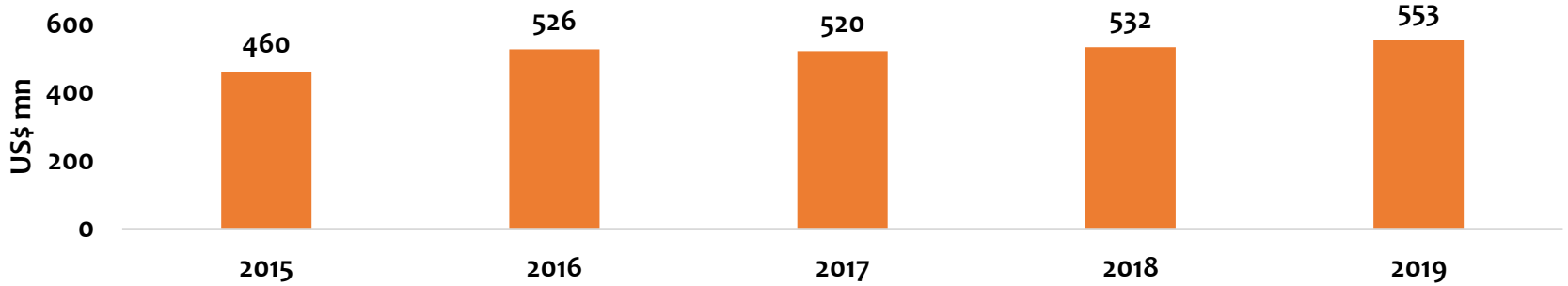
Source : World's Top Exports

Industry Status - Sri Lanka

Contribution to Domestic Pharmaceutical Market

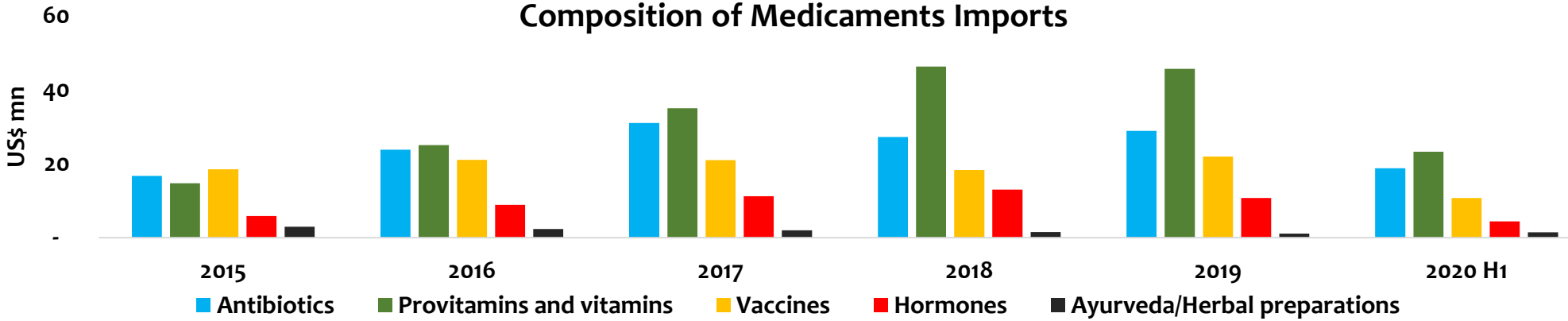


Import value of pharmaceuticals (medicaments and other pharmaceutical goods)



Share (2019)
2.8 per cent
of Total Imports

Composition of Medicaments Imports



Import Origin Countries

India
China
United States
France
Pakistan

**Most of the medicaments imports are categorized under "other" category (Import value - 75% - 85% of total medicaments import value)*

Source : Sri Lanka Customs

Industry Status - Sri Lanka

Total Imports of Medicaments to Sri Lanka

	2014	2015	2016	2017	2018	2019
Antibiotics	13.3	16.7	23.8	31.0	27.1	28.8
Ayurveda/Herbal preparations	0.3	3.0	2.3	2.0	1.5	1.1
Hormones	5.1	5.8	8.9	11.2	13.1	10.7
Provitamins and vitamins	12.7	14.6	25.0	35.0	45.9	45.6
Vaccines	17.5	18.5	21.1	21.0	18.2	21.9
Other Medicaments	284.4	341.4	374.3	354.5	348.7	359.6
o/w HS Code 30049090 "Other"	*281.7*	*338.3*	*371.8*	*351.2*	*345.8*	*356.1*
Medicaments Total	**333.2**	**400.0**	**455.4**	**454.7**	**454.4**	**467.8**

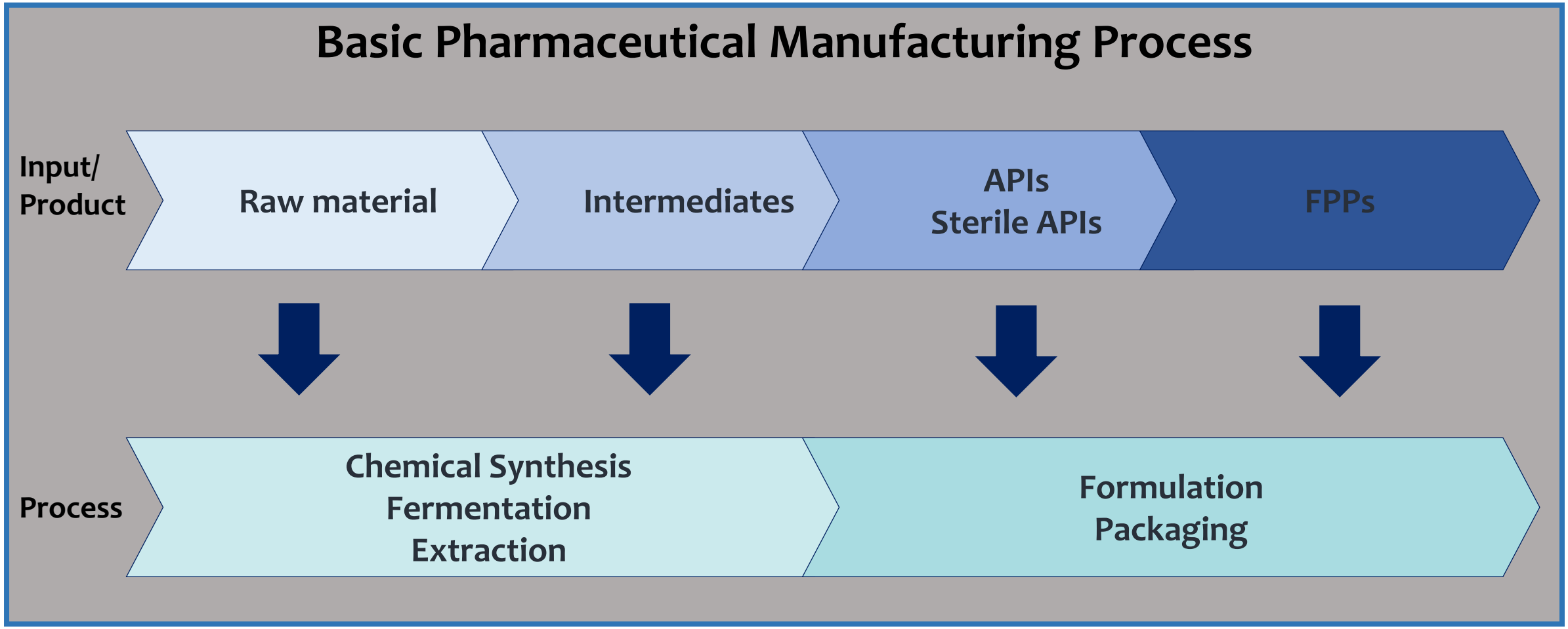
Source : Sri Lanka Customs

Industry Status - Sri Lanka

- Pharmaceutical manufacturing industry of the country produces around *20 per cent* of the requirement of the Health Department and around *less than 20 per cent* of the private sector requirement, indicating high dependency on imports
- Key pharmaceutical manufacturers:
  - ✓ State Pharmaceutical Corporation (SPC)
  - ✓ Joint ventures with SPC
  - ✓ Independent Pharmaceutical manufacturing companies
- Currently, there are around 150 locally manufactured brands listed in the NMRA (capsules, tablets, syrups etc.)
- Distribution of pharmaceutical products:
  - ✓ Pharmacies - 30,000
  - ✓ Osusala - 45
  - ✓ Franchised Shops - 150

Pharmaceutical Manufacturing

Primary processing - Production of the Active Product Ingredients (APIs)
Secondary processing - Conversion of the APIs into medication products



Industry Value Chain

Research and Development

- Basic research
- Drug discovery
- Drug formulation
- Clinical trials
- New drug application
- Approval

Manufacturing

- Ingredient sourcing and procurement
- Manufacturing plants

R&D, API & formulation

- Continuous production
- Quality regulation
- Testing

Warehousing and Transportation

- Warehouse management

Quality, safety, security & traceability

- Supply chain logistics

Safe, secure & efficient

-Retailing to end user

Hospital, Pharmacy, etc.

Supplying of Pharmaceutical Products

Direct supplying to Medical Supply Division (MSD)

-Around 14 companies provide around 55 drugs to MSD

-Companies will be chosen with an approval from the Cabinet

-Prices of drugs are determined by the Pricing Committee

-Allowed to yield profits up to 20% of the production cost

Joint ventures with the SPC (Buy Back)

-Purchasing of drugs based on a Buy Back agreement

-Manufacturers will be chosen with an approval from the Cabinet sub-committee

-Prices of drugs are determined by the Pricing Committee

Supplying by the SPC

- Competitive national and international tenders are called to purchase products

Key Industry Players – Sri Lanka

Astron Limited

Astron Limited specializes in pharmaceuticals, nutritional supplements, nutraceuticals, cosmeceuticals, herbals and animal healthcare

Certifications/ Standards

- cGMP under WHO-GMP certification
- ISO/IEC 17025, ISO/IEC 17025: 2005 certified by Sri Lanka Accreditation Board for Conformity Assessment

Celogen Lanka (Pvt.) Ltd.

Specializes in the production of tablets, and hard and soft gelatin capsules

Certifications/ Standards

- cGMP under WHO-GMP certification
- EU-GMP certification

Emergen Life Sciences (Pvt.) Ltd.

Emergen specializes in the manufacturing of products covering the entire range of dry powder inhalation preparations (DPIs) to treat asthma and Chronic obstructive pulmonary disease (COPD)

Certifications/ Standards

- GMP certification (NMRA)

Morison PLC

One of the oldest manufacturers of pharmaceutical and OTC products in the country, Morison (part of the Hemas Group) also imports and distributes healthcare and products

Certifications/ Standards

- EU GMP Compliant— European, Medicines Agency (EMA)

Lina Manufacturing (Pvt.) Ltd.

A pharmaceutical manufacturer specializing in dry powder inhaler capsules, nasal sprays, tablets, and creams

Certifications/ Standards

- cGMP under WHO-GMP certification, ISO 9001: 2008, EU GMP— Proposed (next 2-3 years)

Smaller Players

Glaxo Wellcome Ceylon Ltd.

Company offers several products including anti-ulcerants, respiratory products, systemic antibiotics, anti-virals, dermatologicals and anti-emetics

Interpharm (Pvt.) Ltd.

Engaged in the manufacturing and marketing of liquid oral dosages, and generic drugs including antihistamines, multivitamins and antacids

C. D. De Fonseka & Sons (Pvt.) Ltd.

Engaged in the manufacturing of pharmaceutical products including the antiseptic liquid 'DETTOL' brand

Gamma Pharmaceuticals (Pvt.) Ltd.

Gamma engaged in the manufacturing of mouthwashes, pharmaceutical creams, and ointments

Navesta Pharmaceuticals (Pvt.) Ltd.

Navesta Pharmaceuticals specialized manufacturer of injectable penicillin - dry powder injectable Beta Lactam antibiotics

Potential and Opportunities for Sri Lanka

'Rule of Thumb' for manufacturing pharmaceuticals for consumption is that the manufacturing country should have a minimum population of 10 mn

- **Sri Lanka = 21 million people → Strong Potential to Benefit**
- **Domestic market demand will not be sufficient if there is *more than one producer* for a single pharmaceutical product**
- **Hence, *developing an export market is vital* in promoting pharmaceutical industry as a winning industry**

Challenges to Developing the Pharmaceutical Industry

Supplying of raw materials

- Raw materials are the key factor in the production of pharmaceuticals
- Components used in the pharmaceutical manufacturing:
  - ✓ Active Product Ingredients
  - ✓ Excipients (eg: the sweetener in a cough syrup)
  - ✓ Primary packing material (i.e. the material that comes into contact with the medicine)
  - ✓ Secondary packing material
- Local manufacturers are 100 per cent import dependent for APIs (about 75% of the world's API requirement is made in China)
- Producing raw materials domestically seems challenging due to possible environmental damage
- This would limit the net return from exports as well as competitiveness in the export market
- The cost of imported raw materials is much lower than the value of importing drugs, resulting in about 66 per cent savings in foreign exchange for the government

Challenges to Developing the Pharmaceutical Industry

Supplying of raw materials

- In the initial stages of export promotion, concessions on raw material imports should be extended for domestic pharmaceutical manufacturers in view of reducing unit cost of production

  Ex: PAL on imports of pharmaceutical raw materials and packaging materials removed with effect from 26 May 2020

- To manufacture medicines locally, foreign exchange may have to be spent on plant and machinery in initial stage
- Primary and secondary packing material industry for medicines also should be developed, as it costs 5 per cent of the imported pharmaceutical raw materials cost
- Planned to set up an API manufacturing plant in the Hambantota pharmaceutical manufacturing zone. However, the types of API to be manufactured there and the amount has not been decided yet

Challenges to Developing the Pharmaceutical Industry

- **Maintaining high quality of pharmaceutical products**
  - ✓Majority of quality fails in drugs are mainly stemming from supply chain issues such as transport, storing as well as distribution
- **Difficulty in obtaining International Standard Accreditations and Certifications**
  - ✓EUGM certification, WHO pre-qualification and USFDA certification
  - ✓Takes about 2-4 years for obtain certifications
  - ✓High cost incurred in obtaining international registration for exports
- **Lack of standardized laboratories and lack of skilled labour**
- **Absence of National Drug Formulary to decide on type of drugs, quantity, price as well as to evaluate drug complication and side effects**

Way Forward

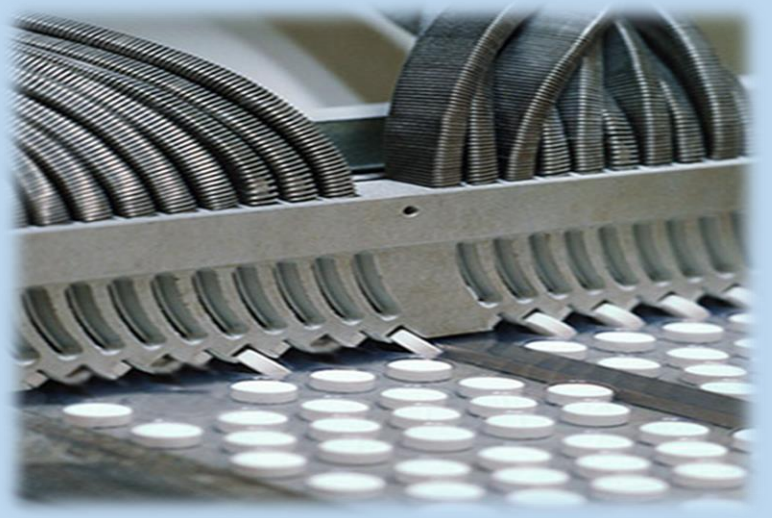
- Upgrading the supply chain and improve to ISO standards
  - ✓Sri Lanka should develop the packing material industry for medicines urgently
- Improving the quality of manufacturing items
  - ✓The government can start a consultation unit to advice the manufacturers to get qualification standards
  - ✓Usually foreign consultants charge about 50,000 US dollars for their consultation service
- Establishing quality assurance laboratories
  - ✓National Medicines Regulatory Authority (NMRA) laboratory needs to be upgraded to the required standard and to the capacity
  - ✓SPC has started upgrading the laboratory in collaboration with the WHO to expand their services and the quality assurance of all the medication going through the SPC
- Central monitoring system to evaluate quality checks
- National competitive bidding to improve efficiency in manufacturing

Way Forward

- **Skill development and vocational training in relation to pharmaceutical manufacturing**
  - ✓ A thorough programme should be started in collaboration with responsible institutions to have adequate work force within the next three years
- **Promoting post-graduate knowledge on bio-chemistry/bio pharmaceuticals to create required specialized knowledge for pharmaceutical industry**
  - ✓ Currently, foreign consultation services are being utilised in relation to required knowledge on bio-chemistry for the industry
  - ✓ When institutions start to formulate molecules they will be able to even sell the formulae to new manufacturers. In addition they can do the quality testing of the manufactured products
- **Export promotion/Export market assessment**
  - ✓ Identifying countries with less than 10 mn population (as registration cost is very low) as export destination, especially in African region, Far East region, East European countries, Arabian countries
- **Development of infrastructure facilities**

Strategic Objectives for Pharmaceutical Manufacturing Development

- Improve access to medicines through quality local production
- Strengthen the national medicine regulatory system
- Create incentive designs to move companies along the value chain
- Develop human resources through relevant education and training
- Encourage cluster development and production of APIs
- Create research and development platform
- Attract foreign direct investment into the pharmaceutical industry

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