Since 1961

SLCPI

Sri Lanka Chamber of the Pharmaceutical Industry

The Future of Pharmaceutical Manufacturing in Sri Lanka

Final Report

August 2020

Stax

This report has been privately commissioned by the Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI). The research herein has been conducted independently by Stax Inc., and the viewpoints expressed are those best supported by currently available data and inputs from multiple stakeholders across the industry.

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Abbreviations & Acronyms – Global

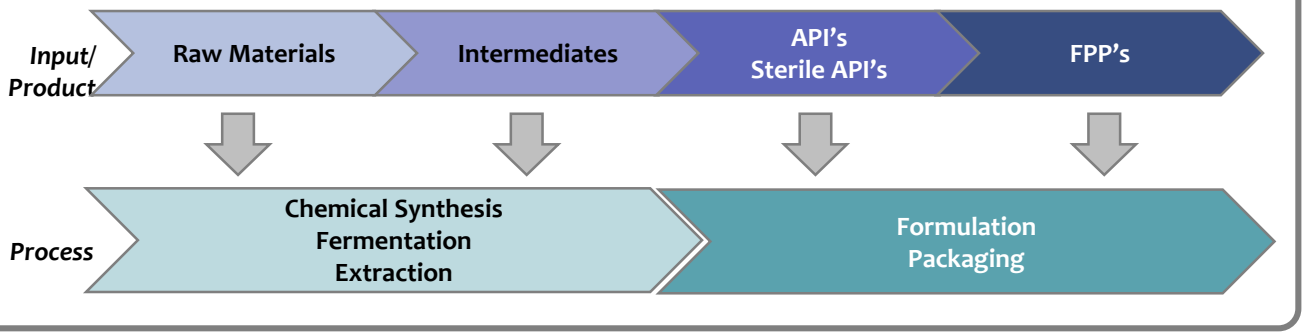
API	Active Pharmaceutical Ingredient
BP	British Pharmacopoeia
BRIC	Brazil, Russia, India and China
CAGR	Compounded Annual Growth Rate
CHE	Current Healthcare Expenditure
CIP	Competitive Industrial Performance
CMO	Contract Manufacturing Operations/Organization
COPD	Chronic Obstructive Pulmonary Disease
EML	Essential Medicines List
(EO)DB	(Ease of) Doing Business
FDA	Food and Drug Administration (US)
FPP/FDP	Finished Pharmaceutical Product/ Finished Dose Product
FTEs	Full Time Employees
FX	Foreign Exchange
GLP	Good Laboratory Practices
(c)GMP	(Current) Good Manufacturing Practices
HCP	Health Care Provider
HIC	High Income Country
ICT	Information & Communication Technology
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
INN	International Non-proprietary Name
MINT	Mexico, Indonesia, Nigeria and Turkey
MRP	Maximum Retail Price
NCDs	Non-Communicable Diseases
OOP(E)	Out-of-Pocket (Expenditure)
PFIs	Pharmaceutical Formulation Intermediates
PIC/S	Pharmaceutical Inspection Convention/ Pharmaceutical Inspection Co-operation Scheme
SCM	Supply Chain Management
THE	Total Health Expenditure
TRIPS	Trade Related Aspects of Intellectual Property Rights
USP	United States Pharmacopeia **OR** Unique Selling Proposition
WHO	World Health Organization
WTO	World Trade Organization

Abbreviations & Acronyms – Sri Lanka

BOI	Board of Investment
CBSL	Central Bank of Sri Lanka
CDDA	Cosmetics, Devices and Drugs Act
GMOA	Government Medical Officers' Association
GOSL	Government of Sri Lanka
IHP	Institute for Health Policy
MOH	Ministry of Health
MSD	Medical Supplies Division
LKR	Sri Lankan Rupee
NES	National Export Strategy
NMQAL	National Medicines Quality Assurance Laboratory (formerly NDQAL)
NMRA	National Medicines Regulatory Authority/ Act
PAL	Port and Airport Development Levy
RMSD	Regional Medical Supplies Division
SLCPI	Sri Lanka Chamber for the Pharmaceutical Industry
SLMA	Sri Lanka Medical Association
SLMC	Sri Lanka Medical Council
SLPMA	Sri Lanka Pharmaceutical Manufacturers' Association
SP(M)C	State Pharmaceutical (Manufacturing) Corporation
VAT	Value-Added Tax

Industry Primer & Definitions

Basic Pharmaceutical Manufacturing Process



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.'
4. ***Sterile API:*** An API that has been subjected to additional processing steps to remove micro-organisms.
5. ***FPP:*** Finished Pharmaceutical Product.

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.

Source: World Bank; WHO; Investopedia; Britannica online; NIH; Scientific American.

Executive Summary:
Objectives & Approach

Study Objectives

This report details Stax's findings in the five areas described below, which have been examined with the objective of answering these two key questions:

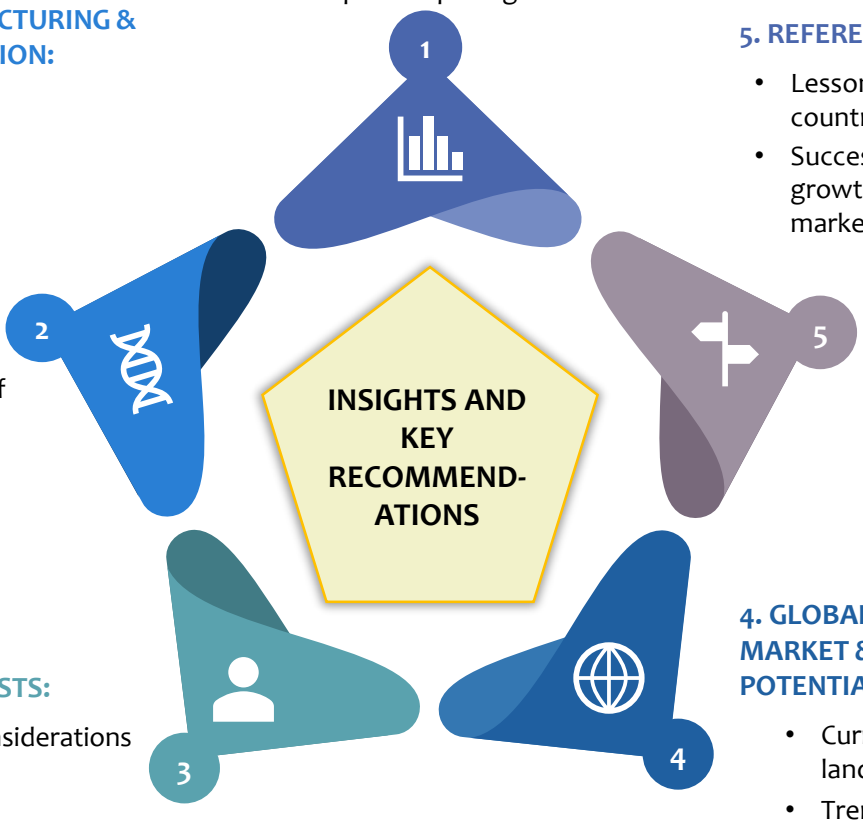
1. Can a policy of pharmaceutical import substitution save a considerable amount of foreign exchange outflow for Sri Lanka?
2. Is there real export potential for Sri Lanka's pharmaceutical industry? Is import substitution a pre-requisite for realizing that potential?

1. SL PHARMA MARKET:

- Key drivers of demand
- Imports & pricing

2. LOCAL MANUFACTURING & IMPORT SUBSITUTION:

- Current local manufacturing
- Reliance on imports for APIs
- Extent to which import substitution is feasible and potential saving of FX outflow



5. REFERENCE MARKETS

- Lessons from reference countries
- Success factors for export growth in reference markets

3. PATIENT INTERESTS:

- Key patient considerations
- Essentiality
- Accessibility
- Affordability
- Efficacy

4. GLOBAL PHARMA MARKET & EXPORT POTENTIAL:

- Current global landscape
- Trends in global pharmaceutical market
- Potential for exports from SL into the global market

The purpose of this study is to provide an independent evaluation of the potential in Sri Lankan pharmaceutical manufacturing, using objective data to the extent possible, while also consulting with a range of industry stakeholders.

Study Approach

For this study, Stax conducted a desk review of the latest industry data available, and also incorporated in-depth conversations with key industry stakeholders.

Primary Research Sources

Private Sector Suppliers

- SLPMA Members
- Importers and Distributors

Public Sector

- State Sector Doctors
- NMRA
- SPC
- EDB

Other Stakeholders

- Colleges of Specialist Doctors
- Other Industry-related Organizations
- Regional Experts

Select Secondary Research Sources

World Health Organization

THE WORLD BANK

IQVIA

International Trade Centre

NMRA

Executive Summary: Report Highlights

Key Findings Summary

Report Highlights

Report Context

- The Sri Lankan (SL) pharmaceutical (pharma) industry is heavily reliant on imports. The Government is considering an import substitution (IS) policy to stimulate local production and to encourage exports.
- **The focus of this report will primarily be on the potential for :**
    1. Reduction in FX outflow from IS, and
    2. Exports.
- While there are many discussions in the industry regarding the quality of imported vs. local drugs, for the purposes of this report, quality will be considered a neutral factor. It will however include the opinions and perspectives on quality expressed by key stakeholders interviewed, as they pertain to both import substitution and pharma exports.

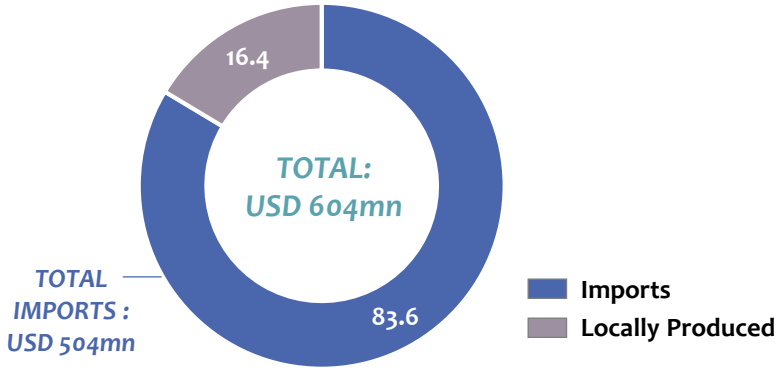
Key Findings

- If the top 10 generics on the essential medicines list, which local manufacturers currently have the capability of producing, were to be sourced completely locally—i.e., with a complete ban on their imports—it would mean a reduction in FX outflow of ~USD 66m (see pages 27-32 of this report for calculations). This would shift the percentage of locally manufactured pharma supply from the current 16% to 27%. However, whether this would entail an actual saving for the government would only be determined by the value of buyback agreements signed with local manufacturers for each drug, as certain medicines can be imported more cheaply from countries with greater economies of scale in manufacturing, such as India (see p.23 of this report for an example).
- The arguments often made against imports from countries like India are that of low quality and that currently, there are too many imported brands in the country and too few resources for the regulatory body (the National Medicines Regulatory Authority or NMRA) to monitor these effectively. Only 38 foreign GMP inspections are listed as having been conducted by the NMRA on their website (from 2015 onwards)—to provide some context on scale, there are currently 38 suppliers of the single generic drug Metformin alone, from India alone. Rationalizing the number of suppliers in the market and increasing resources available to the NMRA would help reduce concerns about quality of drug supply.
- To address the interests of multiple stakeholders in the value chain, what is more logical is **an import rationalization instead of a complete substitution**. This is also the approach that is recommended by specialist doctors who regularly subscribe both locally manufactured and imported medicines for Sri Lanka's prevalent NCDs (see p.17 of this report). A carefully selected basket of imports can ensure that FX outflows are minimized, without compromising patients' access to essential medicines.
- While it has been suggested that pharma could be one of the next billion dollar export sectors for Sri Lanka, such a vision is still a long way off. SL does not currently have the capacity and unit economics to compete meaningfully in the global market, especially as a late mover. In 2017, when Sri Lanka registered its highest pharma exports by value, Bangladesh's export value was ~12x greater (India's was over 1400x greater). Hopeful questions have been raised on whether pharma could be the next apparel sector for SL. However, SL entered the apparel market early enough to gain advantage before mass-scale producers like Bangladesh arrived on the scene. Now, SL is competing on quality, niche products/solutions and innovation over mere cost arbitrage in apparel—and will need to do the same to secure a foothold in pharma exports.
- If Sri Lanka is to successfully grow exports over the mid- and long-term, a **clear, comprehensive and consistent export strategy will be required** (which cannot change with changing governments), along with sustained investment and a collaborative effort by public and private sector players.

Report Highlights

Market Highlights

SL Pharma Market 2019
(Percentage)



SL Pharma Exports 2019

$5.9M

Top Countries Exported to (by value)

Top Countries Imported from (by value)

1. Import Substitution (IS)

The Government's (GOSL) cash crunch, the LKR's devaluation, and supply chain risks due to the current pandemic have all brought into focus the country's pharma import reliance. The GOSL has also recently identified the Pharmaceutical and Food Processing industries among new sectors on which there should be greater emphasis for development.

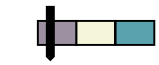
An import ban of the top 5-10 generic drugs that are in high demand, and manufactured locally, could help reduce some FX outflow, but the selection of those drugs must be done extremely carefully, as such a policy would have far-reaching consequences. Whether there would be an actual saving for the government would only be determined by the value of buyback agreements signed with local manufacturers, as certain drugs can be imported more cheaply.

- A range of specialists in the relevant therapeutic areas must be consulted to understand the quality and effective molecular differences (if any) between the locally produced drugs and those to be banned, and whether there would be any impact to efficacy and patient outcomes.
- Too often, the opinions of the patients themselves are dismissed. For NCDs, many patients are put on a variety of drugs before the one best suited to them is found, and they will have strong opinions if they are used to a certain drug. There should be a representative patient survey to assess any potential resistance and concerns regarding possible switching of drugs.
- A policy like this should not go into effect without due notice. All stakeholders must be given a fair timeline (at least 12 months) in which to adjust and plan for the future.

Report Highlights

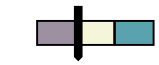
Potential FX Outflow Reduction from IS

Short-term (2021)



- If we were to consider a complete ***import ban on the top 10 molecules by spend, which are currently locally manufactured, SL could reduce FX outflow of ~USD 66 million from the current pharma import bill.***
- This would mean shifting the import to local ratio from 84:16 to 73:27.
- Whether this would entail an actual saving for the government would only be determined by the value of buyback agreements signed with local manufacturers (as certain drugs can be imported more cheaply).
- Stax's calculations for this estimated FX outflow reduction is available on pages 27-32 of this report. It must be noted here that the local manufacturers' associative body (the SLPMA) makes this calculation using a different methodology (see Appendix 2 of this report).
- A process of rationalization of imports, rather than a complete ban/substitution, is more advisable.

Mid-term (2023)



- Several private local manufacturers are planning to increase capacity and portfolio breadth. Many of these capacity expansions are slated to come online within the next 1-2 years.
- Local manufacturers will benefit from improving the range, scale and value of the GOSL buyback program so that more of the public sector imports accrue to them.
- Focusing on manufacturing more of the top spend, EML drugs and improving unit economics (to compete with cheaper Indian alternatives) would enable local manufacturers to further capture market share, and to move the import to local ratio toward greater local sourcing of medicines.

2. Pharma Exports

The current export potential is low, as SL is a laggard in this market and has very few competitive advantages compared to regional and global players. Import substitution (IS) alone will not enable local manufacturers to play on the world stage, as Sri Lanka's domestic market will not provide the economies of scale that countries like Bangladesh and Egypt have achieved. IS is not a pre-requisite for increasing exports, but a coherent and consistent national strategy is.

SL does not currently have the capacity and unit economics to compete meaningfully in the global market, especially as a late mover. Questions have been raised on whether pharma could be the next apparel sector for SL. However, SL entered the apparel market early enough to gain advantage before mass-scale producers like Bangladesh arrived on the scene. Now, SL is ***competing on quality, niche products/solutions and innovation over mere cost arbitrage*** in apparel, and will need to do the same to secure a foothold in pharma exports.

While IS is not a pre-requisite for increasing exports, other types of government support are crucial. One of the most vital factors in stimulating growth to the current level has been the GOSL's signing of 10- to 15-year buyback agreements with local manufacturers since 2015. Continued support in this vein, and a clear, consistent national strategy for the sector (of which IS could, if at all, be a small component) will be required, along with a concerted implementation effort from multiple private and public actors.

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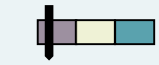
Report Highlights

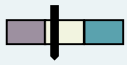
Export Potential

Short-term (2021)



- In the short-term, potential is low, as SL is a laggard in the pharma export market. Within the past 5 years, the highest recorded value exported from the country was USD 8.8M in 2017—which ranked SL behind 98 other exporter nations that year.
- High achieving nations such as Bangladesh, Ireland, Israel and Singapore have at times been highlighted as reference markets for SL—in terms of success stories to study—and these are examined in detail in Chapter 5 of this report.
- Varying routes countries have taken to achieve success in pharma exports are summarized below.
- In our analysis, we find that Morocco, Jordan and Taiwan are more comparable markets for SL—based on demographic and economic indicators.

Mid-term (2023)



If SL is to successfully grow exports over the mid- and long-term, a clear, comprehensive and consistent strategy will be required (which cannot change with changing governments). *Initial* research indicates that one or more of the following avenues would need to be agreed upon and invested into:

i. ***Differentiation by focusing on a niche area*** (e.g., Ayurvedic products that have undergone clinical trials and can prove therapeutic value at international standards).

ii. ***Creating a unique selling proposition via an attractive end-to-end offering*** (e.g., downstream assured through strong ties with regional API suppliers that use Sri Lankan Free Zones; manufacturing floor and upstream equipped with next-gen facilities that can provide additive manufacturing, robotics, telemetrics etc. as required).

iii. ***Creating a consortium of local manufacturers*** who are EU-GMP (or equivalent) certified, which together can achieve some of the economies of scale that are otherwise lacking.

VARYING ROUTES TO EXPORT SUCCESS

Other nations have used various strategies—such as leveraging a large domestic market (e.g., Bangladesh) or positioning itself as a regional hub (e.g., Jordan)—to advance as exporters. Betting on the domestic market alone will not be sufficient for SL to succeed. *Combining* a variety of lessons learned from other countries however, could provide a winning formula for Sri Lanka. A careful strategy plan would need to use not just such lessons from other markets, but also consider how SL's distinctive advantages (e.g., Ayurvedic products or being a logistics hub) could be used to create an attractive USP.

Dominating Domestic

Protect local market first and supply 70-90% of that need, which would help build scale. Also capitalize on cheap labor. Over time, keep improving unit economics.

 *BANGLADESH*

 *PAKISTAN*

 *INDIA*

 *EGYPT*

Trading on Tech

Invest in talent & R&D though both government funds and FDI. Position country globally as a leader in innovation by using success in other tech areas too (e.g., Taiwan's semiconductor success being leveraged). Keep moving the bar higher by investing further in latest tech.

 *SINGAPORE*

 *ISRAEL*

 *TAIWAN*

Continental Conduit

Build infrastructure to become gateway to broader region (e.g., Morocco to Sub-Saharan Africa). Hub strategy to reinforce that position (e.g., Jordan first-mover in free zones in Gulf). Keep positioning for FDI.

 *JORDAN*

 *MOROCCO*

High-Income Haven

Use national high income to invest into talent and infrastructure. Incentivize investment through tax haven status.

 *IRELAND*

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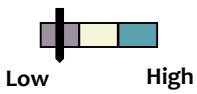
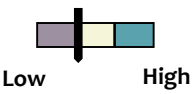
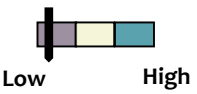
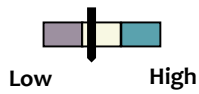
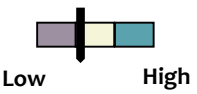
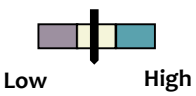
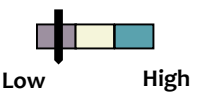
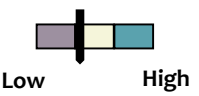
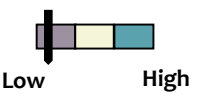
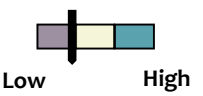
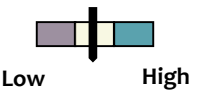
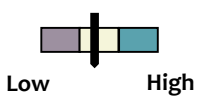
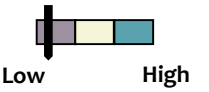
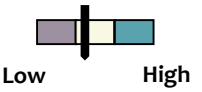
Report Highlights

Taking a Balanced View on the Arguments Generally Made in Support of Local Manufacturing

More Local Production: *Positive Impacts*	***Likelihood of Impact Occurring***		***Rationale for Likelihood Rating***
	Short-Term	***Mid- to Long-Term***	
1. Reduce Foreign Exchange Outflow			• Currently low but once capacity is ramped up, imports could be further reduced; APIs still cause FX outflow
2. Stimulate Exports			• Currently lagging, high competition. However, if a clear USP is identified and strategy plan is well executed, higher potential over time
3. Improve Quality over Cheap Imports			• Currently, no evidence in terms of clinical trials for local products. NMRA needs to be better funded to test more frequently (both local products and imports). There are a few manufacturers that have global standards certifications however, and that # is set to increase in the mid-term
4. Improve Affordability			• With price controls, lack of taxes on imports, and cheaper Indian products—prices for essential drugs are already quite low. Over time, if more molecules are manufactured locally and cheaply, there could be higher affordability
5. Improve Supply Security			• Meeting totality of demand extremely unlikely; API supply could still be threatened, but more essential drugs could be manufactured locally over time
6. Create Jobs			• Facilities will need a mix of skilled and unskilled labor; unskilled will be further automated in a few years while high skilled will need sustained investment
7. Facilitate Technology Transfer			• Will depend on ability to attract large global firms to set up in SL over time (i.e., will depend on developing USP and executing strategy plan well)

Executive Summary:
Key Findings Detail

Key Takeaway #1: Import Rationalization not Substitution

- Stax discussed the possibility of IS with several specialist doctors and experts in the field. Their recommendation is that even if a drug is manufactured locally, there should not be reliance on a single supplier. However, many also agree that there are far too many brands in circulation, for the same molecule, within a market as small as SL.
- Many of the local manufacturers we interviewed also did not believe a complete ban was necessary, but that there should be better and more consistent regulation/enforcement on imports. While the NMRA has streamlined the industry better since 2015, they should be provided more resources in order to carry out more quality testing.
- The most logical takeaway, taking into account multiple stakeholder views, is the following:
  - ❖ Identify the top (by both volume and value), essential molecules sold in SL, and manufactured locally, across the public and private sectors. For those molecules, encourage more than one local manufacturer to supply the market (if that is not already the case).
  - ❖ In total, for any molecule, have no more than 5-6 brands coming in to the market:
    1. The original innovator drug (1)
    2. Two generics by local manufacturers (3)
    3. Two to three proven quality imported generics (5-6).
  - ❖ The logic for such rationalization is that with a lower number of suppliers to monitor, the NMRA will not be as over-burdened and will have the resources to carry out more consistent checks on importers as well as local manufacturers.

"The country shouldn't rely 100% on any one supplier for a drug. But we also don't need the high number of brands that are in the market today. About 5-6 brands for one drug are more than enough—the original and 4-5 others of varying prices. "

—Senior Council Members, Sri Lanka Heart Association

"A complete ban on [pharma] imports is very bad. Malaysia's public sector effectively did this for most molecules and it encouraged inefficiency."

—Dr. Ravi Rannan-Eliya, Director, Institute for Health Policy

"There shouldn't be an arbitrary import ban without careful study or assessment. In the end, everyone should be on the side of the patient. More emphasis should be on building the ecosystem needed for exports. Developing talent, strengthening the regulator, focusing on ancillary industries like packaging – these are all going to be crucial to grow exports."

—Director, Local Pharma Manufacturing Firm

Source: Stax Primary Research and Analysis, June-July 2020.

For Example, the Supply of Metformin Could Be Rationalized

N.B. *The following is an* ***illustrative case*** *made solely by an objective examination of the numbers available, and not in terms of molecular analysis.* ***Stax does not recommend that any drugs be discontinued without the consultation of relevant specialists in the field.***

With nearly 1 in 5 adults in the Western Province reported to be suffering from diabetes, medicines treating this NCD are in high demand. A quick analysis of the basic drug prescribed for diabetics, metformin, shows that SL has 52 suppliers registered with the NMRA, including 4 local manufacturers.

Metformin Suppliers in SL by Country of Manufacture

Country	# of Suppliers
INDIA	38
SRI LANKA	4
BANGLADESH	4
MALAYSIA	2
FRANCE	1
GERMANY	1
INDONESIA	1
PAKISTAN	1
Total	**52**

- The question can be raised as to why this many suppliers are needed, if they are all producing the same generic with no major changes in molecular properties, and given that Sri Lanka is such a small market to supply (even with high diabetes prevalence).
- While having many competitors is generally favorable in a free market to keep prices competitive, in this case there cannot be such an advantage—as a price ceiling is imposed by the GOSL on metformin.

Local Manufacturers of Metformin

Astron

CELOGEN LANKA

SPMC

CIC Nurturing Life

Select Importers of Metformin

Emerchemie NB helping add life to years

HEMAS PHARMACEUTICALS

MARKSS

sunshine

Morison

Access

Source: NMRA website, accessed June 2020; Diabetes Association of Sri Lanka website, accessed June 2020; Province and ethnic specific prevalence of diabetes among Sri Lankan adults, Sri Lanka Journal of Diabetes Endocrinology and Metabolism, 2011.

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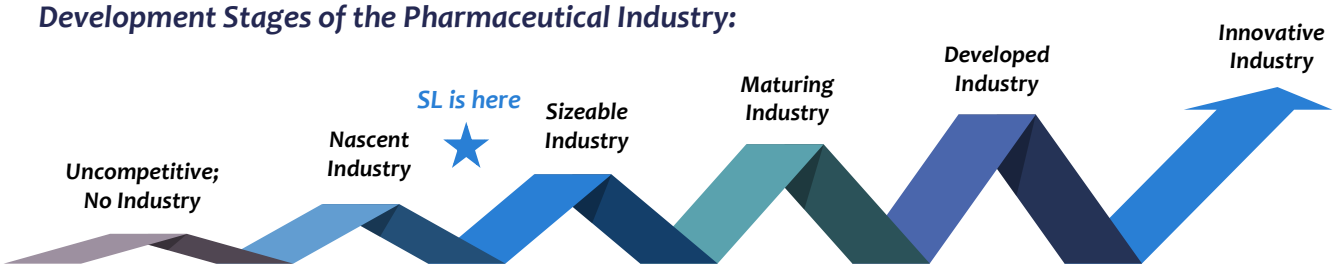
Key Takeaway #2: Clear, Consistent, Comprehensive Strategy for Exports

- As highlighted previously, and detailed in Chapter 5 of this report, currently leading pharma export nations have taken varying routes to success. What they all have in common however is a long-term, consistent commitment by the government and other stakeholders to lay the groundwork and procure the investments necessary to grow their exports in this sector.
- Many of the reference countries have been steadily investing into the ecosystem necessary for pharma exports since the 1960s. They also have not rested on their laurels but kept moving the bar higher in order to remain competitive. Those who failed to do so, are seeing some declines.
  - ❖ For example, Jordan implemented new ideas in the sixties and seventies, like setting up the first Free Zone in the region. However, they have not kept innovating and in recent years have lost some ground to competing nations.
  - ❖ Conversely, Taiwan has consistently invested into the sector and also kept innovating. E.g., its biomedical firms are experimenting in emerging areas such as e-health, cell therapy, precision robotics and AI applications within pharma.

The Plan should take into account a realistic assessment of the current market status as well as the unique factors that SL can use to differentiate.

Development Stages of the Pharmaceutical Industry:



Uncompetitive; No Industry	Nascent Industry	Sizeable Industry	Maturing Industry	Developed Industry	Innovative Industry
• Few, if any, local manufacturers • Heavily import-reliant with local players involved in import distribution only	• Growing number of local producers • Import substitution occurs at low to moderate levels	• Many producers with possibility of oversaturation • Emerging export base, even if import-reliant for certain products	• Stabilizing number of producers as consolidation occurs • Maturing export base, with imports still necessary for some items	• Stable number of producers following industry consolidation • Well-established export base with some imports still necessary	• Stable number of producers, with some moving into innovative R&D • Well-established export base with new, innovative products

Excerpts from the 'Island of Ingenuity' SL Investment Positioning Document (highlighting Sri Lanka's differentiating factors):

"Sri Lanka has among the most rigorous intellectual property (IP) protection regimes in the region."

A.T. Kearney

Sri Lanka's budding island economy comes complete with an enabling environment for R&D, SMEs, financing and more. More than 75% of entrepreneurs are between 20–35 years old and 48% are IT/software engineers.

Source: Pharma Boardroom; UNIDO; World Bank; McKinsey; Island of Ingenuity.

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For Example, the Government of Ethiopia has a 10-year strategy plan to develop its pharma sector

The Plan includes clear strategic objectives and set KPIs to monitor progress:

National strategy for pharmaceutical manufacturing development In Ethiopia, 2015–2025

Strategic Objective 1	***Improve access to medicines through quality local production - implement the GMP Roadmap***
Strategic Objective 2	***Strengthen the national medicine regulatory system***
Strategic Objective 3	***Create incentives designed to move companies along the value chain***
Strategic Objective 4	***Develop human resources through relevant education and training***
Strategic Objective 5	***Encourage cluster development and production of active pharmaceutical ingredients***
Strategic Objective 6	***Create a research and development platform***
Strategic Objective 7	***Attract foreign direct investment into the pharmaceutical sector***

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: National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025), July 2015.

Arguments for Augmenting Local Manufacture

1. *"Local Production Will Save Foreign Exchange"*

- Local production could save some foreign exchange outflow if drugs that are in high demand can be matched by local producers, at a competitive or cheaper price point than imports. Our research shows that several drugs can currently be imported more cheaply from countries with better economies of scale, like India and Bangladesh .
- Currently, 100% of the APIs required for local FPPs is imported. There will still be some outflow of FX to procure those prior to locally manufacturing a FPP.

2. *"Local Production Will Stimulate Exports"*

- There has been some level of local pharmaceutical manufacturing in Sri Lanka since the late fifties. But with no consistent policies or strategies to stimulate growth, there has only been a small measure of progress in the intervening years.
- To put the country's pharmaceutical export status into perspective—in 2017, Sri Lanka was ranked at 99 in the list of pharmaceutical exporter nations (in terms of total value of exports).*
- While there are pockets of export potential to be explored, becoming an attractive pharma manufacturing hub will require sustained effort and resources by public and private sector players working together toward a clear strategic roadmap.

> "For this country to go forward, I see a couple of sectors that need to be worth a billion or multi-billion dollars [in exports]. One sector is pharma. We're heavily dependent on getting our pharmaceuticals from foreign countries. We have the capability, we have the know-how. There are some good, successful local companies. We're trying to build a pharma zone, looking at a billion dollars over time. It'll be a 5-7 year journey. Unless you try now, you won't get a chance, and it is a good time to start because the whole ecosystem is getting moved around."
>
> —*Sanjaya Mohottala, Director General, BOI of Sri Lanka, June 2020*

* Based on ITC data. Official government export data from CBSL put export figures even lower.

Source: ITC trade database; Astron website; Stax Primary Research, June 2020; Sanjaya Mohottala's Address at the 23rd AGM of the MBA Alumni Association, University of Colombo, YouTube, June 2020.

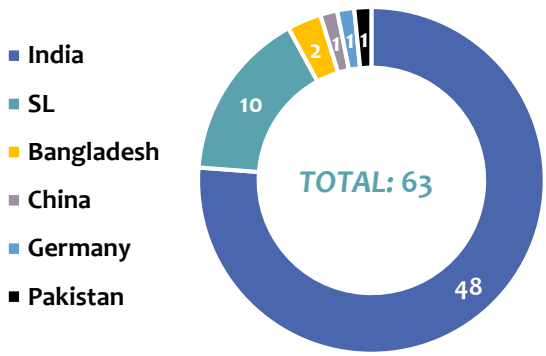
Arguments for Augmenting Local Manufacture cont'd

3. *"Local Production Will Improve Quality over Cheap Imports"*

- The predominant view expressed by SL manufacturers and its associative body, the SLPMA, is that locally produced drugs are of superior quality to certain imports from regional suppliers. Unfortunately, testing often and holding clinical trials can be costly.
- As a proxy of quality, the standards maintained by local manufacturing facilities can be assessed: of the 20 manufacturers currently approved by the NMRA, 7 are WHO-GMP certified while 1 is EU-GMP certified. Three each are in the process of being EU-GMP and PIC/S certified (See Chapter 2 and Appendix 5).
- Across the board, stakeholders did also acknowledge that imports from India in particular tend to have more quality failures.

- A quick analysis of product recalls for 2019 listed on the NMRA website shows that India is indeed the major culprit in terms of quality failures, with over 75% of the products recalled being of Indian origin. However, it must be kept in mind that India does account for a large share of the total imported drugs in SL (with ~50% of imports being from there).
- The 10 local products recalled were from two manufacturers.
- All the foreign products recalled, except one, were distributed by an authorized importer. There was no marketing authorization holder for the German product, which was supplied by MSD on a waiver of registration.

Country of Origin of Products Recalled by NMRA, 2019 (Number)

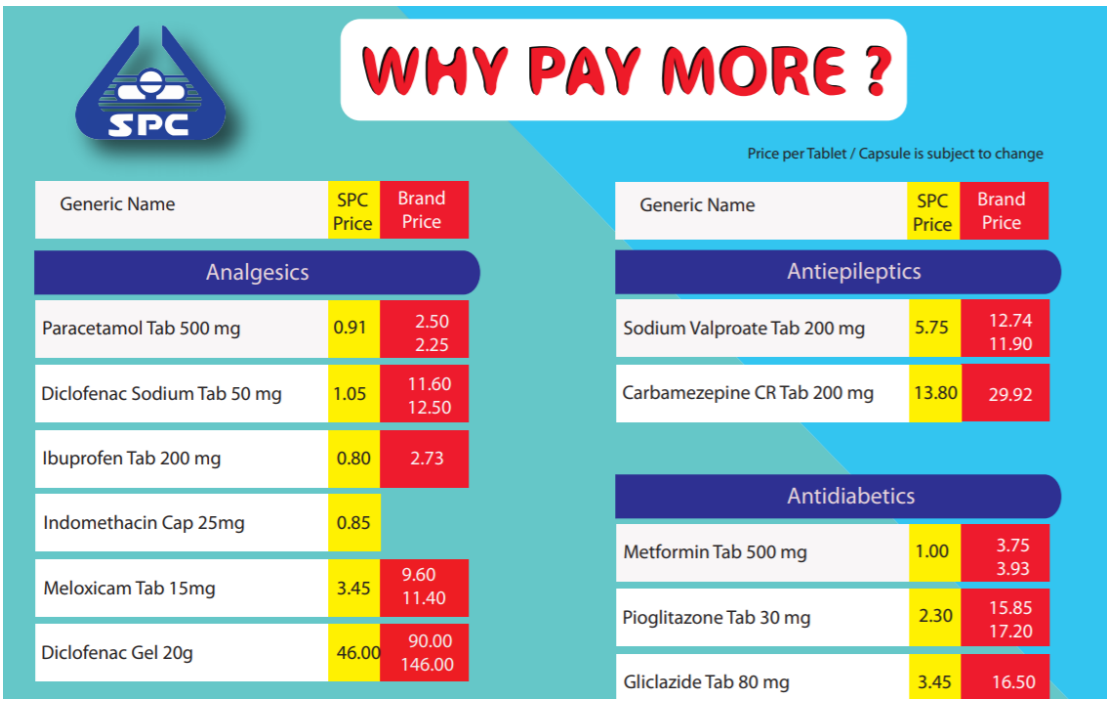


Source: NMRA website and manufacturer websites, accessed July 2020; Stax primary research, June 2020; SLPMA Facebook page, accessed July 2020.

Arguments for Augmenting Local Manufacture cont'd

4. "Local Production Makes Medicine more Affordable"

- Local production of generic drugs can make a difference in price compared to innovator or brand name drugs. For example, the drug of the generic name Gliclazide is manufactured by the SPMC and sold at a retail price of LKR 3.45 per tablet (80mg). The same drug made under the French brand name Diamicron retails at LKR 13.58 per tablet (80mg).
- However, the source country of the import affects the price of the drug too. Certain Indian imports sold in Sri Lanka fetch a lower price than a domestic make. E.g., an Indian brand 500 mg Amoxycillin capsule (Theomox) retails at LKR 6.00 per capsule, while the same drug at the same dose made by the SPMC sells for LKR 6.60. While this appears to be a very minor difference, in the bulk quantities bought by the state, over time, this difference will add up to a significant amount.



Generic Name	SPC Price	Brand Price
Analgesics		
Paracetamol Tab 500 mg	0.91	2.50 2.25
Diclofenac Sodium Tab 50 mg	1.05	11.60 12.50
Ibuprofen Tab 200 mg	0.80	2.73
Indomethacin Cap 25mg	0.85	
Meloxicam Tab 15mg	3.45	9.60 11.40
Diclofenac Gel 20g	46.00	90.00 146.00

Generic Name	SPC Price	Brand Price
Antiepileptics		
Sodium Valproate Tab 200 mg	5.75	12.74 11.90
Carbamezepine CR Tab 200 mg	13.80	29.92
Antidiabetics		
Metformin Tab 500 mg	1.00	3.75 3.93
Pioglitazone Tab 30 mg	2.30	15.85 17.20
Gliclazide Tab 80 mg	3.45	16.50

5. "Local Production Makes Drug Supply Secure"

- The closing down of borders during COVID-19 has highlighted the need for drug security in terms of a country being able to produce a majority of its pharmaceutical needs (at least essential drugs) on its own shores.
- Very few countries in the world are able to claim this however (there are only ~20 net exporters of pharmaceuticals in the world), and most countries do not manufacture the APIs needed to ensure security across the supply chain.

Source: SPC website, accessed June 2020; Healthguard pharmacy website, accessed June 2020; COVID-19: Impact on API Production and Global Pharmaceutical Supply Chains, DHL, March 2020; Pharma trade balance by country, ITC, accessed June 2020.

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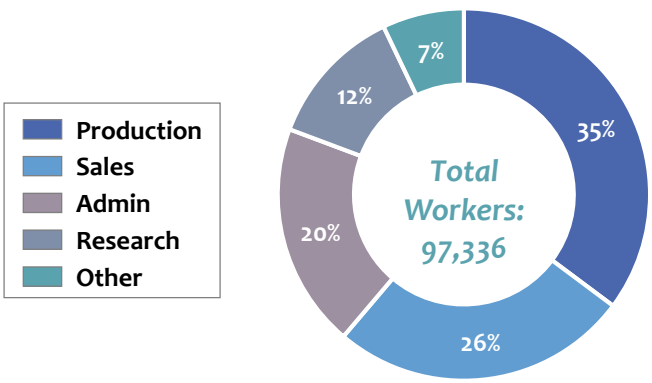
Arguments for Augmenting Local Manufacture cont'd

6. "Local Production Creates Jobs"

- There is evidence from many countries that increased pharmaceutical manufacturing can lead to high levels of job creation. For example, an analysis of Korea's pharma industry showed that the employment growth rate of the sector was 8.6% from 2014 to 2018—being ~8x higher than the job growth rate in manufacturing (1.1%) in the country and nearly twice the average of overall industries (3.6%).
- A common perception of this industry is that very high skill levels are needed. While that is true to an extent, a 2019 US congressional report revealed that ~30% of workers in their pharmaceutical industry are involved in low-skilled 'production occupations,' which only require a secondary-level education. In Korea, 35% are in production occupations and only 12% are in high-skilled research occupations.
- While low-skilled jobs will be created in the near-term, over the long-term, much of those jobs will be automated—like elsewhere in manufacturing. In order to attract innovative companies to set up in SL, investment must be focused on the practical and clinical aspects of tertiary scientific education.

Types of Jobs in Korea's Pharma Industry, 2018

(Percentage)



7. "Local Production Facilitates Technology Transfer"

- Increased pharmaceutical manufacturing with JV partners from innovative companies is a good way to build up scientific skills within a country.
- Indeed, the stated objective of the TRIPS agreement is, "the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations."
- An important aspect of creating a strategy for exports will be in understanding why big pharma companies have not invested in Sri Lanka in recent years, and what kind of groundwork would need to be laid to attract them.

Source: Job Creation in the Manufacturing Revival, Congressional Research Service, 2019; Pharmaceutical sector's job growth twice of all industries' average, koreabiomed.com, August 2019; Korea Pharmaceutical and Bio-Pharma Manufacturers Association, 2019; TRIPS Agreement, WTO, amended 2017.

Possible Pitfalls of Promoting Local Production & IS

1. "Restriction of Choice"

- If an import ban is considered for certain drugs, patients and doctors will have restricted choice.
- Further, if the majority of a global firm's sales in this country comes from drugs that are to be banned, operations in a market as small as SL may cease to make financial sense. This could lead to the withdrawal of its entire portfolio of drugs —including any innovator/highly specialized drugs that it distributes here (but are not in particularly high demand).

2. "Requires Substantial Government Support"

- For local manufacturers, the government's buy-back scheme has been a vital boon. Without the state procuring from them at mass scale, some manufacturers would not survive, as 100% of their sales are to the public sector.
- Some regional manufacturers are able to sell drugs in Sri Lanka at a low price due to their economies of scale. Further, SL follows WHO guidelines and does not tax pharma imports. Even if an Indian drug is only a few cents cheaper per unit than the local one, for an agency like the SPC that procures in bulk, the difference over time will be substantial.
- Given that importing certain drugs could be cheaper, then procuring those from local manufacturers is a form of subsidy that the government is providing, and the industry will continue to need this at least in the near- to mid-term, along with the funding needed to position the country attractively if pharma is to become an export pillar.

"Both 2019 and 2020 so far have been very challenging years for reasons beyond our control. If the buyback agreements were not in place, our Company would've crashed."

—MD, Local Pharma Manufacturing Firm

"Politicians want to maximize MOH medicines supply whilst reducing tax levels and not increasing MOH budget (we are the only APAC economy, in the past 30 years, which has not raised public spending on health as a % of GDP, even as per capita income grew). The only way these contradictory goals can be reconciled is with competitive imports. Given Malaysia's relevant experience [see p.70 of this report], large scale import substitution is likely to raise MOH purchasing/private retail prices, reduce MOH drug supply, and lose the government votes."

—Dr. Ravi Rannan-Eliya, Director, Institute for Health Policy

Source: NMRA website, accessed June 2020; Stax primary research, June-July 2020.

Possible Pitfalls of Promoting Local Production & IS cont'd

3. "It's a Polluting Industry"

- If not adequately treated, effluents from pharma manufacturing facilities can cause pollution of ground and surface water. E.g., several studies have mapped the adverse reactions on ecosystems surrounding API manufacturing facilities in India.
- However, the effluence levels and types caused by FPPs are significantly different from those produced by the manufacture of APIs. API manufacturing is far more hazardous for the environment—this is one reason why there are only a few nations currently producing APIs.
- In order to be GMP-certified, guidelines require that "neither the product or its residues of hazardous products handled in a facility should be allowed to be discharged directly to normal drainage systems" and the local FPP manufacturers, in order to receive certification, are required to implement waste management and wastewater treatment at source.

4. "Protectionism is Frowned Upon by Global Institutions"

- In the seventies and eighties, India and Bangladesh introduced a slew of regulations to protect their local pharma manufacturing industries. With increasing market liberalization in the nineties (dissolution of the USSR in 1991; WTO established in 1994), such protectionist policies were increasingly frowned upon, and the WTO now closely monitors the industry to allow for the free trade of not just goods but ideas.
- Further, several of the global institutions that SL is a member of (such as the IMF) expect their members to promote open markets.
- With recent events (China-US trade war and COVID-19), protectionist policies are being considered by many countries. India stopped exporting 13 crucial APIs (including that for paracetamol) in March 2020 in order to protect its domestic market's needs. However, it is unlikely that the effects of COVID-19 on global supply chains will substantially change views on protectionism in the long-term (India's API ban was lifted within a month).

> "We also have to recognize that in a pandemic, restricting the movement of medical supplies is only going to make the pandemic meander around the world longer. We really have to work hard to not allow for this to turn into all-out protectionism."
>
> —*Kristalina Georgieva, MD, IMF, May 2020*

Source: German generic drugmaker warns against EU protectionism, FT, June 2020; Impacts of Pharmaceutical Pollution on Communities and Environment in India, Nordea, 2016; WTO website, accessed June 2020; Pharmaceutical Industry of Bangladesh, EBL Securities, 2019; Government lifts ban on export of key APIs, Hindu Business Online, April 2020; Great Lockdown must not lead to Great Protectionism, Australian Financial Review, May 19, 2020; Stax primary research, June-July 2020.

Estimating Reduced FX Outflow from IS—Methodology

Step 1: Identify top spend molecules

This includes molecules that recorded the highest sales (at consumer prices) based on data reported in IQVIA (IMS); i.e. sales made by ~96% of the A Grade retail pharmacies in the country (including Osu Sala sales in the open market). Molecular spend includes a detailed breakdown of sales of a particular drug identified by its INN and by all dosage types (tablets/ capsules/ syrups/ oral suspension etc., as applicable).

Assumptions/ Limitations:

1. IQVIA data covers ~45% of the overall market.
2. SPC sales in the open market account for~ 14% of its supply, of which ~4% is captured in the IQVIA data.
3. The molecular breakdown for the following are currently unavailable to Stax: SPC sales to the open market (other than what is reported on IQVIA), SPC sales to state hospitals, sales made by private hospitals and private practitioners.
4. The molecular breakdown for these segments has been assumed to be the same as across retail pharmacies for the purpose of this exercise.
5. SPC sales to government hospitals for 2019 is ~USD 240mn, accounting for ~40% of the overall market—constituting ~78% imports.

Step 2: Prioritize essential molecules

To prioritize molecules, Stax took into consideration the EML, based on the MSD revised list for essential medicines 2020.

Assumptions/ Limitations:

1. Essentiality of a molecule varies by its dosage and composition. If any of the dosage or compound forms of the molecule were considered essential, we have retained that molecule on our prioritized list:
    - For example: Paracetamol has been retained on the list as tablets and syrups are marked essential, although suppositories are non-essential.
2. Certain drugs that were among the top spend but not listed on the MSD EML in any dosage/form were excluded.
    - For example, Rosuvastatin accounts for LKR 1.2bn (~USD 6.7mn) in spend but was not on the MSD list, and hence has been excluded from this analysis.

Estimating Reduced FX Outflow from IS—Methodology Cont'd

Step 3: Shortlist the top essential drugs manufactured locally

Stax further identified the essential molecules that are already being manufactured in SL. This is based on data available on the NMRA website that lists local manufacturers with GMP certification, and the molecules being made by each of them.

Assumptions/ Limitations:

1. If any dosage or form of the shortlisted essential molecule is currently being manufactured in Sri Lanka, it has been included on the list.
2. This analysis does not assess import dosage type or compare to locally manufactured dosage types. For example: Overall spend on Amoxicillin has been taken into consideration although SL currently only manufactures certain dosage types (capsules and oral dosages), and the current spend includes other dosage forms as well (e.g., Amoxicillin injections).
3. The spend data includes all compounds that contain the molecule in consideration. Whilst SL may not have all molecules to make a particular compound in the short run, this exercise explores the possible FX outflow reduction that could be achieved even if one molecule is currently manufactured locally.
4. Out of the top 30 molecules accounting for high spend in retail pharmacies, there are 22 molecules manufactured locally. However, not all of them are essential, or some of the local brands are only sold to the state and not sold in retail pharmacies—there are only 12 locally manufactured, essential molecules sold in retail pharmacies. This analysis focuses on the top 10 (of these identified 12 molecules).

Step 4: Estimate import value of top 10 shortlisted molecules

Firstly, the sales value of locally manufactured drugs in retail pharmacies for the top molecules was subtracted. For the top 10 shortlisted molecules:

- Overall sales in retail pharmacies (imports +local) = USD 52mn
- Retail pharmacy sales (only local) = (USD 3.4mn)
- Retail pharmacy sales (only import) = USD 48.6mn

Step 5: Calculate net reduction of FX outflow

- As all APIs are imported, an average estimated percentage was discounted to account for FX outflow for procurement of APIs.
- Our primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

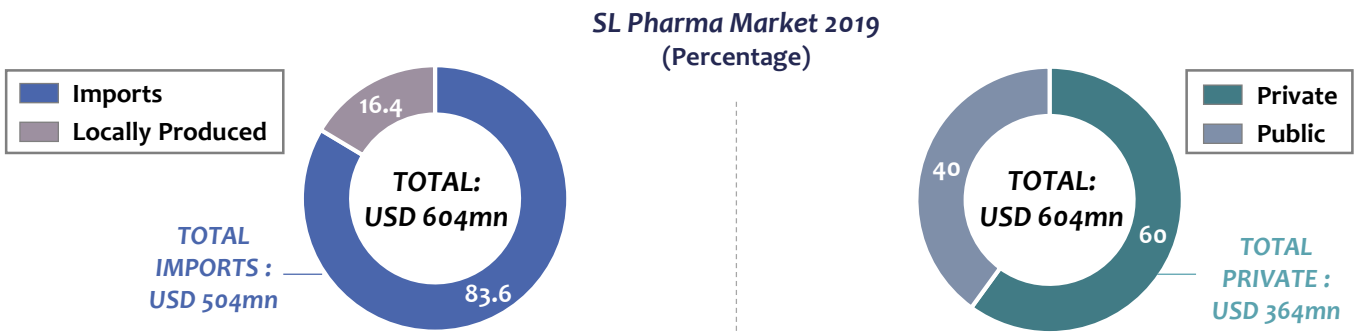
Estimating Reduced FX Outflow from IS—1. Defining the Market

Pharma Market: Public Sector

Description	LKR	USD [e]	Imports	Source/ Notes
DHS (SPC Sales to Public Hospitals)	42,959,659,808	239,998,099	78%	SPC Financial Statements 2019; Import % - based on past SPC Financial Statements
Public Market 2019	*42,959,659,808*	*239,998,099*		
Value of Imports	***33,688,478,657***	***188,203,791***		

Pharma Market: Private Sector (also referred to as the Open Market)

Description	LKR	USD [e]	Imports	Source/ Notes
Retail Pharmacy Sales (incl. SPC) [a]	48,592,737,802	271,467,809	96% [b]	Value -IQVIA 2019; Import % based on SLPMA presentation, April 2020
SPC – Other Open Market [c]	8,591,569,594	47,997,595	33% [b]	Value -SPC Financial Statement 2019; Import % based on past SPC Financial Statements
Pvt. Hospital Pharmacy Sales [d]	6,927,546,259	40,670,122	96%	2018/19 Hospital Annual Reports; Import % based on SLPMA presentation, April 2020
Pvt. Practitioners [d]	692,754,626	3,870,138	50%	Stocking Doc. Sales = 10% of Pvt. Hospital Sales (based on IHP market segmentation, 2015); Import % based on SLPMA presentation, April 2020
Total Private Market 2019	*64,804,608,281*	*364,005,664*		
Value of Imports	***56,647,148,548***	***316,464,517***		



a. IQVIA data includes sales of 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts only for ~4% of overall SPC sales in the open market). This figure excludes sales made by Private Practitioners and Private Hospitals.

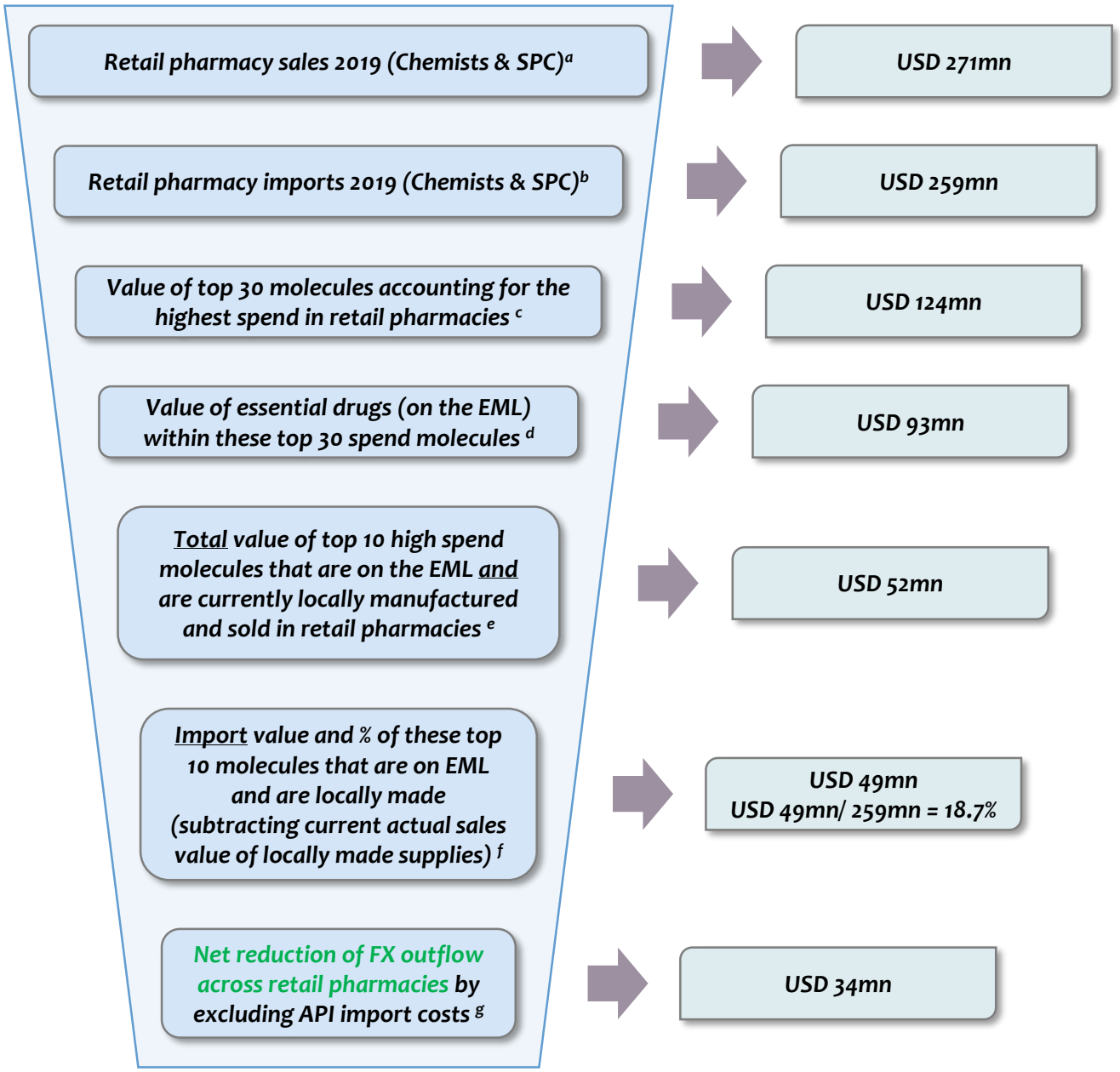
b. 96% of retail pharmacy sales and 33% of SPC sales are from import supplies – Refer Appendix 1 for detailed computation.

c. The rest of SPC sales on the open market (~96% of LKR 8.9bn) have been segmented separately to avoid the underestimation of market size.

d. This is a conservative figure that includes only the largest private hospitals providing sales data in their latest annual reports. Being derived from this figure, the value for stocking doctors is also a conservative figure.

e. Avg. 2018 XR: 1 USD = LKR 162.5 ; Avg. 2019 XR: 1 USD = LKR 179

Estimating Reduced FX Outflow from IS—2. Prioritizing the Top Spend and Essential Molecules *



* Avg. 2019 XR used across this estimation is: 1 USD = LKR 179

[a] The molecular level analysis includes only sales recorded on IQVIA (~45% of the overall pharma market), given that a molecular breakdown for other sales channels was not available to Stax. IQVIA data includes sales in 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts for ~4% of overall SPC sales in the open market). This figure excludes sales made by Private Practitioners and Private Hospitals.

[b] 96% of retail pharmacy sales and 33% of SPC sales are from import supplies – Refer Appendix 1 for detailed computation.

[c] Top 30 molecules were identified by sorting IQVIA data to prioritize **high spend, locally made molecules**, eliminating any duplication from other molecules not made locally/ low spend molecules that are made locally. Locally manufactured molecules were identified based on listings on the NMRA website, and then cross-checked on IQVIA to ascertain if it is supplied in the open market.

[d] Assessed based on the MSD revised list for essential medicines (EML) 2020. Of the top 30 molecules on the EML that are sold at retail pharmacies, 12 are made locally.

[e] Amoxicillin, Metformin, Gliclazide, Zinc, Atorvastatin, Fluticasone, Folic Acid, Paracetamol, Magnesium and Clopidogrel were shortlisted as the top 10 molecules.

[f] Sales value of local brands for the top 10 molecules have been deducted to derive import value.

[g] Stax primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

Estimating Reduced FX Outflow from IS—3. Applying Across Segments

- The initial percentage of the top 10 molecules, which are on the EML and also made locally, was computed based on data from IQVIA for retail pharmacies, and then applied across all other segments, given that a molecular breakdown for other channels was not available to Stax.
- This application across segments assumes that the molecular breakdown of medicines in high demand at retail pharmacies is similar across segments.

Factors	Private Sector				Public Sector (DHS)	Total Market
	Retail Pharmacies [f]	SPC (excl. sales on IQVIA) [g]	Private Hospitals	Private Practitioners		
Total sales 2019 (USD)[a]*	271mn	48mn	41mn	4mn	240mn	**604mn**
Import percentage [b]	96%	33%	96%	50%	78%	**83.6%**
*Total import value 2019 (USD)**	259mn	16mn	39mn	2mn	188mn	**504mn**
Top 10 molecules' overall value (USD)[c]*	52mn	9mn	8mn	1mn	46mn	**116mn**
% of 10 molecules that are on EML+ locally made	18.7%	18.7%	18.7%	18.7%	18.7%	18.7%
*Top 10 molecules' import value (USD)*d*	49mn	3mn	7mn	1mn	35mn	**95mn**
Discount API value [e]	30%	30%	30%	30%	30%	**30%**
Net reduction in FX outflow (USD)*	**34mn**	**2mn**	**5mn**	**0.7mn**	**25mn**	**66mn**

***** Avg. 2019 XR: 1 USD = LKR 179

[a] Overall market size is a conservative estimate. Refer Appendix 1 for detailed market sizing methodology.

[b] Refer appendix 1 for detailed computation of import share.

[c] Top 10 molecules were identified by sorting IQVIA data to prioritize **high spend, locally made molecules**, eliminating any duplication from other molecules not made locally/ low spend molecules that are made locally. Locally manufactured molecules were identified based on listings on the NMRA website, and then cross-checked on IQVIA to ascertain if it is supplied in the open market. Only medicines listed on the MSD revised list for essential medicines (EML) 2020 and sold at retail pharmacies were included among the shortlisted molecules. Amoxicillin, Metformin, Gliclazide, Zinc, Atorvastatin, Fluticasone, Folic Acid, Paracetamol, Magnesium and Clopidogrel were shortlisted as the top 10 molecules.

[d] Sales value of local brands in retail pharmacies for the top 10 molecules have been deducted to derive import value. The top 10 molecules' import value was computed as a percentage of the Retail Pharmacy import spend and then applied consistently on the respective import value of each segment.

[e] Stax primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

[f] Includes sales recorded on IQVIA, covering sales in 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts for ~4% of overall SPC sales in the open market).

[g] The rest of SPC sales on the open market (~96%) have been segmented separately to avoid the underestimation of market size.

[h] This is a conservative figure that includes only the largest private hospitals providing sales data in their latest annual reports. Being derived from this figure, the value for stocking doctors is also a conservative figure.

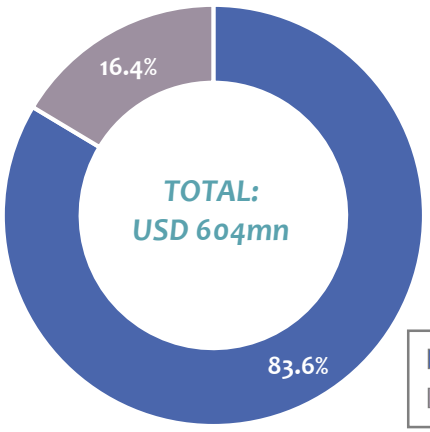
Estimating Reduced FX Outflow from IS—4. Estimating Possible Market Shift

Ratio of Imports to Locally Sourced Pharma—Current	85:15
Total Market Net Reduction of FX Outflow after excluding API import cost*	USD 66mn
Current Value of Local Manufacturing (604mn x 16.4%)	USD 99mn
Increased sales for local manufacturers (66mn/99mn)	66%
Ratio of Imports to Locally Sourced Pharma—Post-Complete IS**	73:27

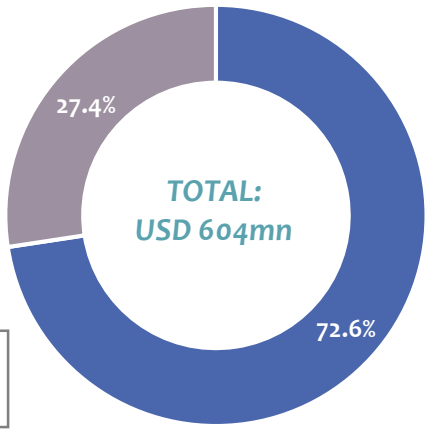
SL Pharma Market

Imports vs. Locally Made

Current Actual Market Share (2019)



Est. Market Share Post-Complete IS for Shortlisted Molecules



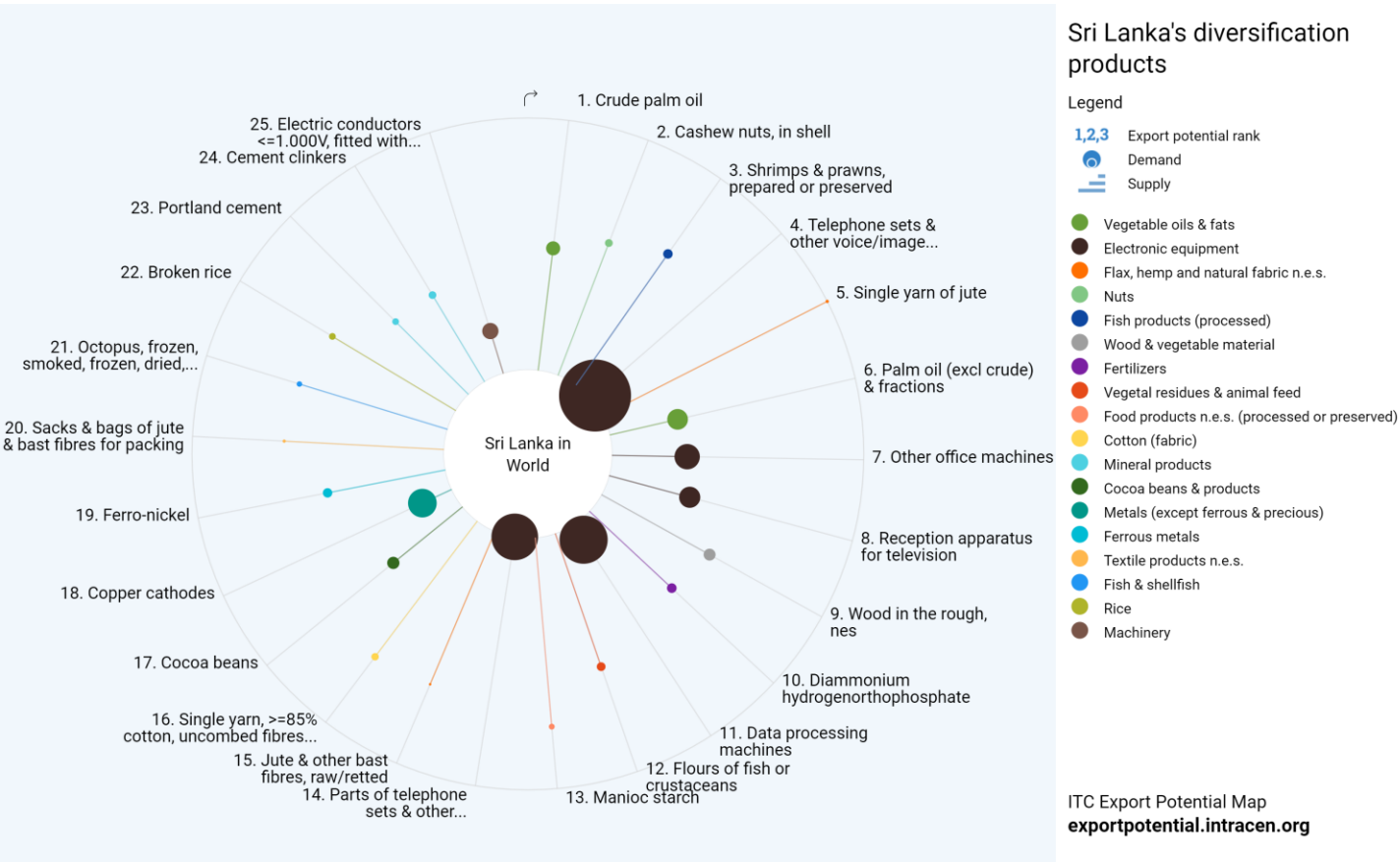
Imports
Locally Produced

*Stax primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

**Assuming that locally manufactured drugs will be sold at the same price as imported ones.

ITC's Product Diversification Map for SL

- The International Trade Center's (ITC) market analysis tools are used globally by companies and government institutions (including the EDB) when formulating trade strategies. The ITC's Product Diversification Indicator (PDI) identifies products that the exporting country does not yet competitively export, but which seem feasible given the country's current export basket and that of similar countries.
- The PDI does not list pharmaceuticals within the top 25 products to be considered for diversification of exports from Sri Lanka. In the graphic below, the numbers refer to the ranking, the bubble size to the extent of global demand, and the colored radial line to SL's ability to supply (the closer the radial line is to the outer circle, the easier for SL to supply).
- According to the PDI, currently, Sri Lanka's best options for diversification in global export are in crude palm oil, cashew nuts (in shell), and shrimps & prawns (prepared or preserved). The easiest product for SL to supply is jute (single yarn). Of the products ranked, telephone sets & other voice/image transmission apparatus has the strongest global demand potential.



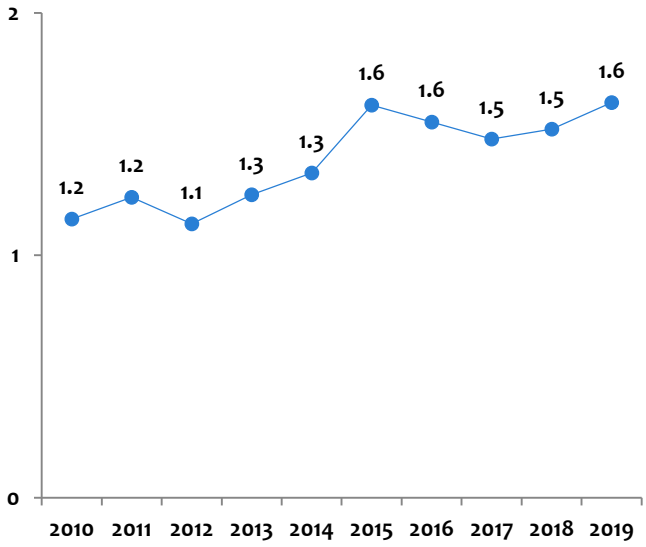
- However, the ITC itself points out that there are factors outside their estimations (such as FDI) that would affect export potential, and that the PDI should be seen as a starting point, which needs to be followed up with further research and consultations with public and private sector stakeholders in the country.

Source: ITC product diversification tool and trade database, accessed June 2020; Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine, World Bank, 2005.

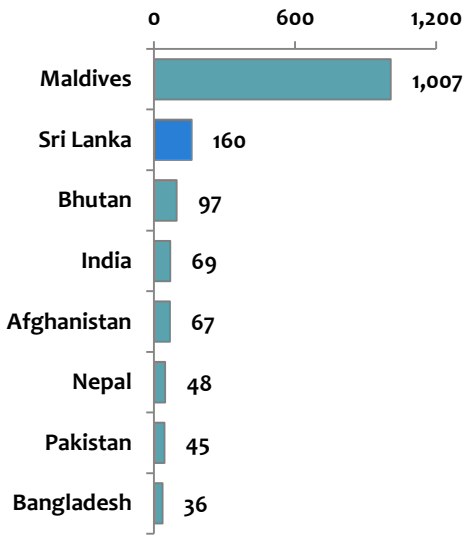
Success Factors Related to Pharma Exports

- A World Bank study found that there is strong positive correlation between successful pharmaceutical production and a country's:
    1. domestic market size being large,
    2. total governmental health expenditure being high, and
    3. Competitive Industrial Performance Index (CIP) score being high.
- The first two factors are partly why import substitution has come to be considered a crucial factor in laying the groundwork for pharmaceutical exports—many of the countries that have succeeded have started by catering to a large local market, in terms of absolute size in number of domestic consumers and also high demand from the public sector. However, since SL cannot claim such a population, other avenues will need to be explored.
- In comparison to regional neighbors who are large pharma exporters, SL spends more on health per capita. Sri Lanka's health expenditure as a percentage of GDP has remained at a fairly constant rate over the past decade, despite the country's elevation to upper middle income status.

Sri Lanka Total Health Expenditure, 2010–2019 **(as a % of GDP)**



CHE per Capita, South Asia by Country **(Current USD, 2017)**

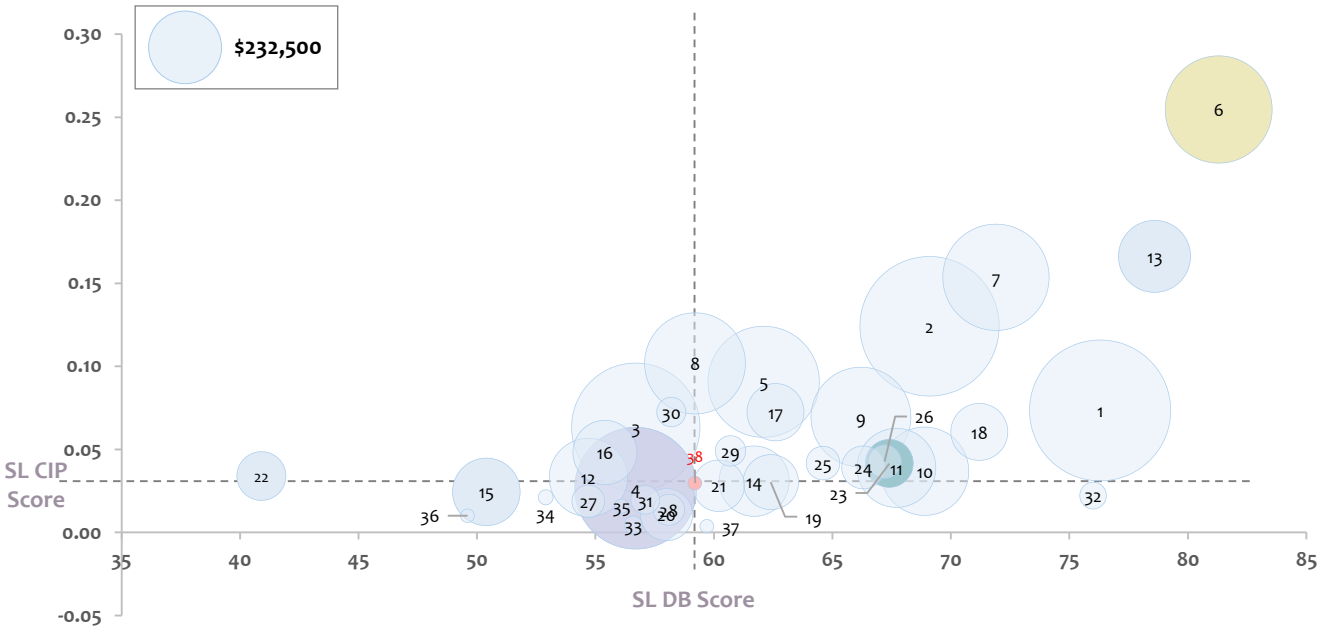


Note: Estimates of current health expenditures include healthcare goods and services consumed during each year. This indicator does not include capital health expenditures such as buildings, machinery, IT and stocks of vaccines for emergency or outbreaks.

Source: World Bank Databank; CBSL Annual Reports & Statistical Appendices; Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine, World Bank, 2005; SLHA, MOH, 2014-2016.

Comparing SL to Low- to Mid-tier Exporters

- A country highlighted in the aforementioned WB study, which succeeded despite not having a large population, was Jordan. In 2017, Jordan's pharma exports value was more than 75x greater than Sri Lanka's despite having lower scores on both the World Bank's Ease of Doing Business (DB) Ranking and the UNIDO's Competitive Industrial Performance (CIP) Index.
- The following chart depicts the DB and CIP scores of select low- to mid-tier exporting nations (with exports lower than USD 1 billion in value and greater than Sri Lanka's. 2017 export data is used here, as this was the year with the highest export value reported for SL by the ITC).



	Economy	Ease of DB Score 2017	CIP Score 2018	Pharma Exports value 2017 (USD Thousands)
1	UAE	76.3	0.0735	$ 893,795
2	Turkey	69.1	0.1242	$ 875,310
3	Argentina	56.7	0.0633	$ 743,308
4	Jordan	56.7	0.0267	$ 668,150
5	Indonesia	62.1	0.0907	$ 557,699
6	Taiwan	81.3	0.2547	$ 517,540
7	Thailand	71.9	0.1536	$ 508,827
8	Saudi Arabia	59.2	0.1018	$ 460,116
9	South Africa	66.2	0.0694	$ 450,912
10	Colombia	68.9	0.0369	$ 351,731
11	Costa Rica	67.7	0.0389	$ 281,354
12	Egypt	54.7	0.0331	$ 279,542
13	Malaysia	78.6	0.1662	$ 235,108
14	Guatemala	61.7	0.0309	$ 223,476
15	Pakistan	50.4	0.0245	$ 207,673
16	Iran	55.4	0.0482	$ 187,846
17	Vietnam	62.6	0.0724	$ 148,379
18	Chile	71.2	0.0606	$ 147,210
19	El Salvador	62.4	0.0303	$ 139,149

	Economy	Ease of DB Score 2017	CIP Score 2018	Pharma Exports value 2017 (USD Thousands)
20	Kenya	58	0.0108	$ 124,186
21	Uruguay	60.2	0.0281	$ 121,270
22	Bangladesh	40.9	0.034	$ 109,069
23	Morocco	67.4	0.0415	$ 104,091
24	Oman	66.3	0.0392	$ 84,962
25	Tunisia	64.6	0.0418	$ 52,741
26	Peru	67.2	0.0426	$ 51,455
27	Lebanon	54.7	0.0188	$ 48,884
28	Paraguay	58.1	0.0136	$ 44,999
29	Kuwait	60.7	0.0491	$ 42,247
30	Philippines	58.2	0.0725	$ 39,952
31	Ecuador	57.1	0.0196	$ 38,411
32	Mauritius	76	0.0222	$ 33,472
33	Uganda	56.6	0.0045	$ 15,029
34	Cambodia	52.9	0.0212	$ 10,688
35	Honduras	56.1	0.0159	$ 9,466
36	Senegal	49.6	0.0101	$ 9,144
37	Nepal	59.7	0.0037	$ 8,940
38	Sri Lanka	59.2	0.0298	$ 8,860

Source: ITC trade database, accessed June 2020; doingbusiness.org; UNIDO.org; Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine, World Bank, 2005.

Comparing SL to Select 'Success Stories'

- Taiwan has a population that is only slightly bigger than Sri Lanka's, but is one of the most successful APAC regional pharma manufacturers. They are not competing due to the development of a large domestic market but on the strength of their technology and innovation.
- Jordan's per capita GDP is very similar to that of SL, as is Morocco's. Further Morocco's CHE per capita is almost identical to that of SL. These are not particularly wealthy nations nor do they have high CHE spend (like Ireland), but Morocco's CIP is higher than Sri Lanka's.
- The successes of Taiwan, Morocco and Jordan will be examined in detail in this report, along with other select markets for context.

	Country	Population 2020 (M)	GDP p.c. (current USD) 2019	CHE p.c. (Current USD) 2017	CIP Score 2018	Pharma Exports Value (USD M) 2019
0	Sri Lanka	21.8	3,853	160	0.0298	5.9
1	India	**1,380.0**	2,104	69	0.0830	16,264.0
2	Bangladesh	164.7	1,856	36	0.0340	71.6
3	Pakistan	220.9	1,285	45	0.0245	217.6
4	Israel	9.0	43,641	3,145	0.1318	3,315.8
5	Jordan	10.2	4,330	341	0.0267	327.5
6	Egypt	102.3	3,020	106	0.0331	271.8
7	Morocco	36.9	3,204	161	0.0415	117.1
8	Cyprus	1.2	27,859	1,732	0.0159	372.6
9	Singapore	5.8	65,233	2,619	0.2573	8,107.0
10	Taiwan	23.8	27,131	945	0.2547	602.6
11	Ireland	4.9	**78,661**	**4,977**	**0.3172**	**53,555.3**

VARYING ROUTES TO EXPORT SUCCESS:

Dominating Domestic

Protect local market first and supply 70-90% of that need, which would help build scale. Also capitalize on cheap labor. Over time, keep improving unit economics.

BANGLADESH

PAKISTAN

INDIA EGYPT

Trading on Tech

Invest in talent & R&D though both government funds and FDI. Position country globally as a leader in innovation by using success in other tech areas too (e.g., Taiwan's semiconductor success. Keep moving the bar higher by investing further in latest tech.

SINGAPORE

ISRAEL TAIWAN

Continental Conduit

Build infrastructure to become gateway to broader region (e.g., Morocco to Sub-Saharan Africa). Hub strategy to reinforce that position (e.g., Jordan first-mover in free zones in Gulf). Keep positioning for FDI.

JORDAN MOROCCO

High-Income Haven

Use national high income to Invest into talent and infrastructure. Incentivize investment through tax haven status.

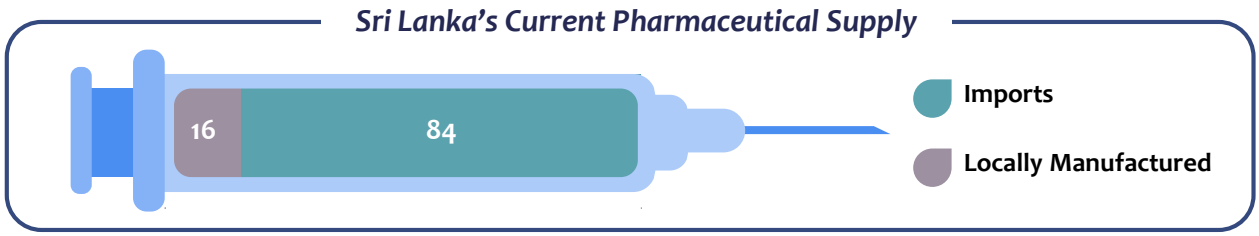
IRELAND

Source: World Bank Databank; National Statistical Bureau of Taiwan; Taiwan Ministry of Health & Welfare; Worldometers.info; UNIDO; Pharma Boardroom country profiles.

1. Overview: Sri Lanka's Pharmaceutical Market

Sri Lanka's Pharmaceutical Market

The government's cash crunch, the Sri Lankan rupee's devaluation, and the discussions on de-globalization due to the COVID-19 pandemic have all brought into focus the country's heavy reliance on imported drugs. This has renewed interest in increasing local pharmaceutical manufacturing to meet rising patient needs while improving the trade balance.



- Sri Lanka's pharmacy market had a value of ~**USD 604mn in 2019—putting imports at ~USD 504mn** (see Appendix 1 for market sizing estimates based on varying sources and methodologies).
- Sri Lanka's healthcare spend is expected to see robust growth over the next ten years, mainly due to an increase in chronic non-communicable disease burdens caused by lifestyle-related risk factors such as obesity, diabetes and tobacco consumption.
- In order to treat these diseases, both the private and public sector of the industry heavily rely on imports. Close to 85% of the demand in the country is met with imports, with the rest being catered to by local manufacturers.
- Given the large reliance on imports and the continuous depreciation of the rupee against the dollar, exchange rates significantly affect margins of importers, wholesalers and distributors, with some costs being passed on to the consumer.
- To safeguard the interests of the public and ensure affordability, the Sri Lankan pharmaceutical regulator (NMRA), implements a price ceiling on certain essential drugs. In an attempt to increase access to essential drugs, the Ministry of Health (MoH) slashed prices (bringing the controlled price down) of a number of drugs and molecules in 2016.
- Since the introduction of controlled prices, the Sri Lankan rupee has depreciated 18%–19% against the US dollar. This alarming exchange rate trend forced the SLCPI to appeal for a currency depreciation-linked price control formula.
- Without adequate price relief, continued dollar depreciation could lead to the withdrawal of certain products. Hence, in order to alleviate financial pressure on importers, the government increased the prices of 60 molecules by 14.4% in May 2019.

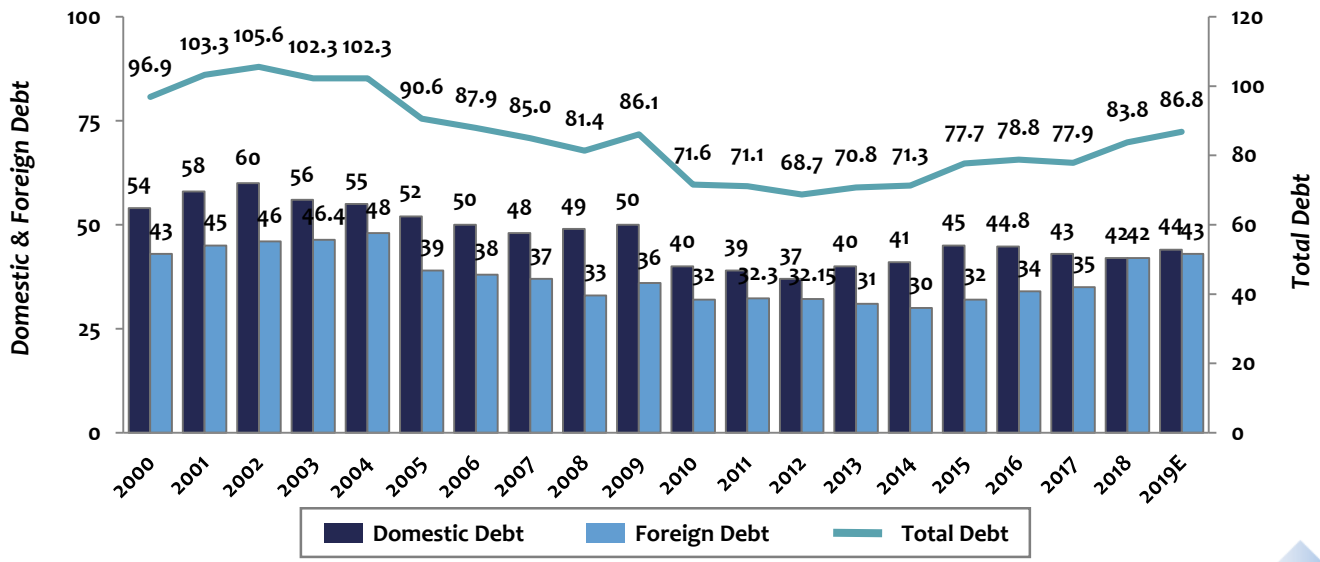
Source: Sri Lanka Pharmaceuticals & Healthcare Report, Fitch Solutions, 2019; Sri Lanka's success: ensuring affordable essential medicines for all, World Health Organization, 2016; Pharma Chamber welcomes drug price revision, Adadereanabiz.lk, May 2019.

Sri Lanka's Cash Crunch

Sri Lanka is faced with a cash crunch with high debts leading to non-payment of several bills, including pharmaceutical ones, which has threatened the supply of imported pharmaceuticals to the State.

- Sri Lanka's government owes LKR 25.7bn in arrears to foreign pharmaceutical suppliers, including the cost of medicines purchased by the previous government. Non-payment of bills has posed a threat of delayed supply of pharmaceuticals.
- There are several reasons for the current cash crunch:
  - **Reduced Taxes:** Sri Lanka's new administration, which came in to power in November 2019, slashed several taxes in an effort to stimulate the economy. One of the key fiscal efforts was a cut in value added tax from 15 to 8 percent. This was done to encourage more spending in an economy that was hit by an output shock due to severe currency devaluation in 2018.
  - **Expenditure Rationalization:** Rationalization has been conducted to prioritize recurrent expenditure whilst curtailing most of the productive investment expenditure. This has led to a large fiscal overhang over the last three years.
  - **Increased Debt Limit:** The Finance Ministry has sought to raise the debt limit by LKR 367bn for the first four months of 2020, amending a vote-on-account. However, that provision was not sufficient to realize unclaimed bills, which has been a challenge for the continuation of essential cost items such as fertilizer and pharmaceutical products.
  - **High Foreign Currency Exposure to Debt:** The import of pharmaceutical products has also contributed to a high foreign currency exposure to debt, which is at almost 50 percent.
  - **COVID-19:** Unexpected and high government spending on the control of COVID-19 has increased additional financing needs by an estimated 2% of GDP.

Central Government Debt (as a % of GDP)



Source: Govt.'s unpaid bills mounting, Sunday Times, June 2020; Sri Lanka fiscal cash crunch hits medical suppliers, Economy next, Feb 2020; CBSL; Sri Lanka Ministry of Finance.

Challenges Compounded by COVID-19

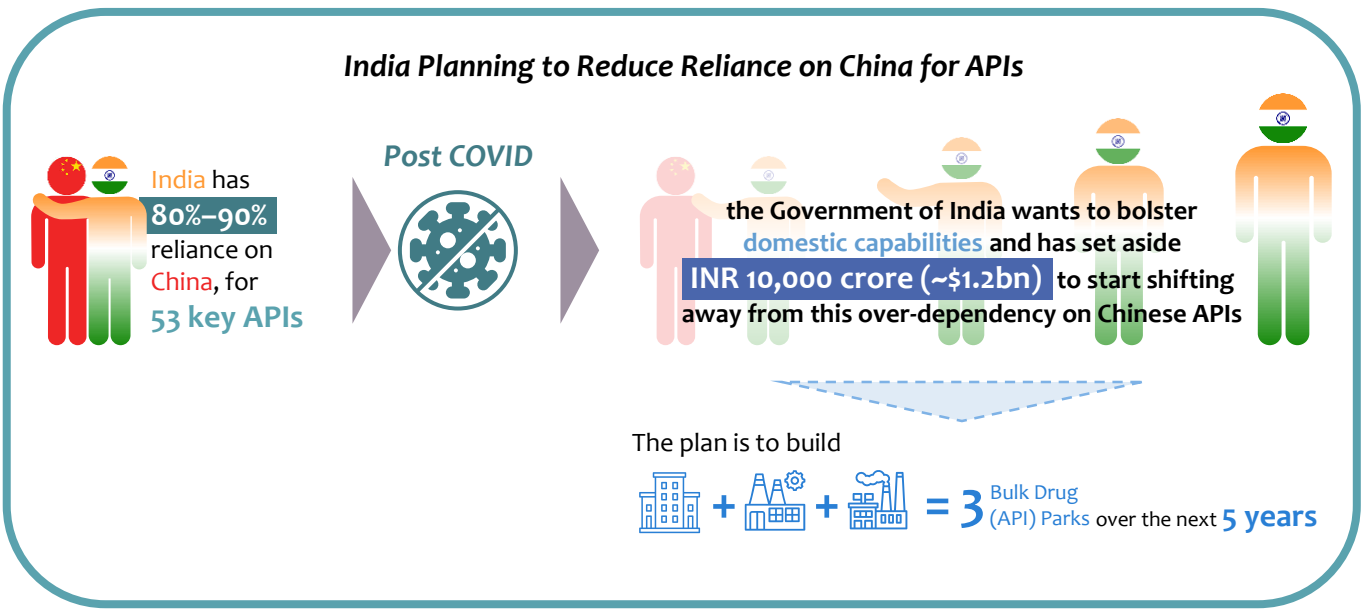
Post-COVID19, compromised supply chain and de-globalization bias will create pressure for essential medical goods to be sourced onshore and for supply chains to be de-risked to avoid shortages.

- Large parts of the global supply chain are almost entirely dependent on India and China. Due to COVID-19, most manufacturers have sought to curb exports and put domestic needs first. For example, in March 2020, India temporarily stopped exports of 13 APIs and drugs, in order to assure sufficient stocks for its own industry's use (see Appendix 3 for list). This ban was lifted in a month, but has caused ripples across the industry.

- Given that the entire industry runs a lean supply chain, globally, any disruption to production can cause shortages lasting up to 3 years.

- The overall impact of the above have highlighted the risks of relying so heavily on drug imports. Consequently, there has been renewed interest, not just in Sri Lanka but across the world, of increasing security across the pharma supply chain. Crucial to this discussion are the increased supports for the local manufacture of drugs, along with the debate on whether import substitution policies are required or not.

- In the aftermath of COVID-19, the GOSL has identified the Pharmaceutical and Food Processing industries among new areas where local manufacturing is to be further supported.

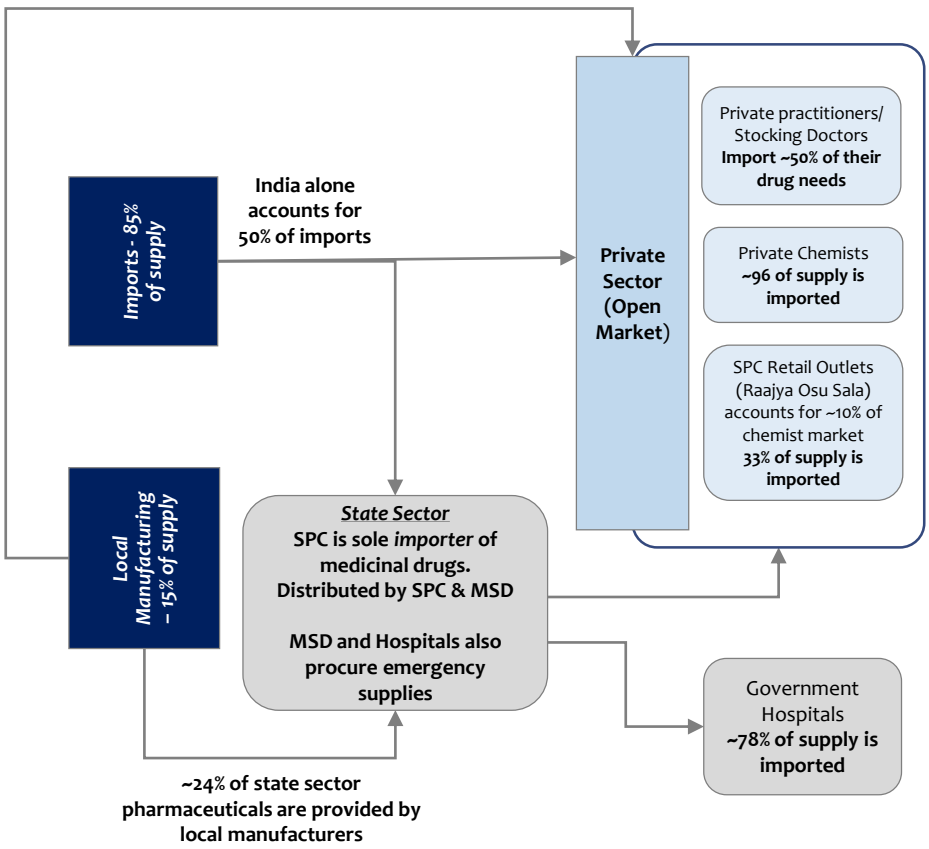


Source: India's restrictions on API exports only temporary, fiercepharma.com, March 2020; COVID-19: Impact on API Production and Global Pharmaceutical Supply Chains, DHL, March 2020; Government lifts ban on export of key APIs, Hindu Business Online, April 2020; India invests to boost domestic API manufacture, outsourcingpharma.com, March 2020; Local Pharma API companies to gain from Rs 10,000 crore scheme, Economic Times India, June 2020.

Flow of Medicinal Supplies in Sri Lanka

- The industry comprises of companies that manufacture biological, medicinal and pharmaceutical products in various forms, including ampoules, tablets, capsules, vials, ointments, powders, solutions and suspensions.
- Industry products are predominantly distributed via wholesalers, and are then sold via pharmacies or distributed in hospitals.

Flow of Pharma Supplies in Sri Lanka



- All drugs imported for the state sector are procured through the SPC. The MSD and hospitals also procure some emergency supplies directly, but primarily procurement happens via the SPC.
- The government's Medical Supplies Division (MSD) and the regional MSDs distribute drugs via state hospitals while the SPC retail outlets (Raajya Osu Salas) and Franchise Osu Salas sell directly to consumer as well.
- A majority of the private sector sales are made by chemists (retail pharmacies).

Source: Sri Lanka Pharma market, MP Advisors, 2015; Pharma industry's issue with authorities, Sunday Times, Sep. 2018; Sri Lanka Budget 2019, Ministry of Finance; Sri Lanka Health Accounts. IHP; Stax Primary Research, June 2020.

SL Pharmaceutical System Flowchart

Medicine

Market Authorization / Licensing / Quality Assurance

National regulatory authority: National Medicines Regulatory Authority (NMRA) http://nmra.gov.lk/

Regulatory products:

Medicines: YES **Vaccines:** YES **Medical Devices:** YES **Traditional Medicines:** YES

Medicine quality control laboratory: National Drug Quality Assurance Laboratory:

ISO 17025 certified: NO **WHO Prequalified:** NO

Number of registered medicines: 8,095 allopathic and 960 traditional medicines

Medicine Selection

Agency responsible for selection: Medical Supplies Division, Ministry of Health, Nutrition and Indigenous Medicine

Number of products on essential medicine list:

By active ingredients: 361 **By dosage form:** >400

Traditional medicines products included in essential medicines list: None

Medicines availability is indicated by health facility level: YES

Number of products in national formulary: Not available

Medical Procurement

Public Sector

Agency responsible for public procurement: State Pharmaceutical Corporation

Procurement done at Central ☑ **State** ☐ **Facility** ☑

Commonly used procurement methods: Worldwide tenders

Private Sector

Number of wholesalers: 790

Pricing and Reimbursement

Public Sector

Price control: YES

Mechanism: Tenders are scheduled according to ascending prices and evaluated technically

Health insurance reimbursement price:

No public health insurance for majority of population

Free medicines: YES

Private Sector

Agency responsible for price control:

Ministry of Trade and Industry with Sri Lanka Manufacturers' Association and the Sri Lankan Standards Institute.

Mark-ups regulated: NO

Distribution

Public Sector

Agency responsible for distribution: Medical Supplies Division

Public sector facilities:

Hospitals: 622

Central dispensaries/primary care unit: 475

Private Sector

Number of Retail Outlets: 3,297

Licensed retail pharmacies per 10,000 population: 1.6

Number of traditional medicines outlets: Not available

Patient

Source: Sri Lanka medical products profile 2019, WHO.

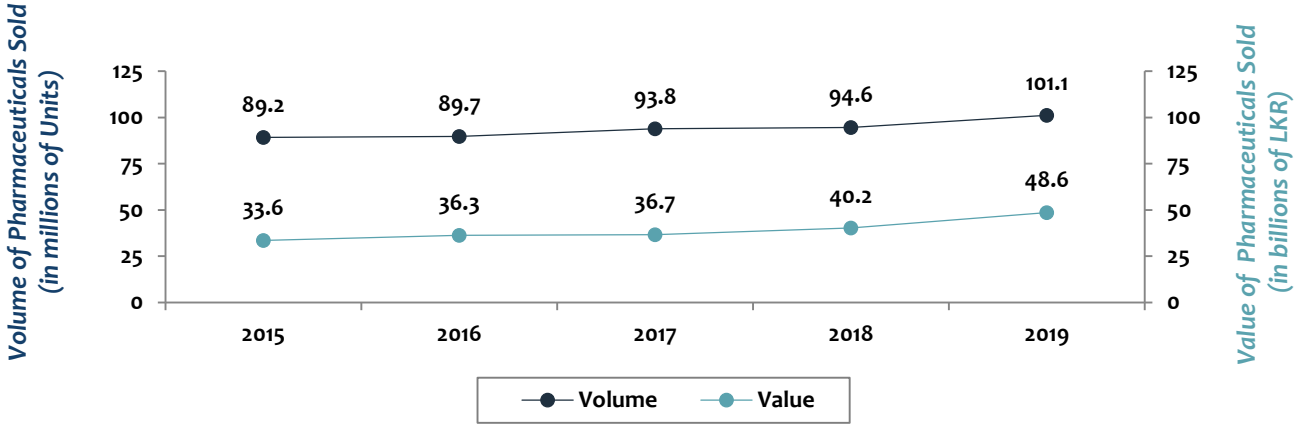
Stax

Demand for Pharmaceuticals in Sri Lanka

The demand for pharmaceuticals in Sri Lanka is largely fulfilled by generics. The chief drivers of demand are higher incomes, an aging population, and rising incidence of NCDs.

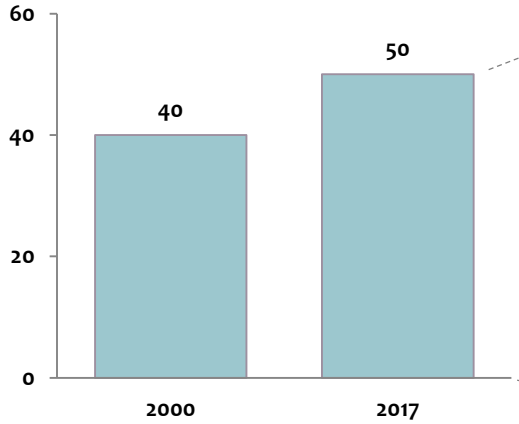
Approximately 82% of Sri Lanka's pharma spend is on generic drugs with the balance being spent on patented medicines. Both the volume and value of medicines sold at retail pharmacies have seen a steady increase in the period of 2015-2019.

Sri Lanka Retail Pharmacy Sales by Volume and Value
(2015–2019)

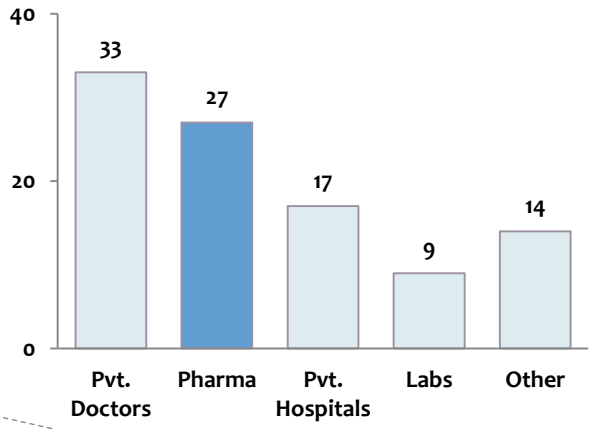


Sri Lanka's GDP rose significantly with the end of the conflict in 2009, and in 2019, the WB reported that SL had transitioned from lower-middle income to upper-middle income status. With rising income, people are spending more out-of-pocket for healthcare expenditure.

Sri Lanka OOP Health Expenditure
(as a % of CHE)



OOP Breakdown—What do Sri Lankans Pay OOP for?
(as a % of Total OOP)

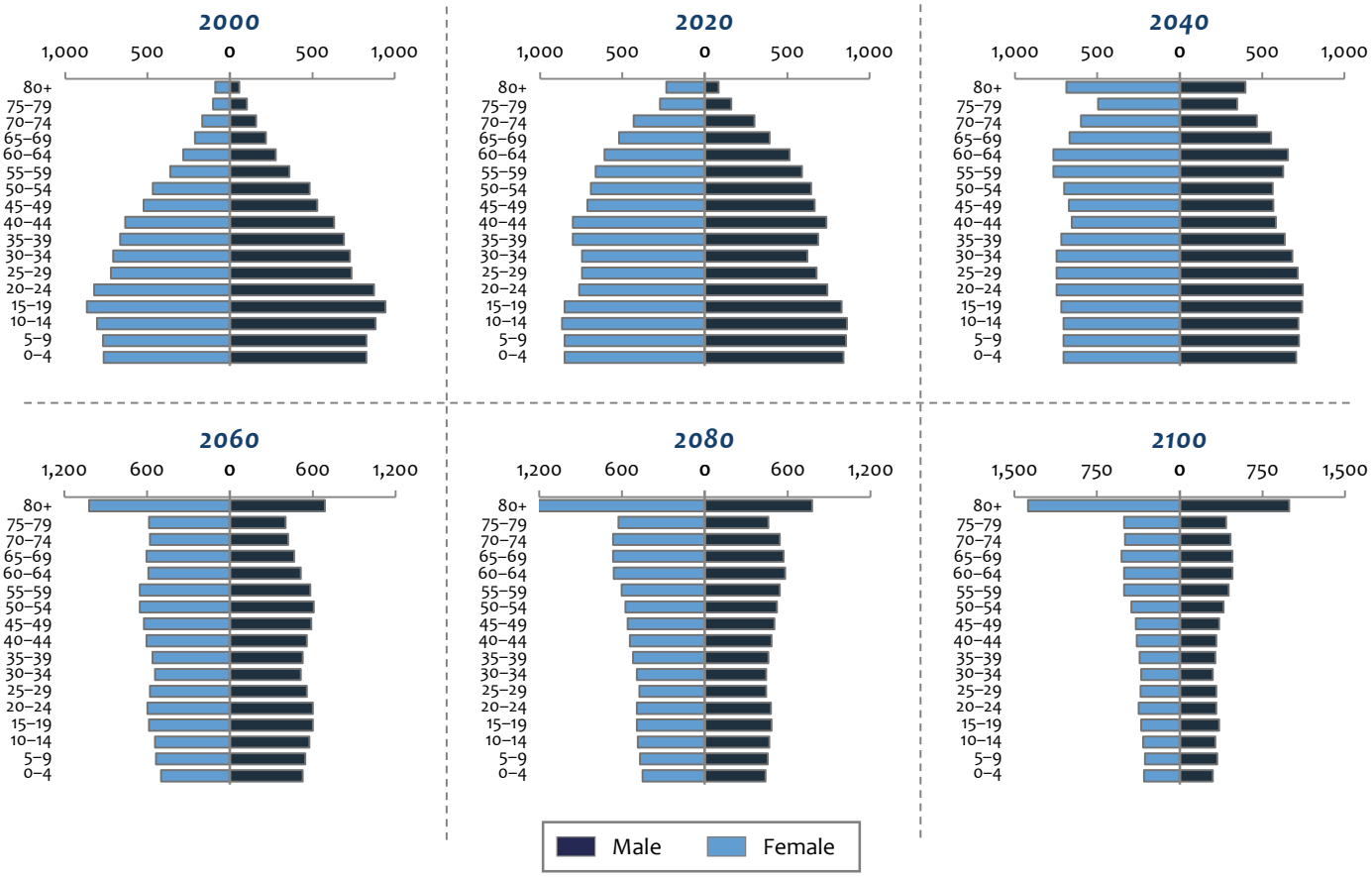


Source: World Bank Databank; Sri Lanka Pharmaceuticals & Healthcare Report, Fitch solutions, 2019; Sri Lanka: Achieving Pro-Poor Universal Health Coverage without Health Financing Reforms, World Bank, 2018 (OOP Breakdown reflects World Bank calculations based on Household Income and Expenditure Survey (HIES) 2015/16); Sri Lanka's elevation to upper middle income status. Daily FT, July 2019.

Demand Drivers—The Large Aging Population

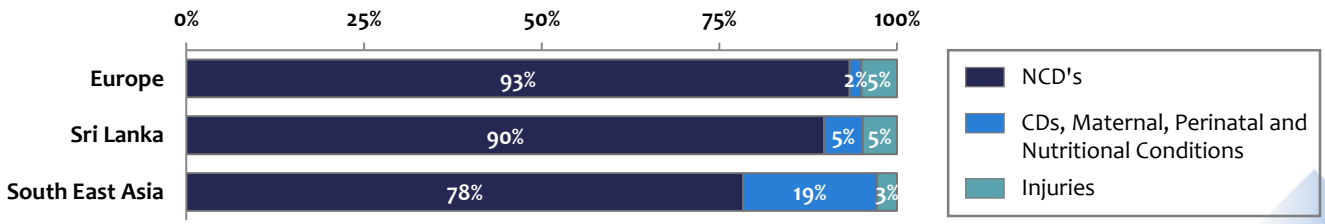
Sri Lanka's population pyramid will change rapidly with the share of population over 65 years expected to grow from 9.4% of the population in 2015 to 21% by 2045 and 35.6% by 2100.

Sri Lanka Population Pyramid by Age, 2000–2100 (Population in thousands)



- Over 90% of the elderly population seeks health care from the existing primary health care network in the country. It is estimated that 32-50% of the senior population needs extraordinary care and geriatric therapeutic measures.
- Mortality among the elderly from NCDs in Sri Lanka is closer to levels in advanced economies than regional economies. In 2016, NCDs accounted for 90% of deaths of people aged 60 years or more in Sri Lanka. The majority of these deaths due to NCDs were from cardiovascular disease (39% of all deaths), cancer (13%), and diabetes (10%).

Deaths by Major Cause among People ≥60 years, 2016 (Percentage)



Source: WHO; Growing Old Before Becoming Rich: Challenges of an Aging Population in Sri Lanka, ADB, 2019.

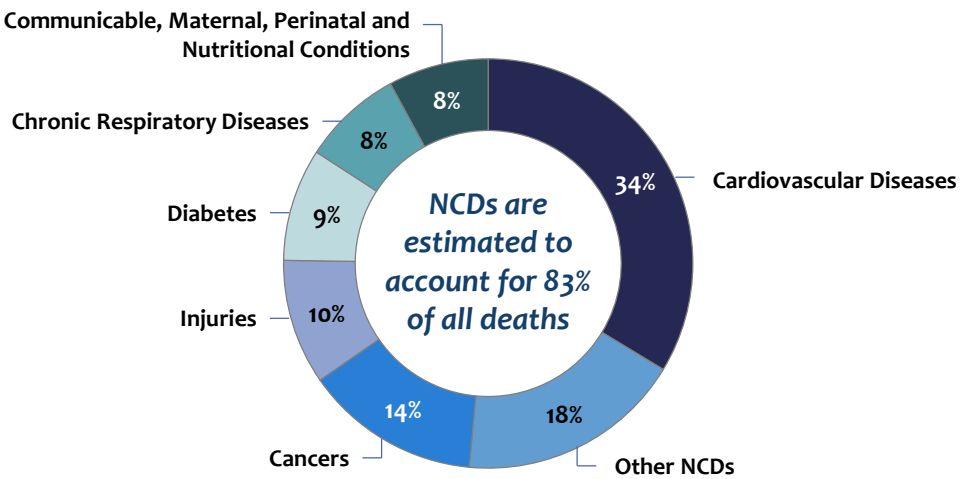
Stax

Demand Drivers— Rising NCDs

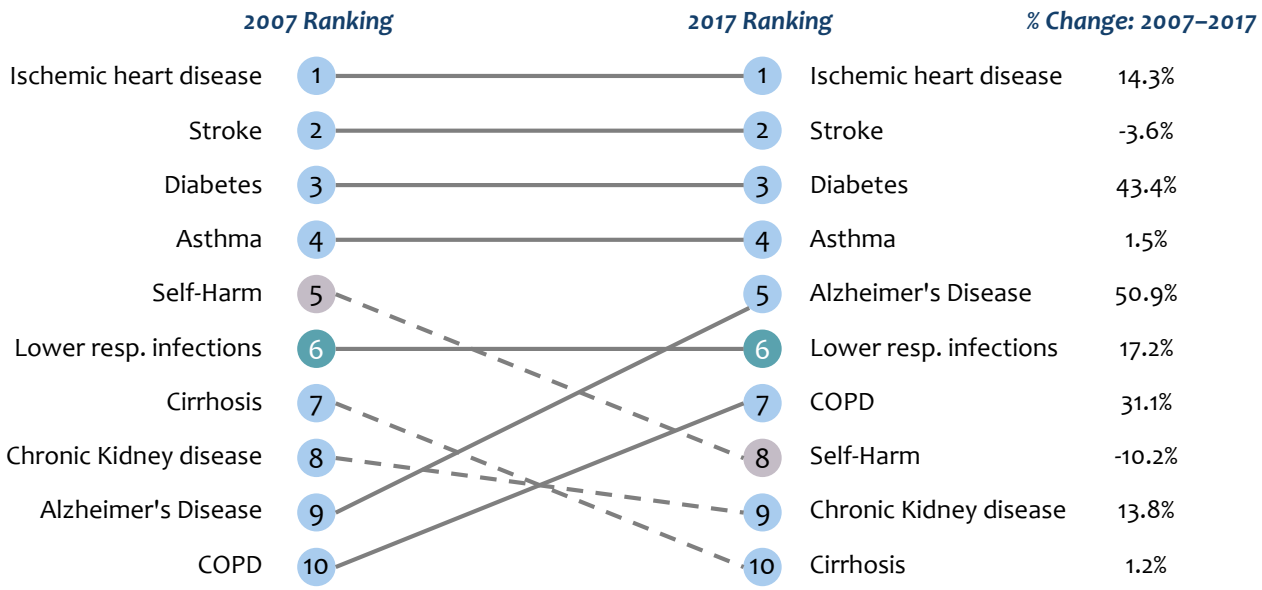
Heart diseases, cancers, and diabetes have remained the top 3 death-causing NCDs in the country for the last decade.

- NCDs are on the rise in Sri Lanka, and accounted for over 80% of deaths in the country as of 2016.
- According to the WHO, in Sri Lanka, cardiovascular diseases account for ~34% of total deaths, while cancers account for 14%, followed by diabetes (9%), and chronic respiratory diseases (8%).

Leading Causes of Mortality in Sri Lanka, 2016



Leading Causes of Mortality in Sri Lanka (% change 2007 to 2017)



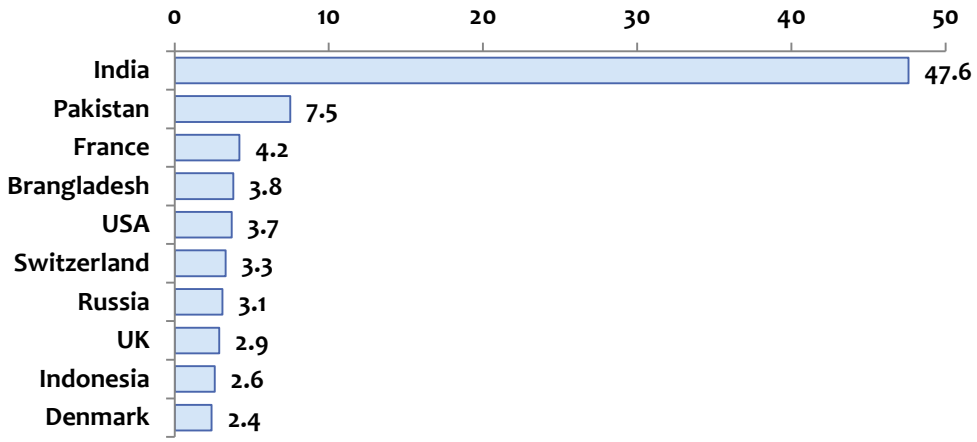
Source: Health data Sri Lanka, IHME, 2017; Non-communicable Diseases (NCD) Country Profile Sri Lanka, WHO, 2018.

Demand for Drugs Mainly Met through Imports

Around 85% of the demand for finished pharmaceutical products (FPPs) in Sri Lanka is met by imports.

- India is by far the largest FPP importing partner of Sri Lanka accounting for nearly 50% of imports, followed by Pakistan and France (under 10% each).

Sri Lanka's Top 10 Import Partners, 2017
(Percentage of total FPP imports)



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.

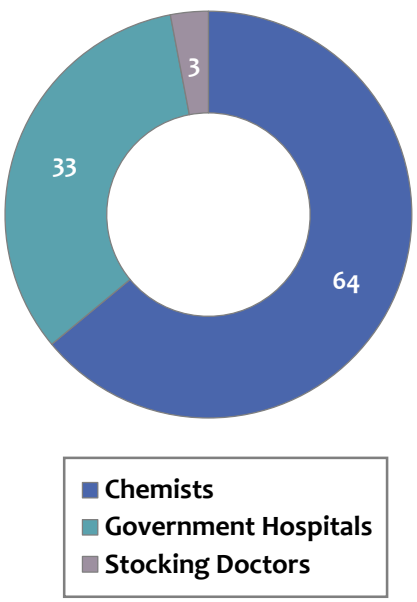
Government hospitals account for ~33% of overall imports:

- 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.

Imports by Channel 2018
(Percentage)



Source: IMS data; UN Comtrade; NMRA website, accessed June 2020; Annual Report, Ministry of Finance, 2019; Sri Lanka Pharma Market, MP Advisors, 2015.

Timeline of Recent Pricing Controls by the GOSL

2003

Price controls were abolished.

2014

Given the increasing burden of NCDs and the rising cost of the drugs treating it, the GOSL froze the pricing of all pharmaceuticals. However, the freeze was not enforced given that the Rupee depreciated from LKR 132 to 162 against the US dollar—a devaluation of 23%.

2015

In 2015, the NMRA enforced a unilateral price freeze for all pharmaceuticals.

2016

The prices of 48 essential drugs were reduced to provide greater accessibility to patients. Losses incurred by the industry (retailers and distributors) due to the slash in prices were reimbursed by pharmaceutical importers. The prices of 272 drugs from various brands were also reduced. Most of the medicines included those treating chronic illnesses that require long-term treatment.

2017

Given that the LKR fell further from 148 to 155 for 1 USD, the price of the 48 essential molecules was increased by 5%. However, the relief received through the price increase was offset by the impact of annual inflation (7%) which led to a rise in the industry's operating costs, especially staffing, fuel and electricity.

2018

The MOH reduced the price of 25 medicines used to treat diabetes, respiratory disorders and other chronic diseases.

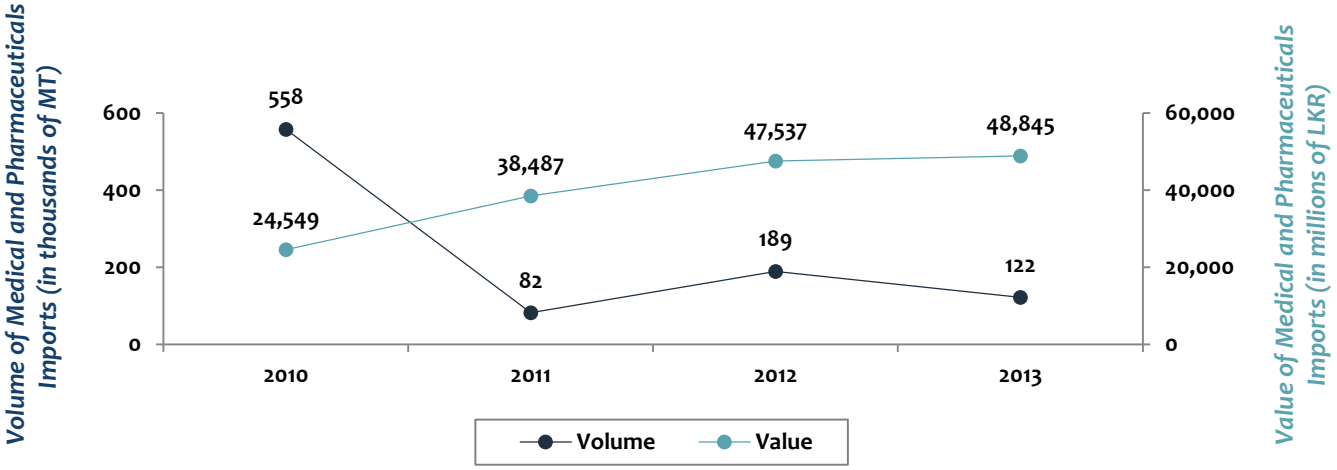
2019

The GOSL, in consultation with the NMRA, approved a 14.4% increase in the MRP of 60 price-controlled pharmaceutical molecules (including the 48 essential drugs). The price hike allows a retailer to mark-up 15% on price-controlled molecules and 17% on non-controlled molecules, alleviating part of the financial pressure on retailers.

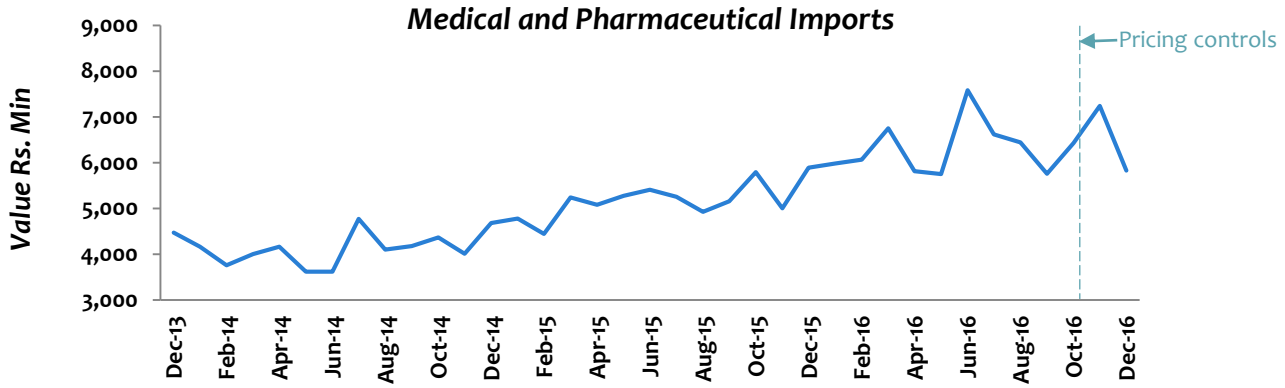
Source: Sri Lanka's success: ensuring affordable essential medicines for all, WHO, 2016; Pharma Chamber welcomes drug price revision, Adadereanabiz.lk, May 2019; Pharma industry's issue with authorities, Sunday Times, Sep 2018.

Impact of Price Controls

Before the price controls were enacted in 2016, the volume of pharmaceuticals imported declined over the years whilst the value continued to rise, indicating the shift towards more expensive drugs. This trend created the need for price controls.



- **Impact on cost:** The price controls enforced in October 2016 on the 48 molecules was expected to result in:
  - An overall price reduction of ~40%–50%
  - Total cost reduction of ~LKR 4bn.
- **Drug selection for price controls** were based on their market share—any drug that commands a market share of 2% or more (by volume). The 48 drugs currently subject to the price ceiling are mainly the drugs identified by Prof. Senaka Bibile in the seventies, with a few additions for new formulas.
- **The median price** is set as the MRP for a particular drug.
- **Impact on volumes:** The assessment below was done soon after the price control was imposed in Oct. 2016, and shows a sharp decline in volume during the month of December 2016.

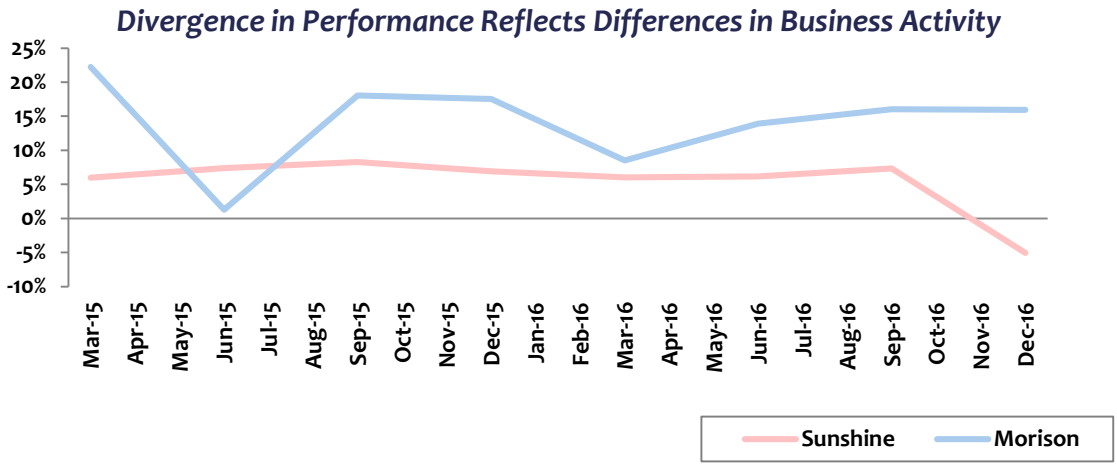


Source: Price Controls in SL, Advocata Institute, Mar. 2018; Economic and Social Statistics of Sri Lanka, CBSL, 2019.

Impact of Price Controls on Suppliers

Impact of price controls on importers/distributors

An analysis of the financial performance of the healthcare segments of Sunshine Holdings, CIC Holdings and JL Morison, post-implementation of price controls, revealed mixed performances: Sunshine experienced a sharp decline in profits (loss-making) while CIC and JL Morison witnessed continued steady profits during the last quarter of 2016. This mismatch in performance can be attributed to the fact that Sunshine was solely an importer, while CIC and JL Morison supplied through their local manufacturing divisions as well.



As seen below, there has been a relatively high impact on the prices of certain drugs, with some imported drugs requiring price changes of as much as 85%.

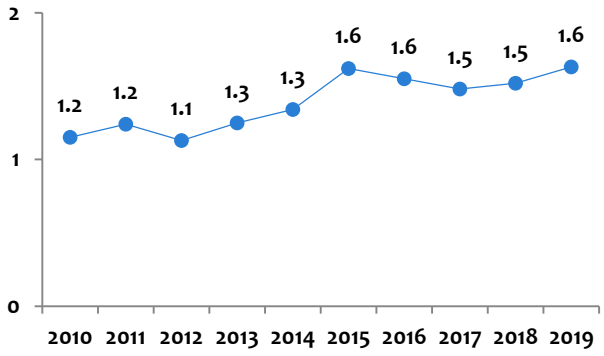
Drug	Sunshine Healthcare Lanka Ltd.	Emerchemie NB (Ceylon) Ltd.	Hemas Pharmaceuticals (PVT.) Ltd.	George Steuart Health (PVT) Ltd	CIC Holdings PLC	Akbar Pharmaceuticals (PVT) Ltd.	A Baur & Co. (PVT.) Ltd.	Maximum Retail Price (MRP)
Amlodipne 5 mg	4.59	15.07	13.08	1.21	10.44	16.33		15.3
Atorvastatin 10mg	311	20.82	21.11	15.25	14.92		8.11	11.15
Atorvastatin 20mg	5.29	29.82	33.64	22.03	25.28	2.65	14.2	17.6
Levofloxacin 250mg	26.45	20.53	25		21.87	21.64		40
Cefuroxime 250mg	49.45	69.98	35.85		47.2			45.5
Losartan K 50mg + HCT 12.5mg combined	12.59	19.99	21.72	6.45	15.74		63.73	19.45
Losartan Potassium 25 mg	2.3	11.11	10.16		8.07		4.06	7.35
Losartan Potassium 50 mg	3.97	16.62	6.42	12.08	14.03	15.93	65.55	10.3
Metformin 500mg	2.3	5.66	3.75	2.3	3.28	6.9		3.95
Pantoprazole 20mg	13.8	22.17	15.4	3.45	23.87			17
Pantoprazole 40mg	23.46	31.63	24.3	15.02	24.87			28
Rosuvastatin 10mg	37	36.92	39.88	17.25	31.83	10.35	19.52	37
Cefuroxtme 500mg	83.95	73.26	71.83		88.68			72.6
Ciprofloxacin 250mg	5.7	4.2			5.42			5.75
Clarithromycin 250mg	119.83	88.84	55.82	21.85	36.79		28.18	36.5
Clarithromycin 500mg	219.65	133.86	79.34	40.25	68.92		75.4	74
Levofloxacin 500m	12.08	42.92	47.13	13.8	52.03	39.64		24.2

Source: Price Controls in SL, Advocata Institute, March 2018; JLM Annual report, 2016; Sunshine Holdings Annual report, 2016.

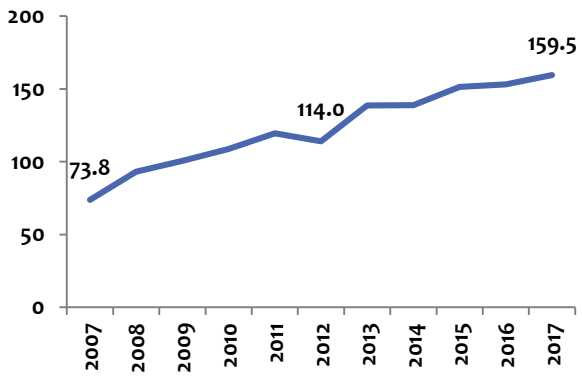
Public Expenditure on Medicines

The allocation of government budget for purchase of medicines is inadequate, at just under a quarter of the overall health budget. There has also been very little variance in healthcare expenditure as a percentage of GDP over the past decade, even though SL has been elevated to middle income status.

Sri Lanka Total Health Expenditure, 2010–2019 (as a % of GDP)

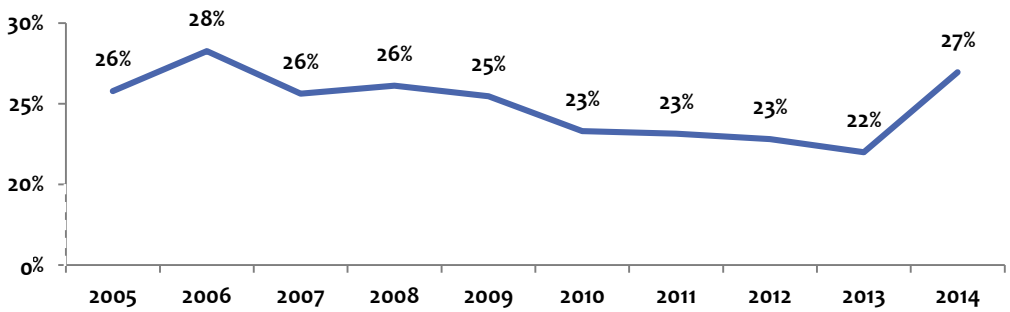


Sri Lanka CHE per capita, 2007–2017 (in current USD)



- In 2019, the Sri Lankan Government spent 23% of its healthcare budget (LKR54bn of the total LKR 235bn) on medicines.
- According to the WHO, in years prior to 2015, close to a third of the health budget was spent on medicines, but this has now been reduced to a quarter:
  - Of the LKR 235bn spend incurred on healthcare by the MoH and the Provincial Councils, LKR 201bn was on recurrent expenditure and LKR 34bn was on capital expenditure.
  - The provision of drugs and pharmaceuticals is the major component of recurrent expenditure and amounted to LKR 54bn in 2019.
  - This was an increase of 24.6 percent, compared to 2018, due to the settlement of outstanding bills of the previous years.

Govt. Spending on Medicines as Share of Total Healthcare Cost



Source: SL Health Accounts, 1990-2016, IHP, April 2018; Sri Lanka fiscal cash crunch hits medical suppliers, Economy Next, Feb. 2020; SL Budget 2019 – Health, Sri Lanka Guardian, Mar. 2019; Medicines in health care delivery, Medical Supplies Division and the Drug Regulatory Authority, facilitated by WHO/SEARO, Jan 2016; Sri Lanka Mirror, Feb 2019.

Current Role of the Regulator

- 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.

Objectives of the NMRA:

- To ensure that all pharmaceuticals available in Sri Lanka are of safe, efficacious and acceptable quality.
- To ensure uninterrupted availability of CDDs and rational usage.

Functions of the NMRA :

- Regulation of 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.
- Regulation of drug prices if required through price controls.
- Regulation of clinical trials.
- Monitoring of suspected adverse drug reactions.
- Conducting quality checks on samples and recalling CDDs 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.

Source: NMRA website, accessed June 2020; Regulatory & Market Profile of SL, Pharmexcil, 2018.

2. Local Manufacturing & Import Substitution

Local Manufacturing

Manufacturers:

- Currently 20 manufacturers approved by the NMRA are in operation and ~5 new facilities are about to be commissioned or are currently being added on by local manufacturers.
- In the private sector, this segment is dominated by players such as Astron Limited, Akbar Pharmaceuticals (Lina Manufacturing), Emergen Life Sciences, and JL Morisons. SPMC is the only public manufacturer.
- Domestic production mainly entails the manufacture of generic drugs. Most Sri Lankan pharmaceutical manufacturers do not focus on Research & Development and the creation of original/innovative drugs.

Raw materials:

- Local manufacturers are 100 percent import-dependent for APIs.

Supplied to:

- Locally manufactured products are generally supplied to the public sector via SPC through open tenders, and buy-back deals, as well as to the private sector through distribution networks.

Products:

- There were 17 locally produced pharmaceutical products before the buy-back agreement. Currently, there are ~ 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.

Top Five Local Manufacturers in the Open Market
(by value of medicines sold in retail pharmacies, 2019)

Astron
Morison
SPMC
EMERGEN
Emerge Enrich Enliven
Lina
"QUALITY HEALTHCARE FOR ALL"

Source: SL targets pharmaceutical self-sufficiency with new production facility, Oxford Business Group, Mar 2018; Regulatory & Market Profile of SL, Pharmexcil, 2018; IMS data, accessed June 2020.

Local Manufacturer Capacity

Local manufacturers currently produce ~8.5bn 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.

- Several of the manufacturers that Stax interviewed for this study reported that their capacity is not fully utilized (between 40-80%), and that they are able to supply more. Some of these manufacturers are also already planning for capacity expansions with the intent of exporting or signing up for contract manufacturing.
- By the end of 2020, Sri Lanka's tablet capacity is expected to increase by another 5bn tablets per annum.
- A majority of current production is sold to the public sector through buy-back deals, with private markets accounting for a mere 5-10% of local manufacturer sales in most cases.

Dosage Forms	*Unit*	*Capacity (Installed) Unit in '000*	
		2018	*2025*
Tablets	Units	5,791,818	14,731,818
Capsules	Units	518,000	1,110,000
Oral Liquids	Liters	3,367	5,584
Ointments, Creams ,Gels & Balms	Kilograms	1,571	2,580
Dry Powder Suspensions	Kilograms	1,230	4.800
Dry Powder Inhalations	Units	220,000	400,000
Dry Powder Injectables	Units	30,900	100,000
Breath Induced Device for OP Caps	Units	180	250
Metered Dose Inhalers (MDI)	Units	—	4,000
Nasal Spray	Units	100	200

Source: SL targets pharmaceutical self-sufficiency with new production facility, Oxford Business Group, 2018; Sri Lanka Pharma Market, MP Advisors, 2015; Problem with pharma industry is excessive profits, themorning.lk, Oct. 2018; Regulatory & Market Profile of SL, Pharmexcil, 2018; Pharmaceutical Manufacturing: The Next Thrust Industry in SL, SLPMA, April 2020; IMS data, accessed June 2020; Stax Primary Research, June 2020.

Local Manufacturers' Employee Size & Certifications

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)*	✓	✓	✓	

✓ *Compliant at Present* | ✓ *Proposed/ In Progress*

Note: One other company listed on the NMRA list of approved manufacturers (M.W.L. de Silva & Co.) does not have a website and could not be reached for a primary interview. It is not included in the above table nor in the manufacturer profiles in the appendices section of this report.

Source: Company websites and press releases; Stax primary research, June 2020; NMRA.

Government Support for the Local Pharma Industry

The GOSL has already put in place several key initiatives and policies to support local manufacturers.

1. **A public procurement system favoring local producers:**

   Approximately 24% of public sector pharmaceutical purchases are from local manufacturers, mainly through buy-back deals and tenders. There are several local manufacturers who sell 100% of their product to the state sector.

   – **SPMC buy-back deals:** The State Pharmaceutical Manufacturing Corporation, the state-run drug manufacturer, has signed 38 deals for local drug production to be bought back for 15 years by the government hospital system through guaranteed long-term deals. SPMC will supply drug formulations and monitor the companies.

   – **Non-SPMC deals:** A further 18 companies will produce drugs independently without SPMC involvement, and they have been given 10-year buy-back deals.

   – **Cost Plus Mark-up:** The government has agreed to buy the drugs back at a fixed price—cost plus 20 percent profit for the businesses, without competitive bidding. The cost will be based on raw material imported, labor and other costs, and they will be submitted to the government every six months.

   – **Regulation:** Local firms are monitored closely by the NMRA through scheduled as well as spot checks.

2. **Relief on raw material taxes:**

   – Efforts made by SLPMA recently (May 2020) helped receive tax exemption from the government on the PAL for importation of raw materials and packing materials for manufacture of pharmaceuticals.

3. **Legal provision for import restriction of drugs produced locally:**

   – The NMRA Act of March 2015 makes provision for authorities to restrict the import of products that are sufficiently supplied by local manufacturers. At the time, authorities intended to leverage the bill to reduce the types of medicines imported into Sri Lanka from ~10,000 to 500.

The government goal in 2018 was to meet 60% of the domestic demand for pharmaceutical products through locally made drugs by 2020. A currently realistic revised goal could be to change the balance from 15:85 to 30:70 in 1-2 years.

Source: Regulatory & Market Profile of SL, Pharmexcil, 2018; Annual Report 2019, Ministry of Finance; Sri Lanka generic drug producers eye 60-pct of state pharma budget, Economynext, Jan. 2018; Pharma sector needs a level playing field-Astron MD, Sunday Observer, Sep. 2019.

Government Support for the Local Pharma Industry Cont'd

4. Legal provision for doctors and pharmacists to make patients aware of generic options:

The National Medicine Drug, Devices & Cosmetic Authority Bill necessitates that doctors prescribe medicines according to their international non-proprietary (generic) name. The doctor may write a recommended brand name in addition to the generic. 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. While these may not always be put into practice, the legal framework is the first step to allowing a somewhat level playing field for local manufacturers to compete against branded drugs.

> **56.** (1) Every Medical Practitioner, Dentist or Veterinary Surgeon shall write the generic name of the medicine in every prescription issued by him.
>
> **56.** (5) The Pharmacist shall inform the customer of the range of generic medicines with or without brand names available in the Pharmacy and their prices enabling the customer to buy the medicine according to his choice.
>
> —Excerpt from NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

5. Promotion of Ayurveda products:

- In addition to the investments in Western medicine, LKR 139mn has been invested in Indigenous Medicine in 2019. The Department of Ayurveda has made efforts to implement herbal plant cultivation projects in Polpithigama, Ravana Ella, Bogollagama and Alawwa, as medicinal plants/ herbs are the main ingredient for Ayurvedic pharmaceuticals.
- A further LKR 135mn has been allocated for the development of the Haldummulla and Pattipola herbal gardens with the aim of developing the Ayurveda field.
- Under the project "Traditional Medical Knowledge Conservation," 15 Audio-Visual Programs have been completed and ~1,800 data sheets have been computerized in order to preserve the knowledge of traditional Ayurvedic doctors.

6. Investments to meet skill requirements in the private sector:

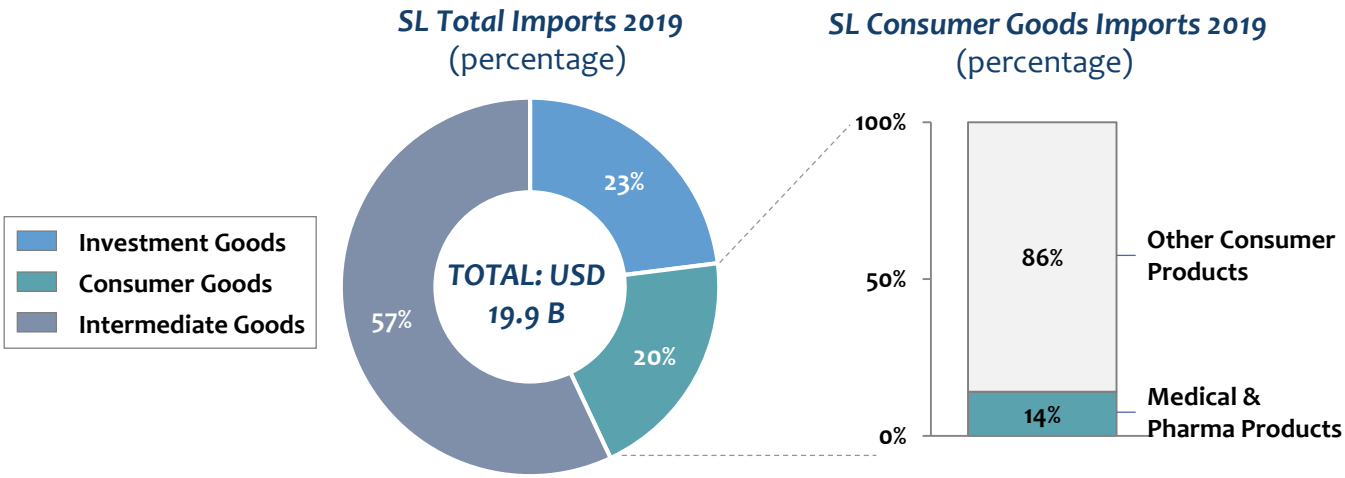
The 2019 government budget included plans to share costs for training nurses and pharmaceutical professionals by developing an apprenticeship model. During the apprenticeship, the government will provide a stipend (nurses LKR 10,000 and pharmaceutical professionals LKR 15,000) to support the salary of the trainee.

Source: Regulatory & Market Profile of SL, Pharmexcil, 2018; SL Budget 2019 – Health, Sri Lanka Guardian, March 2019; Medicines in health care delivery, Medical Supplies Division and the Drug Regulatory Authority, WHO/SEARO, Jan 2016.

Why Is SL Considering Import Substitution (IS)?

Over-reliance on imported pharmaceutical drugs has resulted in an extensive outflow of foreign currency, and uncertainty about the continuous supply of drugs in times when the global supply chain is disrupted.

- Sri Lanka currently relies on imports for the majority of its drugs, in both the private and public sector. A ratio of 85:15 of imports to local supply is increasingly seeming unsustainable, especially given its impact on foreign currency outflow and the rising levels of government debt.
- In 2019, ~20% of Sri Lanka's imports consisted of consumer goods. Medical and pharmaceutical products (including devices) accounted for ~14% (USD 553mn) of consumer goods.
- The emergence of the COVID-19 pandemic has raised several concerns, globally, around the continuity of essential supplies, especially due to export curbs by leading regional manufacturers.



After an assessment of local capacities and capabilities, an import ban could be imposed on 5-10 molecules based on:

- Essentiality: Within the list of essential drugs identified by NMRA
- Expenditure: Total spend on the drug
- Affordability: Cost of local drug vs. imports per unit

As for those drugs that are essential NCD treatments which account for high spend but are not made in SL, FDI needs to be sought to set up manufacturing facilities here:

- A favorable investment plan would need to be set up, addressing reasons for low investment by Big Pharma in SL in recent times
- JVs with local partners should be encouraged to facilitate technology transfer

Source: IMS; Stax primary research and analysis; June 2020; Annual Report, 2019, SL Ministry of Finance.

Essential Drugs Treating NCDs as a Starting Point for IS

SL spends millions of dollars on essential drugs for treating NCDs. Some of these are already being manufactured locally, although at a very small scale. The National Drugs and Therapeutic Committee of the MSD updates the EML and the hospital formulary regularly, based on previous consumption patterns.

"Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." *—Medical Supplies Division (MSD)*

Name of Essential Drug – Treatment	*Imported From*	*Local Manufacturer*	*Dosage form manufact-ured locally*	*Price in LKR (Standard Cost)*	*VEN**	*2019 retail pharmacy spend on all dosage forms (LKR)*	*Within top 20 spend in retail pharmacy market? – Rank*
AMOXICILLIN - Antibiotic	India, Bangladesh, Indonesia	Astron, SPMC	Capsules and Oral suspension	Cap: 1.3-4 Syrup: 96	E	1.5bn	YES - 1
METFORMIN – Diabetes mellitus type 2	France, Indonesia, India, Pakistan, Bangladesh	Astron, Celogn, SPMC, CIC, Morison	Tablets	Tablet: 0.8-5	E	1.4bn	YES - 2
GLICLAZIDE -Diabetes mellitus type 2	India, France	CIC, Interpharm, SPMC, Astra Zeneca	Tablets	Tablet: 1.02-1.6	E	1.3bn	YES - 3
Zinc - Nutrient	Philippines, India	Astron, Gamma	Capsules	Tablet 18-33	E	1.2bn	YES-6
ATORVASTATIN - cardiovascular disease	India, Bangladesh, Pakistan, Germany	Astron, CIC, Celogen, SPMC, Morison	Tablets	Tablet: 1.0-1.84	E	0.9bn	YES- 8
Fluticasone - Steroids to treat nasal symptoms	India, Bangladesh, UK	Emergen	Capsules and Dry powder for inhalation caps	Tablet 4.8-8 Nasal 200-1500	E	0.8bn	YES- 9
Folic Acid - Vitamin B9	Australia, India, Thailand	Astron, Celogen, Morison	Tablets, Capsules and Syrup	Tablet 0.3 - 4 USP 250 BPCRS 450	E	0.7bn	YES - 11
PARACETAMOL – treat pain and fever	India	Diyatha, Glaxo, Morison, Astron	Oral solution, Oral suspension, Syrup, Tablet, Capsule	Tablet: 0.94-5 Syrup: 45 Supp: 32-50	E	0.6bn	YES - 13
Magnesium - Nutrient	Australia, India, Malaysia	Interpharm	Tablets	Tab: 12 Oral: Varies Inj: 147-482	E	0.5b	NO
Clopidogrel - cardiovascular disease	France, India, Bangladesh, Pakistan	Astron, CIC	Tablets	Tablet: 2.07	E	0.4b	NO

2020 Essential list of priority drugs to manage NCD at primary-level healthcare institutions

* VEN has been marked as Essential if at least if one dosage form of the molecule was listed as 'Essential.'

Source: Medical Supplies Division and the Drug Regulatory Authority, facilitated by WHO/SEARO, 2016; Approved list of Pharmaceutical items 2016/2017, MSD; National EML, Ministry of Health, 2013-2014; NMRA website, accessed June 2020; Price Controlled Drugs, the Gazette of the Democratic Socialist Republic of Sri Lanka, Ministry of Health, 2019; IMS data, 2019.

Estimating Reduced FX Outflow from IS—Methodology

Step 1: Identify top spend molecules

This includes molecules that recorded the highest sales (at consumer prices) based on data reported in IQVIA (IMS); i.e. sales made by ~96% of the A Grade retail pharmacies in the country (including Osu Sala sales in the open market). Molecular spend includes a detailed breakdown of sales of a particular drug identified by its INN and by all dosage types (tablets/ capsules/ syrups/ oral suspension etc., as applicable).

Assumptions/ Limitations:

1. IQVIA data covers ~45% of the overall market.
2. SPC sales in the open market account for~ 14% of its supply, of which ~4% is captured in the IQVIA data.
3. The molecular breakdown for the following are currently unavailable to Stax: SPC sales to the open market (other than what is reported on IQVIA), SPC sales to state hospitals, sales made by private hospitals and private practitioners.
4. The molecular breakdown for these segments has been assumed to be the same as across retail pharmacies for the purpose of this exercise.
5. SPC sales to government hospitals for 2019 is ~USD 240mn, accounting for ~40% of the overall market—constituting ~78% imports.

Step 2: Prioritize essential molecules

To prioritize molecules, Stax took into consideration the EML, based on the MSD revised list for essential medicines 2020.

Assumptions/ Limitations:

1. Essentiality of a molecule varies by its dosage and composition. If any of the dosage or compound forms of the molecule were considered essential, we have retained that molecule on our prioritized list:
    - For example: Paracetamol has been retained on the list as tablets and syrups are marked essential, although suppositories are non-essential.
2. Certain drugs that were among the top spend but not listed on the MSD EML in any dosage/form were excluded.
    - For example, Rosuvastatin accounts for LKR 1.2bn (~USD 6.7mn) in spend but was not on the MSD list, and hence has been excluded from this analysis.

Estimating Reduced FX Outflow from IS—Methodology Cont'd

Step 3: Shortlist the top essential drugs manufactured locally

Stax further identified the essential molecules that are already being manufactured in SL. This is based on data available on the NMRA website that lists local manufacturers with GMP certification, and the molecules being made by each of them.

Assumptions/ Limitations:

1. If any dosage or form of the shortlisted essential molecule is currently being manufactured in Sri Lanka, it has been included on the list.
2. This analysis does not assess import dosage type or compare to locally manufactured dosage types. For example: Overall spend on Amoxicillin has been taken into consideration although SL currently only manufactures certain dosage types (capsules and oral dosages), and the current spend includes other dosage forms as well (e.g., Amoxicillin injections).
3. The spend data includes all compounds that contain the molecule in consideration. Whilst SL may not have all molecules to make a particular compound in the short run, this exercise explores the possible FX outflow reduction that could be achieved even if one molecule is currently manufactured locally.
4. Out of the top 30 molecules accounting for high spend in retail pharmacies, there are 22 molecules manufactured locally. However, not all of them are essential, or some of the local brands are only sold to the state and not sold in retail pharmacies—there are only 12 locally manufactured, essential molecules sold in retail pharmacies. This analysis focuses on the top 10 (of these identified 12 molecules).

Step 4: Estimate import value of top 10 shortlisted molecules

Firstly, the sales value of locally manufactured drugs in retail pharmacies for the top molecules was subtracted. For the top 10 shortlisted molecules:

- Overall sales in retail pharmacies (imports +local) = USD 52mn
- Retail pharmacy sales (only local) = (USD 3.4mn)
- Retail pharmacy sales (only import) = USD 48.6mn

Step 5: Calculate net reduction of FX outflow

- As all APIs are imported, an average estimated percentage was discounted to account for FX outflow for procurement of APIs.
- Our primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

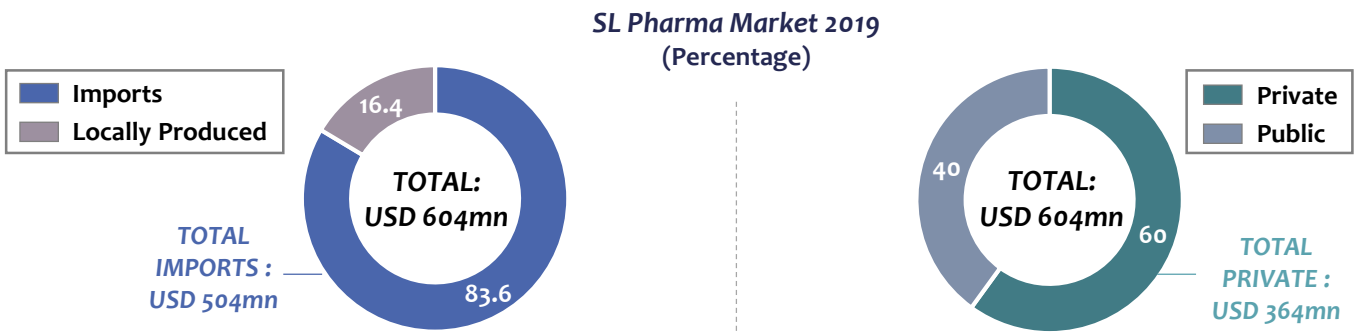
Estimating Reduced FX Outflow from IS—1. Defining the Market

Pharma Market: Public Sector

Description	LKR	USD [e]	Imports	Source/ Notes
DHS (SPC Sales to Public Hospitals)	42,959,659,808	239,998,099	78%	SPC Financial Statements 2019; Import % - based on past SPC Financial Statements
Public Market 2019	*42,959,659,808*	*239,998,099*		
Value of Imports	***33,688,478,657***	***188,203,791***		

Pharma Market: Private Sector (also referred to as the Open Market)

Description	LKR	USD [e]	Imports	Source/ Notes
Retail Pharmacy Sales (incl. SPC) [a]	48,592,737,802	271,467,809	96% [b]	Value -IQVIA 2019; Import % based on SLPMA presentation, April 2020
SPC – Other Open Market [c]	8,591,569,594	47,997,595	33% [b]	Value -SPC Financial Statement 2019; Import % based on past SPC Financial Statements
Pvt. Hospital Pharmacy Sales [d]	6,927,546,259	40,670,122	96%	2018/19 Hospital Annual Reports; Import % based on SLPMA presentation, April 2020
Pvt. Practitioners [d]	692,754,626	3,870,138	50%	Stocking Doc. Sales = 10% of Pvt. Hospital Sales (based on IHP market segmentation, 2015); Import % based on SLPMA presentation, April 2020
Total Private Market 2019	*64,804,608,281*	*364,005,664*		
Value of Imports	***56,647,148,548***	***316,464,517***		



a. IQVIA data includes sales of 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts only for ~4% of overall SPC sales in the open market). This figure excludes sales made by Private Practitioners and Private Hospitals.

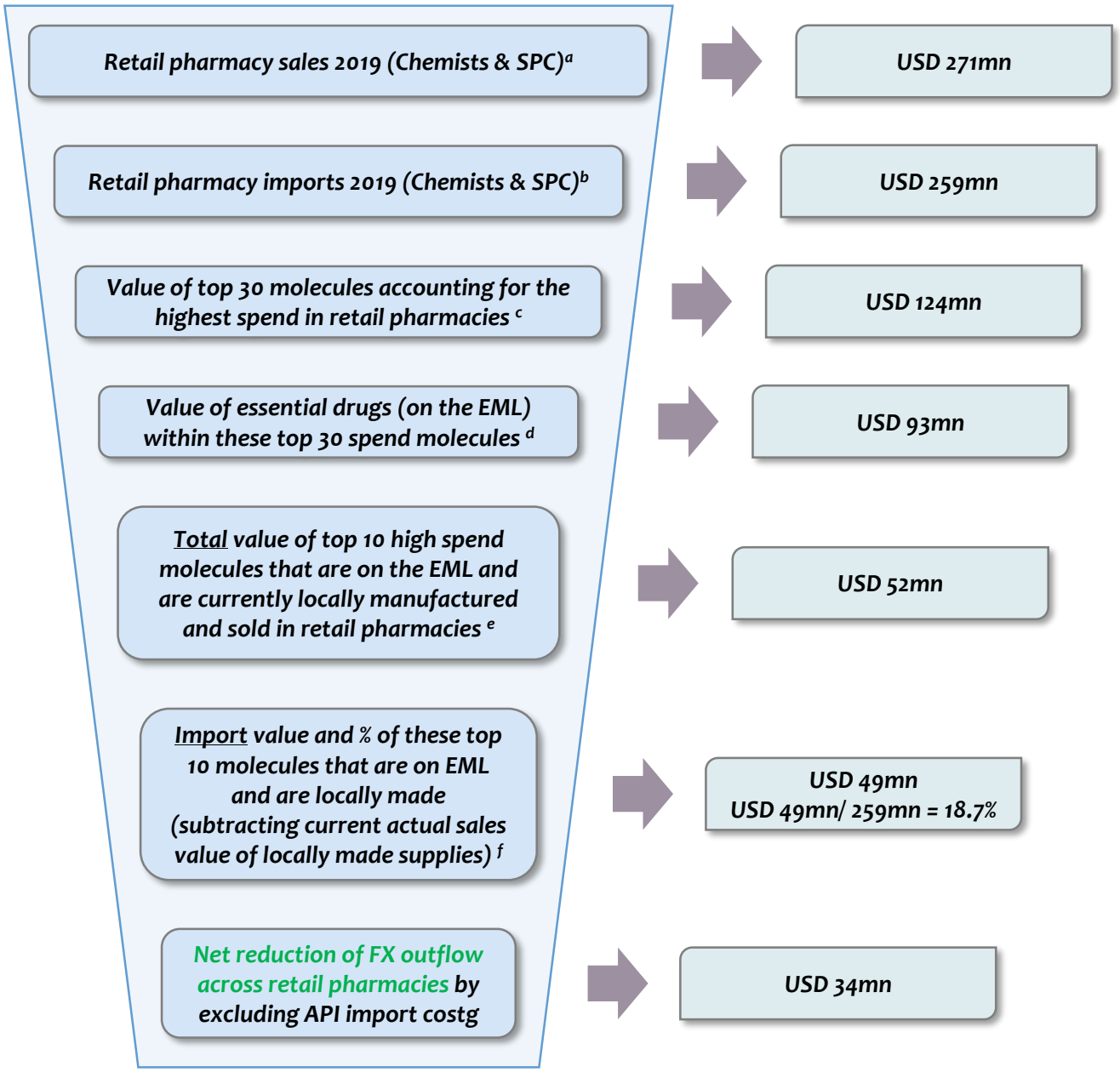
b. 96% of retail pharmacy sales and 33% of SPC sales are from import supplies – Refer Appendix 1 for detailed computation.

c. The rest of SPC sales on the open market (~96% of LKR 8.9bn) have been segmented separately to avoid the underestimation of market size.

d. This is a conservative figure that includes only the largest private hospitals providing sales data in their latest annual reports. Being derived from this figure, the value for stocking doctors is also a conservative figure.

e. Avg. 2018 XR: 1 USD = LKR 162.5 ; Avg. 2019 XR: 1 USD = LKR 179

Estimating Reduced FX Outflow from IS—2. Prioritizing the Top Spend and Essential Molecules *



* Avg. 2019 XR used across this estimation is: 1 USD = LKR 179

[a] The molecular level analysis includes only sales recorded on IQVIA (~45% of the overall pharma market), given that a molecular breakdown for other sales channels was not available to Stax. IQVIA data includes sales in 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts for ~4% of overall SPC sales in the open market). This figure excludes sales made by Private Practitioners and Private Hospitals.

[b] 96% of retail pharmacy sales and 33% of SPC sales are from import supplies – Refer Appendix 1 for detailed computation.

[c] Top 30 molecules were identified by sorting IQVIA data to prioritize **high spend, locally made molecules**, eliminating any duplication from other molecules not made locally/ low spend molecules that are made locally. Locally manufactured molecules were identified based on listings on the NMRA website, and then cross-checked on IQVIA to ascertain if it is supplied in the open market.

[d] Assessed based on the MSD revised list for essential medicines (EML) 2020. Of the top 30 molecules on the EML that are sold at retail pharmacies, 12 are made locally.

[e] Amoxicillin, Metformin, Gliclazide, Zinc, Atorvastatin, Fluticasone, Folic Acid, Paracetamol, Magnesium and Clopidogrel were shortlisted as the top 10 molecules.

[f] Sales value of local brands for the top 10 molecules have been deducted to derive import value.

[g] Stax primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

Estimating Reduced FX Outflow from IS—3. Applying Across Segments

- The initial percentage of the top 10 molecules, which are on the EML and also made locally, was computed based on data from IQVIA for retail pharmacies, and then applied across all other segments, given that a molecular breakdown for other channels was not available to Stax.
- This application across segments assumes that the molecular breakdown of medicines in high demand at retail pharmacies is similar across segments.

Factors	Private Sector				Public Sector (DHS)	Total Market
	Retail Pharmacies [f]	SPC (excl. sales on IQVIA) [g]	Private Hospitals	Private Practitioners		
Total sales 2019 (USD)[a]*	271mn	48mn	41mn	4mn	240mn	**604mn**
Import percentage [b]	96%	33%	96%	50%	78%	**83.6%**
*Total import value 2019 (USD)**	259mn	16mn	39mn	2mn	188mn	**504mn**
Top 10 molecules' overall value (USD)[c]*	52mn	9mn	8mn	1mn	46mn	**116mn**
% of 10 molecules that are on EML+ locally made	18.7%	18.7%	18.7%	18.7%	18.7%	18.7%
*Top 10 molecules' import value (USD)*d*	49mn	3mn	7mn	1mn	35mn	**95mn**
Discount API value [e]	30%	30%	30%	30%	30%	**30%**
Net reduction in FX outflow (USD)*	**34mn**	**2mn**	**5mn**	**0.7mn**	**25mn**	**66mn**

***** Avg. 2019 XR: 1 USD = LKR 179

[a] Overall market size is a conservative estimate. Refer Appendix 1 for detailed market sizing methodology.

[b] Refer appendix 1 for detailed computation of import share.

[c] Top 10 molecules were identified by sorting IQVIA data to prioritize **high spend, locally made molecules**, eliminating any duplication from other molecules not made locally/ low spend molecules that are made locally. Locally manufactured molecules were identified based on listings on the NMRA website, and then cross-checked on IQVIA to ascertain if it is supplied in the open market. Only medicines listed on the MSD revised list for essential medicines (EML) 2020 and sold at retail pharmacies were included among the shortlisted molecules. Amoxicillin, Metformin, Gliclazide, Zinc, Atorvastatin, Fluticasone, Folic Acid, Paracetamol, Magnesium and Clopidogrel were shortlisted as the top 10 molecules.

[d] Sales value of local brands in retail pharmacies for the top 10 molecules have been deducted to derive import value. The top 10 molecules' import value was computed as a percentage of the Retail Pharmacy import spend and then applied consistently on the respective import value of each segment.

[e] Stax primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

[f] Includes sales recorded on IQVIA, covering sales in 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts for ~4% of overall SPC sales in the open market).

[g] The rest of SPC sales on the open market (~96%) have been segmented separately to avoid the underestimation of market size.

[h] This is a conservative figure that includes only the largest private hospitals providing sales data in their latest annual reports. Being derived from this figure, the value for stocking doctors is also a conservative figure.

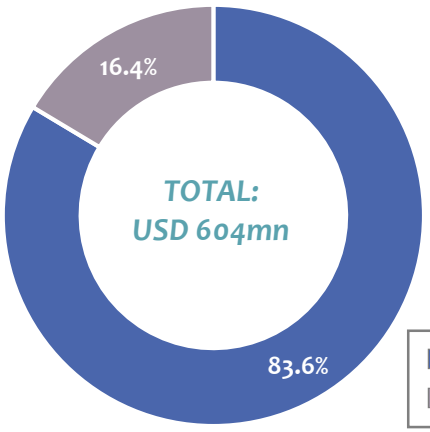
Estimating Reduced FX Outflow from IS—4. Estimating Possible Market Shift

Ratio of Imports to Locally Sourced Pharma—Current	85:15
Total Market Net Reduction of FX Outflow after excluding API import cost*	USD 66mn
Current Value of Local Manufacturing (604mn x 16.4%)	USD 99mn
Increased sales for local manufacturers (66mn/99mn)	66%
Ratio of Imports to Locally Sourced Pharma—Post-Complete IS**	73:27

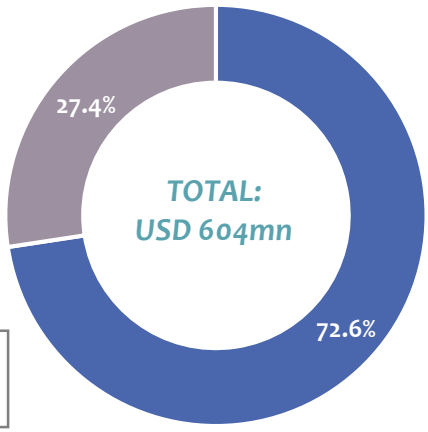
SL Pharma Market

Imports vs. Locally Made

Current Actual Market Share (2019)



Est. Market Share Post-Complete IS for Shortlisted Molecules



Imports
Locally Produced

*Stax primary interviews revealed that, on average, the API cost was between 20%-40% of a FPP's value. In rare cases, it could be as high as 70% (depending on the drug and where the API is imported from) but that has been regarded as an outlier, and an average of 30% has been discounted as the API component.

**Assuming that locally manufactured drugs will be sold at the same price as imported ones.

Key Takeaway #1: Import Rationalization not Substitution

- Stax discussed the possibility of IS with several specialist doctors and experts in the field. Their recommendation is that even if a drug is manufactured locally, there should not be reliance on a single supplier. However, many also agree that there are far too many brands in circulation for the same molecule for such a small market as SL.
- Many of the local manufacturers we interviewed also did not believe a complete ban was necessary, but that there should be better and more consistent regulation/enforcement on imports. While the NMRA has streamlined the industry better since 2015, they should be provided more resources in order to carry out more quality testing.
- The most logical takeaway, taking into account multiple stakeholder views, is the following:
  - ❖ Identify the top (by both volume and value), essential molecules sold in SL, and manufactured locally, across the public and private sectors. For those molecules, encourage more than one local manufacturer to supply the market (if that is not already the case).
  - ❖ In total, for any molecule, have no more than 5-6 brands coming in to the market:
    1. The original, patented drug (1)
    2. Two generics by local manufacturers (3)
    3. Two to three proven quality imported generics (5-6).
  - ❖ The logic for such rationalization is that with a lower number of suppliers to monitor, the NMRA will not be as over-burdened and will have the resources to carry out more consistent checks on importers as well as local manufacturers.

"The country shouldn't rely 100% on any one supplier for a drug. But we also don't need the high number of brands that are in the market today. About 5-6 brands for one drug are more than enough—the original and 4-5 others of varying prices. "

—Senior Council Members, Sri Lanka Heart Association

"A complete ban on [pharma] imports is very bad. Malaysia's public sector effectively did this for most molecules and it encouraged inefficiency."

—Dr. Ravi Rannan-Eliya, Director, Institute for Health Policy

"There shouldn't be an arbitrary import ban without careful study or assessment. In the end, everyone should be on the side of the patient. More emphasis should be on building the ecosystem needed for exports. Developing talent, strengthening the regulator, focusing on ancillary industries like packaging – these are all going to be crucial to grow exports."

—Director, Local Pharma Manufacturing Firm

Source: Stax Primary Research and Analysis, June-July 2020.

For Example, the Supply of Metformin Could Be Rationalized

N.B. *The following is an* ***illustrative case*** *made solely by an objective examination of the numbers available, and not in terms of molecular analysis.* ***Stax does not recommend that any drugs be discontinued without the consultation of relevant specialists in the field.***

With nearly 1 in 5 adults in the Western Province reported to be suffering from diabetes, medicines treating this NCD are in high demand. A quick analysis of the basic drug prescribed for diabetics, metformin, shows that SL has 52 suppliers registered with the NMRA, including 4 local manufacturers.

Metformin Suppliers in SL by Country of Manufacture

Country	# of Suppliers
INDIA	38
SRI LANKA	4
BANGLADESH	4
MALAYSIA	2
FRANCE	1
GERMANY	1
INDONESIA	1
PAKISTAN	1
Total	**52**

- The question can be raised as to why this many suppliers are needed, if they are all producing the same generic with no major changes in molecular properties, and given that Sri Lanka is such a small market to supply (even with high diabetes prevalence).
- While having many competitors is generally favorable in a free market to keep prices competitive, in this case there cannot be much of an advantage—as a price ceiling is imposed by the GOSL on metformin.

Local Manufacturers of Metformin

Astron

CELOGEN LANKA

SPMC

CIC Nurturing Life

Select Importers of Metformin

Emerchemie NB helping add life to years

HEMAS PHARMACEUTICALS

MARKSS

sunshine

Morison

Access

Source: NMRA website, accessed June 2020; Diabetes Association of Sri Lanka website, accessed June 2020; Province and ethnic specific prevalence of diabetes among Sri Lankan adults, Sri Lanka Journal of Diabetes Endocrinology and Metabolism, 2011.

Quick Guide to Potential Rationalization

1. Identify high-demand medicines that are both locally produced and being imported

2. Prioritize the drugs considered essential (considered as needing to be available in reasonable quantities at all times)

3a. Of these, identify which medicines account for the highest spend/foreign currency outflow

3b. Of these, identify which medicines account for the highest consumption/volume

4. For the top 10-15 drugs chosen, based on both a combination of value and volume, estimate the totality of demand – both from the public and private sector

5. Consult with doctors and representative sample of patients on possible adverse implications due to any ban of certain brands

6. Identify which of these are manufactured locally and assess if local manufacturers have the capacity to increase production. Even post-normalization of the economy, a multi-faceted evaluation should be done covering: capacity of local manufacturers, quality assurance capacities of labs, technological and financial requirements, raw material and skill availability, plus adequacy of storage and logistics capabilities

7. Attract foreign investment to inject further capital to local industry and increase capacity as well as portfolio breadth of drugs made locally

8. Rationalize imports of drugs where there are over 6-7 types of generics available in the market already **OR** discourage some imports through the levy of taxes and duties

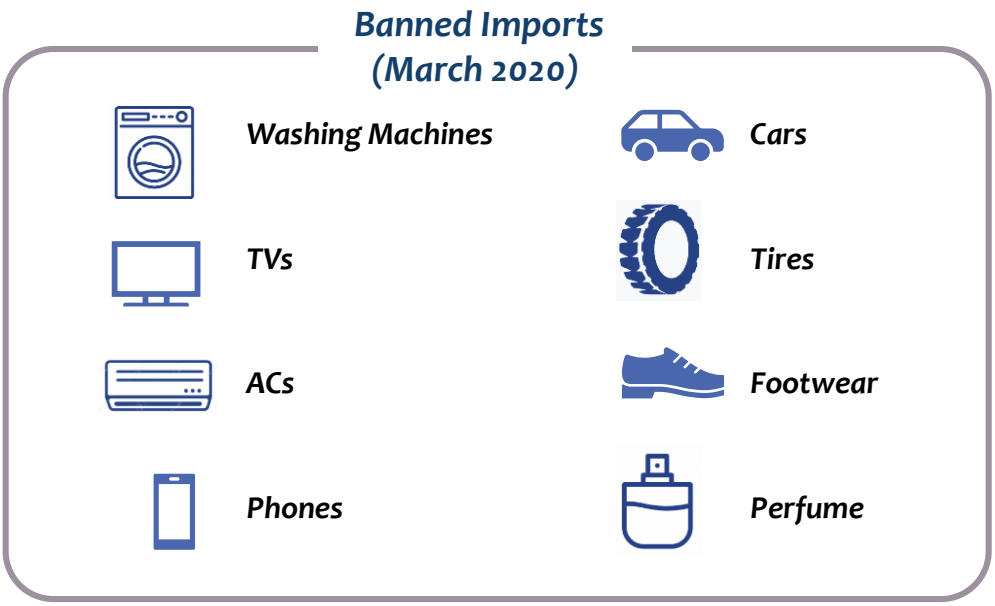
9. Create further awareness about locally manufactured products among doctors, colleges and other medical bodies, and the general public

10. Integrate import rationalization policies into clear, consistent strategy plan for the local pharmaceutical industry which, among other initiatives, encourages backward and forward integration where possible, positions SL to attract further FDI, and makes provision for investing into talent development within the industry

Import Controls and Implications for the Economy

Are import controls advisable? Will they save the LKR from falling further?

- Many governments across the world have announced drastic economic measures in the light of COVID-19. In March 2020, the GOSL announced import controls on certain goods using a provision of Sri Lanka's Banking Act. Banks were instructed by the CBSL not to help customers to import any of the 'non-essential' controlled goods either through letters of credit (LCs) or documents against acceptance or payment (DA/DP).
- This was implemented as a measure to save FX and bring the import bill down, but there is very little empirical evidence supporting the defense of a currency through import controls.
- Further, imposing import controls to defend the currency may send a wrong signal to foreign investors at a time when investments are needed the most. Similar measures in the past have led to the rapid deterioration of the currency and reserves being used to defend the soft peg.



A currency preservation measure that works better is the hard peg.

- Hard peg is fixing a currency to a precious metal such as gold (gold standard) or a stable currency (like the US dollar), which can be managed by a currency board.
- SL currently runs a soft peg where money can be printed without being backed by hard currency. Currency boards impose monetary and, ultimately, fiscal discipline.
- It is indicated that the CBSL has printed ~LKR 100bn between 13th and 24th March 2020, and this will be the primary contributor to the further depreciation of the currency.

Source: Sri Lanka halts imports of cars, electronics, perfumes, after soft-peg pressure, EconomyNext, March 2020; Promises of change on the horizon?, Advocata, June 2020; CBSL.

Stax

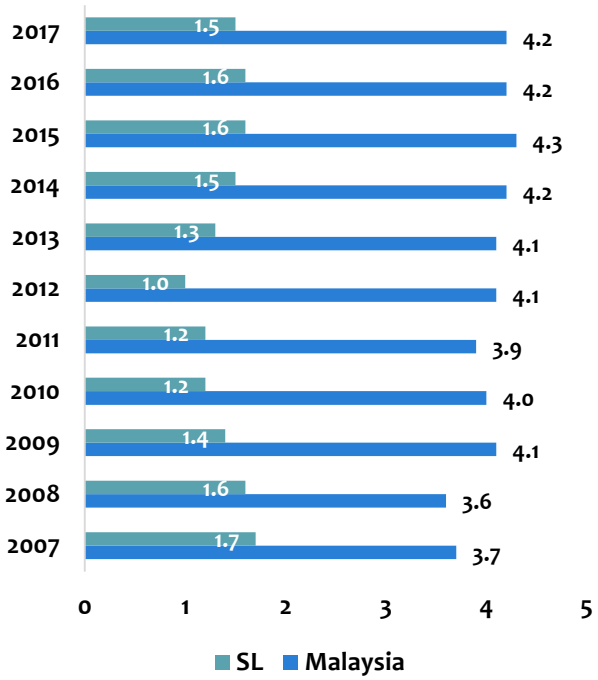
IS and Affordability for the Government

Malaysia Case Study

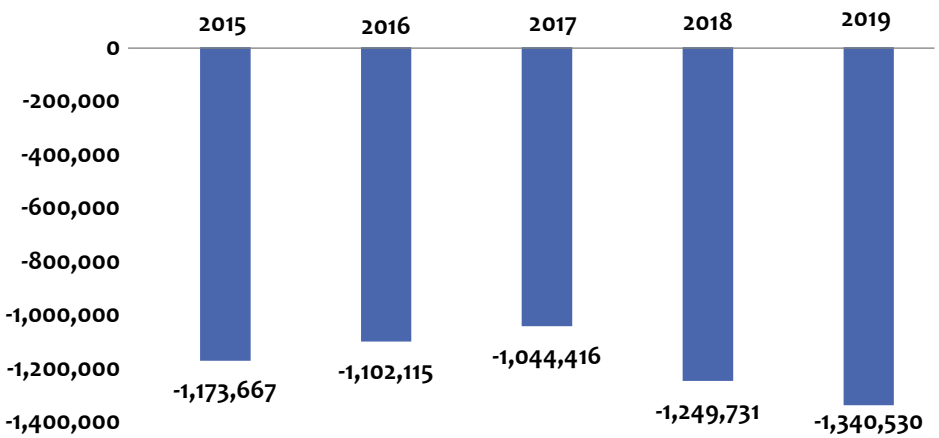
Population	GDP p.c.	CHE p.c.	Pharma Exports
~31M	$11,500	$384	$306M

- Malaysia is not much bigger than SL in terms of population, has far higher GDP, and higher THE.
- It has invested significantly into its local manufacturing sector and has adopted several protectionist policies, including IS.
- **A recent IHP study, commissioned by the Government of Malaysia, found that despite a similar system to SL, Malaysia was paying 2-3x more for medicines than Sri Lanka, largely due to protection of local producers for political reasons.**
- While Malaysia's local producers have created a niche for themselves in global pharma with Halal and herbal products, those exports are still relatively small. The country's trade balance of pharma products has not improved despite all the government support for the local industry, and the IHP study concluded that Malaysia had failed to create globally competitive producers, nullifying the infant industry rationale for protection.

Total Health Expenditure (THE) as a % of GDP 2007-2017



Malaysia Pharmaceutical Products Trade Balance 2015-2019 (in USD thousands)



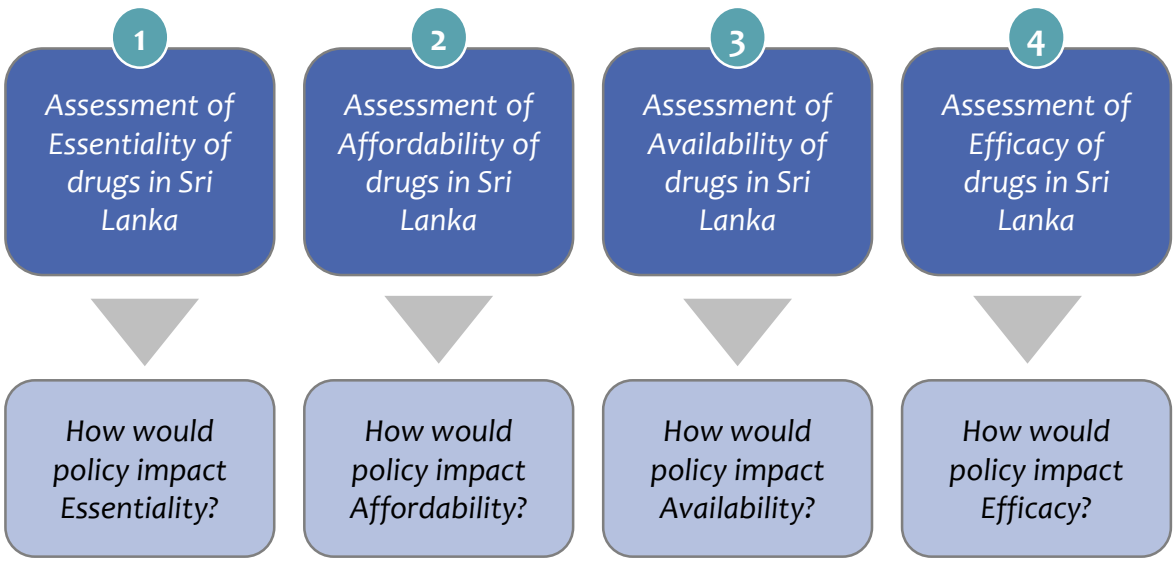
Source: World Bank Databank; Malaysia Competition Commission; Forthcoming Journal Publication on the Impact of Malaysia's Pharma Policies, Institute for Health Policy; Pharma Boardroom; ITC.; Developing the Local Pharmaceutical Industry Through NKEA Healthcare, Malaysia MOH, 2015; Malaysia Drug Market Update, Pacific Bridge Medical, 2017; Malaysia National Health Accounts 1997-2017, MOH Malaysia; Health Statistics 2005-2017, MOH Sri Lanka,.

3. Patient Interests

Substitution/Rationalization and Impact on Patient Welfare

It is essential to consider the welfare of patients and how a policy of import substitution or rationalization would affect them, before putting in place any such policies:

- Whilst foreign currency exposure is one of the primary concerns for the GOSL, restricting choice and banning imports of life-saving essential drugs is a far cry from the ban of perfumes or handloom textiles.
- As such, consulting with a representative sample of both doctors and patients is essential prior to instituting any policies of imports substitution or rationalization.



- In Sri Lanka, patient opinions are hardly ever sought, as doctor knowledge is always deferred to.
- However, care should be taken to understand any patient concerns regarding a switch in medicines too – particularly those being treated for NCDs (who will most likely be consuming these medicines for the rest of their lives).
- Globally, when taking a new drug, patients most frequently request information on adverse drug reactions (ADRs) and drug–drug interactions (DDIs).

Several global studies have indicated positive effects on health outcomes and treatment adherence when there is improved communication, patient involvement, and patient-HCP relationships.

Source: Stax Primary Research & Analysis, June 2020; How to meet patients' individual needs for drug information: A scoping review, Department of Clinical Pharmacology and Pharmacoepidemiology, University of Heidelberg, Germany, 2018.

Challenges to Ensuring Patient Interests

1. *Medication Errors:*

Medication errors are common and result in significant patient harm globally. Data on medication errors from Sri Lanka are limited to the findings from a few prescription surveys. Primary concerns cited on prescriptions include errors, illegibility, non-standard abbreviations, and potentially adverse drug interactions:

- A prescription survey conducted in Aluthgama and Kandy in 2012 reported poor legibility in close to 50% of prescriptions and 37% had used non-standard abbreviations.
- Another study on 1,000 prescriptions dispensed from the private sector in the NC Province in 2010 reported legibility in only 26%, with close to 65% prescriptions being legible only with effort and 9% being illegible. The same survey reported the presence of potential adverse drug interactions in 53% of the prescriptions. Moreover, incomplete, absent or incorrect details on administration route, dose, frequency and duration were seen in 94%, 70%, 34% and 23% prescriptions respectively. Error prone abbreviation use was 69%.
- Another study from 2016 analyzed 503 prescription errors recorded by trainee internal pharmacists in their portfolios. The most common errors were in the dose (42%), drug name (32%), and frequency of administration (28%).

A majority of medication errors are preventable. Improving medication literacy of patients, training health care staff better, and addressing system improvements—including establishing medication incident reporting—is needed.

2. *Systems not sufficiently patient-centric:*

- The supply-driven systems in Sri Lanka have resulted in healthcare becoming a commercial venture for most practitioners.
- The system needs to be more people-centered with a focus on prevention of diseases and holistic health promotion, rather than just the provision of drugs for an isolated observation.
- Adequate time being taken to conduct a thorough analysis of patient history and family disease patterns can improve prescription and treatment effectiveness.

3. *Unethical drug promotions:*

Unethical practices used by pharma sales reps from companies with deep pockets is an open secret in Sri Lanka. They remain a concern, as there are no disincentives for those currently benefiting from such practices.

Source: Country Cooperation Strategy, WHO, 2018; The SL Prescriber, SPC, Mar. 2018; Identity has started to divide us, Daily Mirror, Sep 2018; Stax primary research, June 2020.

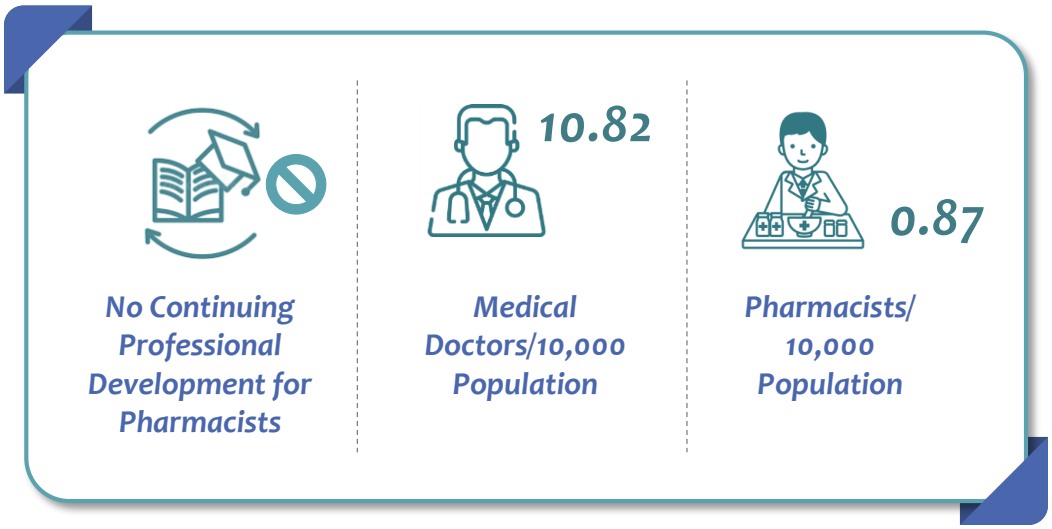
Dearth of Qualified Pharmacists

SL currently suffers from a dearth of qualified professionals in the pharmacy space—the country has more doctors than qualified pharmacists. The availability of more qualified Sri Lankan pharmacists, trained to deliver expanded professional services, could ensure quality use of medicines and minimize medication errors:

- Pharmacists are important members of the healthcare team caring for patients and play a major role in ensuring the judicious use of medicines.
- Global studies have demonstrated that expanded pharmacists' roles have had a significant positive cost-effective impact on the population's health.
- However, pharmacists are not yet an integral part of the multidisciplinary healthcare team in Sri Lanka, and their role is currently limited to drug dispensing, and providing limited medicine information to patients.
- Pharmacist-led healthcare services would need to optimize expertise and training in medicine management. This could gradually lead to pharmacists becoming an integral part of the multidisciplinary healthcare team.

There is a need for ongoing professional development, with high educational standards for pharmacists, in order to deliver expanded professional services:

- Currently there are over 15 diplomas and degrees available in the field of Pharmacology. However, there is no requirement to renew licensing after obtaining the initial qualification or many options for continuing education in the field.
- Improvements to the university curriculum and continuing professional education in Sri Lanka require further development to provide both the theoretical and practical knowledge required for patient-centric care.



Source: Annual Report, Finance Ministry of SL, 2019; Sri Lanka medical products profile 2019, WHO; The Need to Strengthen the Role of the Pharmacist in Sri Lanka, NCBI, June 2019; university and other educational institute websites; Stax Primary Research, June 2020.

Stax

Accessibility of Medicines Supply

Access is defined as, "Having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk."—*UNDP, Millennium Development Goals*

Key questions in evaluating accessibility of medicines

Availability 1

- Has the State allocated adequate funds to purchase all essential medicines?
- Is the private sector procuring and producing enough medicines to meet the demand in the country—in-patient and out-patient?
- Has the government invested adequately to increase local production and effect import substitution?

Affordability 2

- Are the drugs priced equitably so that it can be afforded by the public?
- Are prices of pharmaceutical drugs regulated?
- Are most of the drugs generic?
- Are there adequate local manufacturers making generics?
- Is there sufficient competition to provide options to public, applying downward pressure on prices?

Quality 3

- Is there a quality regulating body?
- How does quality control take place for locally manufactured drugs and for imported drugs?
- Are QC rejects replaced?

Source: UNDP; WHO.

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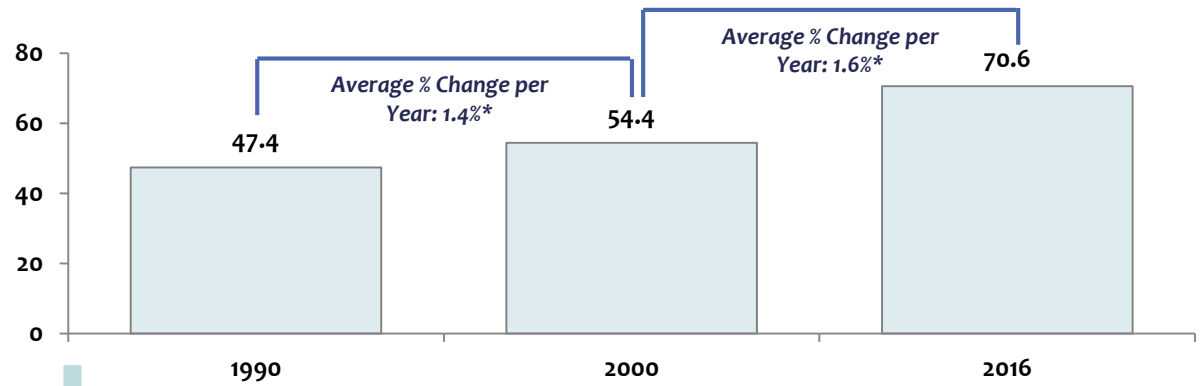
Accessibility Improvements

The Healthcare Access and Quality (HAQ) Index provides a summary measure for a given location. It is based on risk-standardized mortality rates or mortality-to-incidence ratios from causes that, in the presence of quality healthcare, should not result in death—also known as amenable mortality.

SL's HAQ Has Increased Significantly Over the Past Several Decades



*** The average rate of change was statistically significant for this time period**

Sri Lanka achieved a milestone in elimination of vertical transmission of HIV and congenital syphilis in 2019, which ensured the elimination of mother-to-child transmission of HIV and syphilis during pregnancy, childbirth, or breastfeeding.

Top 10 Countries on HAQ Index, 2015

Country	Score
Andorra	94.6
Iceland	93.6
Switzerland	91.8
Norway	90.5
Sweden	90.5
Australia	89.8
Finland	89.6
Spain	89.6
Netherlands	89.5
Luxembourg	89.3

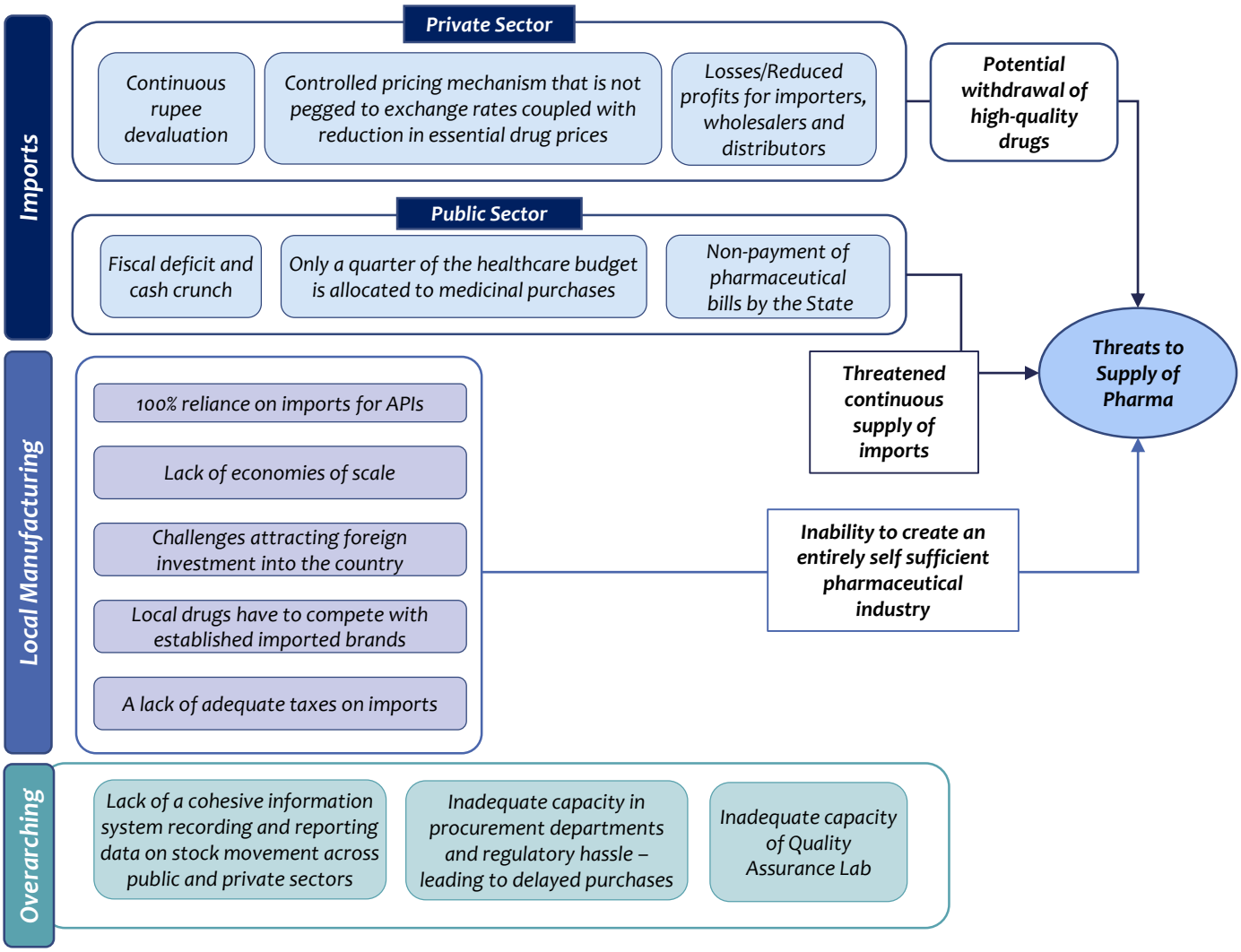
South Asia's HAQ, 2015

Rank	Location	Score
55	Maldives	75.5
64	**Sri Lanka**	**72.8**
131	Bhutan	52.7
135	Bangladesh	51.7
140	Nepal	50.8
163	India	44.8
n/a	South Asia	44.4
171	Pakistan	43.1
195	Afghanistan	32.5

Source: Health data IHME, 2017; Noncommunicable Diseases (NCD) Country Profiles, WHO, 2018.

Potential Threats to Market Supply

Macroeconomic and government policy issues that can threaten the continuous supply of high quality drugs to the industry



Importer view:

- The price control mechanism does not always allow for the import of high-quality original drugs, as it compresses margins.
- Import substitution policies will not work well until there is established production in the country to cater to current needs.

Local Manufacturer View:

- The imported brands have been established for years and with deep pockets they are able to do a lot more marketing, sometimes with unethical practices.
- Foreign drugs are price competitive given their economies of scale (mainly from India), but their quality often leaves much to be desired.

Source: Annual Report, Ministry of Finance, 2019; Reorganising Primary Health Care in SL, Ministry of Health, Nutrition and Indigenous Medicine Sri Lanka, Dec. 2017; Stax Primary Research, June 2020.

Affordability of Medicines

The public sector provides ~90% of in-patient care and ~50% of out-patient care to the public free of charge, with a specific focus on the provision of affordable generics.

Primary Health Care in Sri Lanka is provided free of charge:

- The GOSL Lanka provides free healthcare across the country through state hospitals, which are demarcated as the Primary health care provider.
- This forms a sound basis for providing universal health coverage and has been recognized internationally as a low cost model.

Generic medicines in the country have always been effectively priced and made affordable to the public:

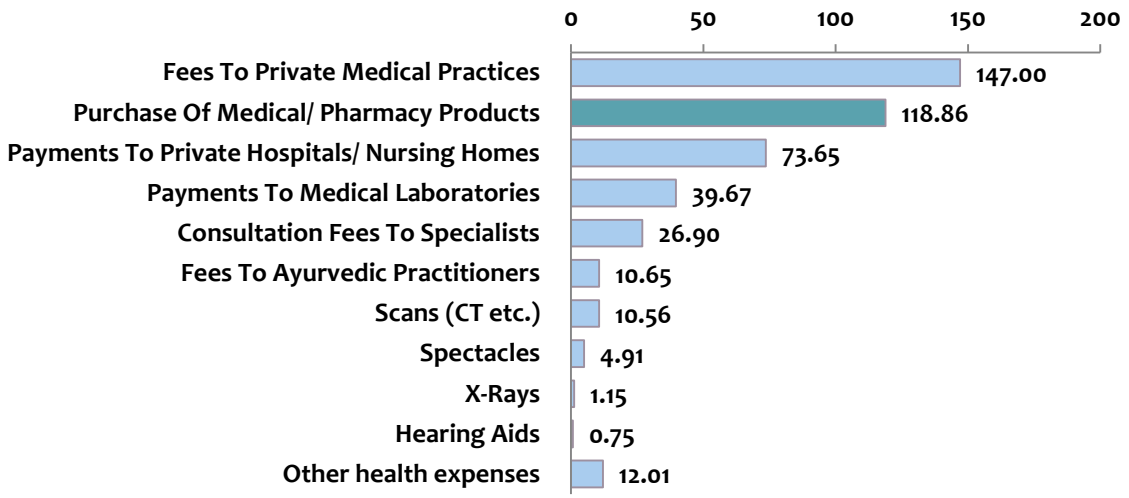
- A study conducted in 2011 on generic drug prices revealed that affordability of generics had always been less than one day's wage, making them affordable to patients in SL, especially the very poor.
- The last Household Survey in 2015/16 revealed that monthly expenditure on medical/pharmacy products per person was ~LKR 119.
- Even without price controls at that time, the minimal variation in prices was attributed to the SPC computing prices in the same manner as when a price control is in place.

Price controls further ensure affordability:

- Inflation, the rising cost of transportation and storage, as well as the depreciating Rupee resulted in higher costs of medicines since the abolition of pharmaceutical price controls in 2003.
- The prices of 48 essential drugs were reduced in 2016, and subject to a price ceiling, to provide greater accessibility to patients.

Average Monthly Spend Per Person On Health Expenses

Sri Lanka, 2015/16



Source: Reorganising Primary Health Care in SL, Ministry of Health, Nutrition and Indigenous Medicine Sri Lanka, Dec. 2017; Medicine prices, availability and affordability in SL, NCBI, Feb. 2011; Household Income & Expenditure Survey 2016, Dept. of Census and Statistics.

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Affordability and Income Levels

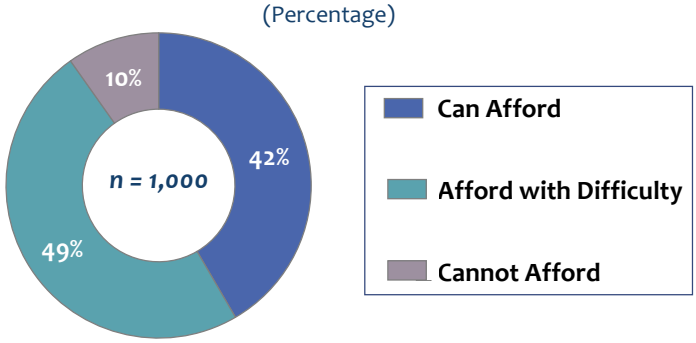
Rising income levels have accommodated a shift towards private out-patient services, but for poorer households, purchasing medicine from the private sector is often involuntary (i.e., only when medicines are unavailable in the public sector do they turn to retail pharmacies).

- The World Bank, in its 2019 country classification release, elevated Sri Lanka from a lower middle income country to an upper middle income country, based on GNI per capita surpassing the threshold of USD 3,996 . As at 1 July 2019, Sri Lanka's GNI was USD 4,020.
- Whilst the GOSL has focused on the provision of affordable generics to the public, the change in income levels is allowing consumers to seek private healthcare when possible. Greater inclination to use private out-patient services, combined with drug stock-outs in the public sector, has led to ~50% of overall OPD medicines and ~10% of hospitalized patients' drug needs being bought OOP.
- IHP survey data collected during the Presidential Election 2019 indicated that MOH medicines supply was the number one voter concern in health, and that most voters prefer increases in public supply whilst only a minority favor price regulation of medicines in retail.

An affordability survey conducted in 2018, by the MoH & WHO, reveals that a majority of the population can afford medicines from the private sector, although a large segment does so with difficulty (n=1,000):

- 41.6% said they can afford medicines in the private sector, 48.6% stated that they can afford 'with difficulty,' and 9.8% claimed that they could not afford private sector medicine at all.
- The pattern of affordability did not differ between males and females.
- Less than 2% of respondents had their spend on pharma reimbursed by insurance.

MOH & WHO Survey on Private Sector Pharma Affordability
(Percentage)



The poorest segments of the population still struggle to afford medicines:

- A 2018 study, based on the 2016 National Household Income and Expenditure Survey, estimated that the average monthly income of the households in the poorest 40% (first to fourth decile) was LKR 22,423 (LKR 747 per day).
- In this segment, money spent on purchasing medicines was 7%–8% of their daily income. Although this does not meet the WHO definition of 'catastrophic household expenditure' (OOPE is considered catastrophic if it exceeds 40% of a household's annual income), a chronic disease would certainly cause severe financial strain.

Source: World Bank Databank; Sri Lanka's elevation to upper middle income status, Financial Times, July 2019; Patient experiences of access to NCD medicines in Sri Lanka, Sage Pub., Sep. 2019; IHP Survey data, 2019; Increased out-of-pocket spending threatens universal health coverage in 'missing middle' countries, IHME, April 2019.

Availability of Medicines in Sri Lanka

Availability of essential drugs in the state sector is below the WHO standard of 80%, but several surveys reveal that key essential drugs are generally available with alternatives to dispense if out of stock.

1

Survey Year	Conducted by	Coverage
2018		Islandwide

- The study concluded that patient experiences in Sri Lanka showed good availability and access to NCD medicines.
- Approximately two-thirds (64.2%) of respondents had exclusively used government hospitals for NCD care during the past 5 years.
- Of the public sector users, a majority (58.3%) had all prescribed drugs available at the last visit to the state clinic, while 35.7% had some of the drugs available.

2

Survey Year	Conducted by	Coverage
2017		Islandwide

- Number of essential NCD medicines reported as generally available: 10 out of 10
- Number of essential NCD technologies reported as generally available: 6 out of 6

3

Survey Year	Conducted by	Coverage
2015		Galle Anuradhapura

- Availability of essential medicines in pharmacies: Over 90% in Government Osu Sala pharmacies and over 80% in private pharmacies.
- Availability of essential medicines in Hospitals: over 90% in teaching hospitals but 72-79% in lower level facilities, where some staff complained of stock-outs and where medicines normally reserved for higher level facilities were sometimes used.
- Number of currently used items out of stock was less than 5% in all facilities
- Despite 20-30% of unavailability, there were usually alternatives and over 90% of all prescribed medicines were dispensed.

Source: Patient experiences of access to NCD medicines in Sri Lanka, Sage Pub, Sep. 2019; Non-communicable Diseases (NCD) Country Profiles, WHO, 2018; Medicines in health care delivery, WHO/SEARO, Jan 2016; Availability of essential medicines in selected public, primary and secondary health care institutions of a rural Sri Lankan District –BMC Health services, 2017

Medicine Shortages

Drug shortages prevail even in 2020, although the situation has improved from the past. These shortages occur due to several factors:

1. **Lack of funds to purchase required drugs:** For example, in 2013, a severe shortage of medicinal drugs was reported because the Treasury failed to release funds to the SPC, which required ~LKR 10bn to purchase and import essential drugs to meet immediate needs.

2. **COVID-19:** During the current pandemic, the GMOA raised concerns over short supply of ~500 essential drugs, calling for measures to import from India urgently.

3. **Regulatory hassles:** In 2020, it was reported that the SPC failed to import drugs despite instructions given by the MOH.

4. **Other common reasons for stock outs:**

    i. The MSD quantification process is delayed,

    ii. The lead time is one year,

    iii. High value tenders go to cabinet for clearance.

Implications of State sector unavailability

- State sector drug availability plays a key role in contributing to OOPE. Healthcare costs in the private sector are generally totally borne by the patients through OOPE.
- A survey conducted in 2018 revealed that 75 respondents had switched from the public to private sector for their NCD follow-up care during the past 5 years, primarily due to issues relating to medicine availability—40.7% quoted this as the reason.

What has the government done so far to ensure availability of essential NCD drugs?

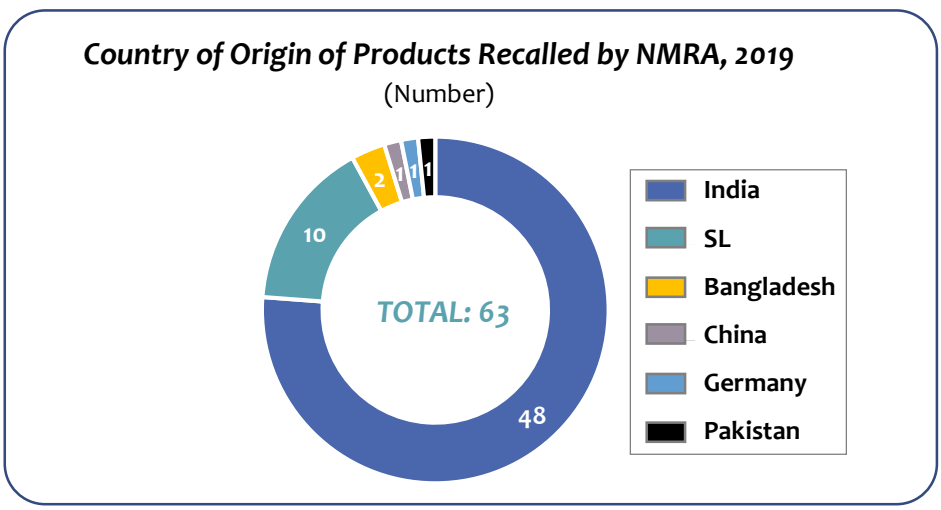
- With the prime objective of ensuring availability and access to medicines and thereby reducing the need of the patients to purchase medicines OOP, the MOH identified 16 NCD medicines and issued a circular (02-174/2013) in 2013 indicating them as a list of priority drugs—mandating for them to be available in primary healthcare institutions at all times.
- Thereafter, as a direct step to reduce OOPE on medicines, the government regulated the price of 48 commonly prescribed groups of medicines by setting a price ceiling through a notice by Extraordinary Gazette in October 2016 (revised in December 2017).

Source: Availability of essential medicines in selected public, primary and secondary health care institutions of a rural Sri Lankan District, BMC Health services, 2017; Severe shortage of drugs in the country, Daily Mirror, Apr. 2013; Shortage of pharmaceuticals: Govt. turns to India, The morning.lk, Apr. 2020.

Efficacy of Medicines in Sri Lanka

Efficacy of drugs needs to be determined by quality tests rather than patient perception or anecdotal evidence. However, there is very little by way of resources dedicated to testing or clinical trials.

- All stakeholders we interviewed for this report stated some concern about the quality of imports coming in to the country, especially from India. Doctors provided anecdotes of quality failures and low efficacy but there is no clinical trial data that can be provided for objective examination.
- With the large number of imports that come into the country, the NMRA currently does not have the capacity to monitor effectively for quality. Since 2015, only 38 foreign GMP inspections have been conducted. To provide some context on scale, there are currently 38 suppliers of Metformin alone, from India alone.
- Many drug quality problems are detected after they arrive at health facilities. Sometimes, all stock has been used up by the time a quality failure is detected.
- Replacement of quality-failed stock is considered a tedious procedure, especially if just a few items have been imported.
- Local manufacturers are reportedly tested more often for quality. One local manufacturer we interviewed stated that in 2019, the NMQAL checked 64 random samples of their products, averaging over 5 samples a month.
- A quick analysis of product recalls for 2019 listed on the NMRA website shows that India is indeed the major culprit in terms of quality failures, with over 75% of the products recalled being of Indian origin.
- However, it must be kept in mind that India does account for a larger share of SL's total pharma imports (~50%) than any other country.
- The 10 local products recalled were all from two manufacturers.
- All the foreign products, except one, were distributed by an authorized importer. There was no marketing authorization holder for the German product, which was supplied by MSD on a waiver of registration.



Source: ; Medicines in health care delivery, WHO/SEARO, Jan. 2016; NMRA website, accessed June 2020; Stax Primary Research, June 2020.

4. Global Pharmaceutical Market & Export Potential

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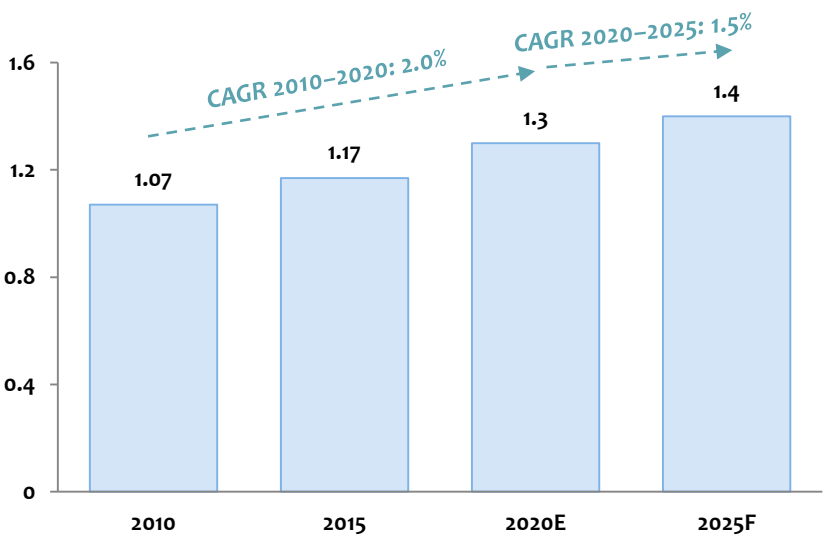
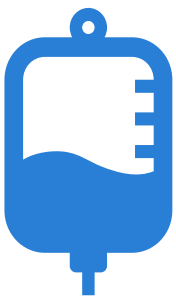
Global Pharma Manufacturing Snapshot

Global pharma manufacturing is a mature industry characterized by slow growth, but is one of the most profitable industries in the world. Just over a quarter of the industry's revenue in 2020 will come from the sale of generics.

Global Pharmaceuticals & Medicines Manufacturing Industry Revenue, 2010–2020
(In USD Trillions)



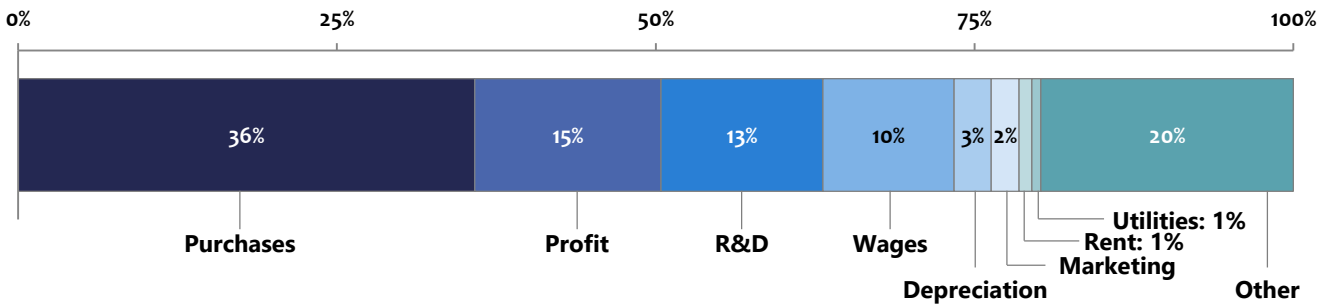
Generic Pharmaceuticals' Share of Global Industry Revenue (2020)



27.2%

Generics comprise 60%–65% of total pharmaceutical sales in lower- and middle-income countries

Average Industry Cost Structure, 2020
(Percentage of Revenue)



- **Purchases** includes the cost of APIs and the purchase of license agreements for contract manufacturers, which have been on the rise as these producers gain market share.
- **Wages** are estimated to remain stable with CMOs increasingly being used by the industry's major operators to better streamline the production of their brand-name drugs.
- **Other** primarily encompasses legal and administrative expenditures.

Source: IBIS World; IQVIA.

Global Industry Drivers

Demand from Emerging Markets

- Emerging markets, which include the BRIC and MINT economies, have been regarded as the 'promised land' for the global pharma industry for some time.
  - Pharmaceutical revenues from such markets are expected to grow by over 220% from 2010, to hit $490B by 2025.
  - With huge populations, increasing prosperity, and improving longevity, these markets have been very attractive for companies suffering from the stagnation of more advanced markets, patent expirations, and increased legislative & regulatory hurdles.

Rise in Chronic Ailments

- Chronic, non-communicable diseases are on the rise globally, primarily due to changes in lifestyle:
  - With a growing middle class, and increased urbanization, most societies are adopting more sedentary lifestyles, leading to rising obesity rates and high prevalence of diseases such as diabetes.
  - Across the globe, there is an increasing number of individuals who suffer from chronic ailments such as hypertension and mental health issues. These conditions have been a leading driver of growth in prescription drugs in the country.

Growth in the Ageing Population

- The world's population is aging rapidly with virtually every country experiencing growth in the number and proportion of older persons in their population:
  - The global population aged >60 years was 962M in 2017, more than twice as large as in 1980— 382M. This number is expected to double again by 2050, to ~2.1B.
  - With an aging population arises the need for more medical care. As a result, governments have enacted health programs such as Medicare, which allow seniors to be covered by insurance for medication.

Source: How emerging markets are driving the transformation of the pharmaceutical industry, pwc.ru, 2013; Key drivers of the UK pharmaceutical market, manufacturingchemist.com, July 2018; World Population Aging, un.org, 2017; Chronic diseases and conditions are on the rise, pwc.com.

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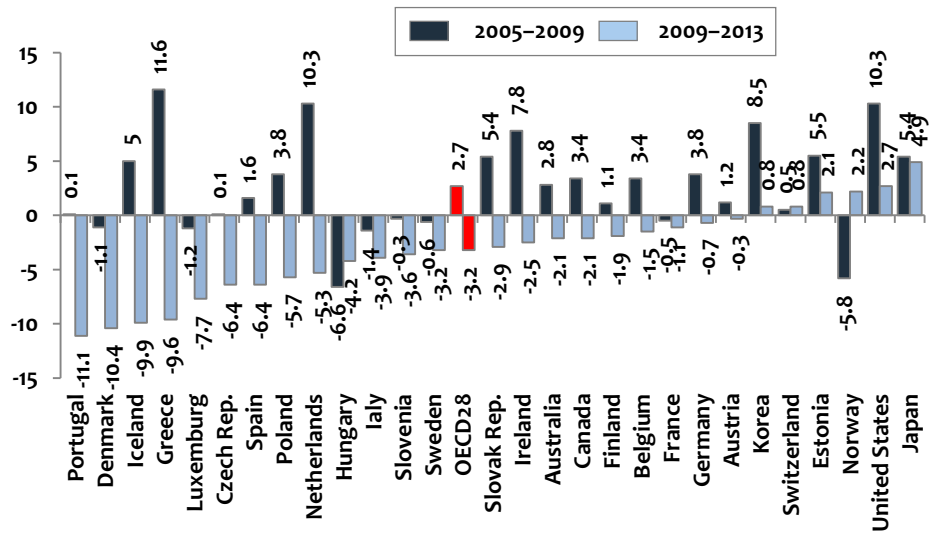
Trends— Widespread Global Adoption of Pharma Cost Controls

- Cost controls set by government reimbursement agencies have affected, to varying extents, the profitability and direction of pharma industry stakeholders.
- In free market economies, as evident in the US, an increasing portion of a consumer's budget is spent on pharmaceuticals.
- However, because pharma spending is influenced greatly by governmental decisions and associated budgets, the correlation between rising national income and pharma spend has been broken in a few key markets such as Europe.

Examples of Global Drug Cost Containment Policies

Policy Class	Specific Type of Action	Representative Countries Adopting Policy
Pricing Controls & Cuts	One-off cut in prices of patented medicines	**Austria, Belgium, Germany, Italy, Portugal, Spain, UK**
	Implementation of reference pricing	**Brazil, Canada, France, Germany, Italy, Mexico, NZ, Spain**
	Change in reference price system by cluster	**Greece, Ireland, Portugal, Spain**
	Reduction of Mark-Up for Distributors	**Austria, Canada, Greece, Ireland, Italy, Portugal, Spain**
	Essential Drug List with Low Prices	**Argentina, China, India, Russia, Vietnam**
	Mandatory Annual Price Cuts	**Japan, Philippines**
	Increase of government rebates	**Germany, US**
Reimbursement Policies	De-listing of products on reimbursement lists	**Czech Republic, Greece, Portugal, Spain**
	Increase in patient co-pays	**Austria, France, Greece, Ireland, Sweden**
Policies to Promote Generic Medicines	Implementation of INN name prescribing	**France, Italy, Portugal, Slovakia, Spain**
	Incentives for physicians to prescribe generics	**Belgium, France, Hungary, Japan**
	Incentives for pharmacists to recommend generics	**Belgium, France, Ireland, Japan**
	Incentives for patients to choose generics	**France, Iceland, Ireland, Portugal, Spain**
	Generic price cuts and tendering approach	**Canada, China, Italy, Vietnam**



Real Pharma Spend Dropped in Almost All European Countries After 2009

Government-mandated price reductions have led to substantial declines in real pharmaceutical spending after 2009 in countries such as Portugal, Denmark, the Netherlands and Spain.

Source: WHO; The Future of the Global Pharmaceutical Industry, torreya.com, 2017; WTO.

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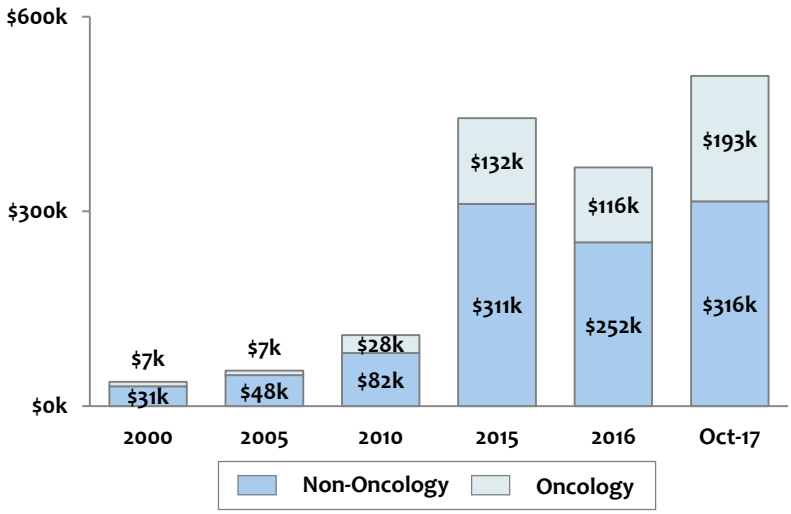
Trends— Greater Focus on Innovative Drugs for Rare Diseases

Globally, rare disease therapeutics are increasingly becoming more important across the pharma industry, with the US playing a significant role.

- In the US, the 1983 'Orphan Drug Act' was designed to encourage drug manufacturers to develop new medicines for smaller, neglected health conditions and diseases that did not necessarily offer significant financial returns.
- In addition to several benefits including tax credits, this legislation granted manufacturers who secured approval of a rare disease drug 7 years of marketing exclusivity. Further, certain orphan disease drug makers also received the right to FDA Priority review vouchers.
- Other countries have also adopted numerous incentives to develop drugs for rare diseases and as a result, such practices have now become increasingly mainstream.
- Due to low development costs and high market value, this segment is expected to grow further with attractive investments in the future.

Total Enterprise Value ($M) of Top 31 Pureplay Rare Disease Therapeutic Companies



- Over the last 2 decades, rare disease therapeutics companies have become an important and growing part of the pharmaceutical industry.
- In October 2017, the total enterprise value of the top 20 pureplay rare disease non-oncology companies was $315B.
- Many oncology companies have pursued drugs treating rare forms of cancer. The sum of the enterprise value of pureplay rare disease oncology companies as of October 2017 was $193B.

Top Pure Play Rare Disease Companies by Market Value (Oct. 2017)

Biogen ~$70B

Shire ~$68B

VERTEX ~$37B

genzyme ~$36B

Continued Growth in the Rare Disease Sector is Expected

- Rare disease companies have made a great difference for patients, with most treatments sold being actually life-saving and extending life by a substantial amount.
- The rare disease business is globalized and is viewed to be less vulnerable to reimbursement changes in any one country. In addition, strong patient advocacy groups underlie government's willingness to reimburse rare disease drugs.
- The number of new drugs in development is rising fast and this trend is expected to continue. With the world still in the early stages of finding cures for rare diseases, the pipeline for new breakthroughs is long.

Source: The Future of the Global Pharmaceutical Industry, torreya.com, 2017; Capital IQ.

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Trends— Growing Importance of China

- The Chinese pharma market grew from $21B in 2005 to $122B in 2017, and in just over a decade has become the second largest pharma market in the world:
  - The country's usage of Western medicines has significantly increased over the years with a high demand for cancer, cardiovascular, and respiratory drugs.
- Further, Chinese companies have also managed to add $84B in shareholder value in ~18 months, despite major changes in the regulatory regime and increasing pressure on prices (especially via Essential Drug Lists).

Company	Value Estimate (2017)
Yangtze River Pharma	***$51B***
Hengrui Medicine	***$22B***
CR Pharma Rx Segment	***$19B***

- The US pharma market is expected to double between 2017 and 2060 while China's pharma market is forecasted to quadruple during the same period. Japan, Germany and France are projected to grow by less than 2X.
- In addition, China's share of the global pharma pie is expected to surpass Western Europe by 2060:
  - In 2017, China had a global market share of ~10% while Western Europe accounted for 22%. By 2060, the landscape is expected to change with China making up 18% and Western Europe shrinking to 17%.

Implications for the Global Pharma Sector from China's Forecasted Rise:

- If forecasts for China's rise in the decades ahead hold true, it is highly likely that the China market will come to rival that of the US.
- Japan will become a less relevant pharmaceutical marketplace in time, given its slower GDP growth.
- Similar to other sectors which have begun to cater their product to the Chinese market, experts predict a trend where pharma manufacturers address diseases that are particularly prevalent in China such as liver fibrosis, hepatitis, and gastric cancer.

Source: IBIS World; The Future of the Global Pharmaceutical Industry, torreya.com, 2017.

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Trends—Emerging Technologies Transforming Pharma…

The Rise of the Digital Era of Pharmaceuticals

- In order to embrace new opportunities and face fresh challenges, the industry is beginning to adopt and integrate emerging digital technologies such as AI, Big Data, IOT, and Blockchain.
- The pharma industry is striving to maintain a balance between the need for: novel blockbuster medicinal drugs, improved operational efficiencies, and innovation in areas such as precision medicine, wearables, and digital therapeutics—all of which can directly impact the pharma value chain.
- Pharma is becoming increasingly democratized due to the digital enablement of non-traditional tech conglomerates such as Apple, Facebook, & Google, which have, in turn, been pushing pharma companies to go 'beyond the pill'.

Pharma Industry— Disruptors

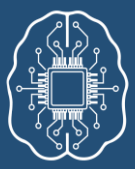
Artificial Intelligence (AI)

Internet of Things (IOT)

Blockchain

Big Data

Big Data & Artificial Intelligence (AI) Disruptions in the Pharma Space



- The adoption of AI & Big Data have made the drug discovery process significantly more efficient, owing to the ability to process large amounts of scientific data in a short timespan.
  - Companies such as Benevolent AI & Exscientia have used AI to great success.
  - Startups are already ahead of big pharma in using AI to mine and analyze data from clinical trials and academic papers—helping researchers and scientists to identify molecules that have failed in trials and to predict how they can be effective for other diseases.
  - AI's predictive power can also help scientists to design new molecules as the countless relationships between genes, targets, diseases, proteins and drugs can be analyzed in a shorter timespan for drug design & development.
- In addition, through AI & Big Data, pharma companies can analyze large amounts of patient data to better identify treatment options.
  - As AI is capable of cross-referencing data and finding commonalities, pharma researchers (such as those of Proteus Digital Health and uMotif) have drawn insights that were previously impossibly to identify, offering the possibility to come up with more comprehensive and holistic views of patients' health and possible treatment options.
- Further, through AI-based collaborative frameworks, pharma companies can analyze Google search trends and information from health organizations to identify what medical supplies people are searching for at a particular location, thereby giving pharma companies insights into the demand for certain drugs and vaccines.

Exscientia

BenevolentAI

proteus® DIGITAL HEALTH

uMotif® Digital Health

Source: Digital Transformation in the Pharmaceutical Industry, biospectrumasia.com, Oct. 2019; AI, blockchain, IoT disrupting global pharma industry, Frost & Sullivan, 2018; Why AI is the future of Pharma, medium.com, June 2018.

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…and Asian Pharma Markets Embracing Digitalization

Blockchain & IOT— The Next Big Disruptors in the Pharma Space

- Globally, Pharma companies have faced a range of challenges with complex supply chains—from lost ingredients to incorrectly identified medicines from faulty computer systems. Technologies such as blockchain are being used to address some of these issues. Examples of companies providing solutions include Elemental Machines and iSolve.
- Applications include drug identification, verification, instant notifications when illegitimate drugs are identified, and ensuring full regulatory compliance:
  - Once Blockchain is completely integrated, each unit of medicine will have a unique and customized identification tag, allowing for seamless transfer of ownership through trusted, transparent, verifiable, and secure networks from upstream suppliers to downstream patients and consumers.
- Similarly, IoT—which corresponds to the inter-network of physical devices that are embedded with sensors, actuators, electronics and connectivity—can further assist the pharma supply chain:
  - By utilizing low-energy sensors, IoT allows for real-time visibility into the movement of goods.
  - In addition, IoT sensors can also be deployed to optimize warehousing and logistics, e.g., ensuring the maintenance of specific temperatures necessary for certain drugs and vaccines in transit and in storage.

ELEMENTAL MACHINES

iSolve

Digital Transformation Opportunities in the APAC region

In the APAC region, digital transformations led to a total market opportunity of $13B in 2019, with digital pathology and e-clinical platforms for clinical studies being the most attractive areas for investment.

Australia & NZ

A market for integrated Continuous Diagnostics & Mitigation (CDM) programs

China

Anticipated to contribute 20%+ of total regional healthcare revenue in 2019 due to aggressive policies to support pharma markets & heavy investments in AI

India

30% growth expected in the pharma markets, fueled by the Digital India & 'Make in India' initiatives and corresponding FDI inflows

Japan

Expected to transform regenerative medicine & become first country globally to use Embryonic Stem (ES) cells for medical treatments

South Korea

Developing a robust clinical trial environment for medical devices & pharmaceuticals with the aim of becoming a global clinical trial hub

Source: How Blockchain Can Improve the Pharma Manufacturing Supply Chain, disruptordaily.com, 2018; How IoT is Transforming the Pharmaceutical Industry?, entrepreneur.com, 2017; Pharmaceutical and Biotech Sectors to Drive Investments in the Asia-Pacific Healthcare Industry, Frost & Sulliva, 2019.

Contract Manufacturing in Pharma

- While contract manufacturing long played a part in the industry's growth, its criticality in bio/ pharma company operations only picked up from the beginning of the 1990s, driven mainly by the growing need for well-equipped manufacturing facilities, advanced technologies, and high containment capabilities.
- Increasing costs resulting from the expiration of many older drug patents, serious competition from the generic drug industry, and stricter government oversight of new drug development in the US and the EU also played a part in the rise of contract manufacturing.
- The pharmaceutical contract manufacturing market was valued at ~$58B in 2014, and is projected to reach ~$96B by 2025.
- Within the last 20 years, 55% of pharma and bio pharma companies had outsourced about half of their global manufacturing. Approximately ~18% used outsourcing for at least 90% of their total output.

Future Outlook

Changing Landscape

- The contract manufacturing market is relatively fragmented with the top 5 companies commanding ~15% of global market share, but the landscape is changing with more M&A taking place.
- Many pharma companies are also choosing to outsource to one full-service contract manufacturer as opposed to numerous niche providers, as this simplifies their supply chains and reduces time to market:
  - In the past, large pharma companies had >300 contract manufacturing partners, but now firms are looking to trim down to ~50.
  - A key reason for this is a shift in focus by large pharma companies to longer-term relationships with fewer vendors.
  - In addition, larger contract manufacturers have also been acquiring smaller, niche facilities particularly in emerging markets, to expand capabilities.

Increasing M&A

Focus on Longer-Term Relationships

Biologics— A Key Driver

- While small-molecule drugs dominate the pharma industry, the share of biologics, biosimilars, and large molecule drugs has been growing. Over 200 biologics have been approved by the US FDA over the last decade.
- The inherent complexity of biologics is expected to prompt a greater demand for specialized expertise & a skilled workforce, providing opportunities for contract manufacturers such as Lonza and Samsung Biologics that serve the market through innovative platforms.

Lonza Pharma & Biotech

SAMSUNG BIOLOGICS

Outsourcing from SMEs

- Over the last few years, there has been a continual increase in the number of SME specialty pharma firms, and these SMEs require contract manufacturers to carry out a large portion of their activities for cost saving purposes.

SME Specialty Pharma business numbers to grow at a CAGR of 7% over the next 5 years

Source: The Future of Pharmaceutical Contract Development and Manufacturing Market, pharmamirror.com,2019; Global Pharmaceutical Contract Manufacturing Global Market Growth Opportunities and Challenges, Medgadget.com, 2019.

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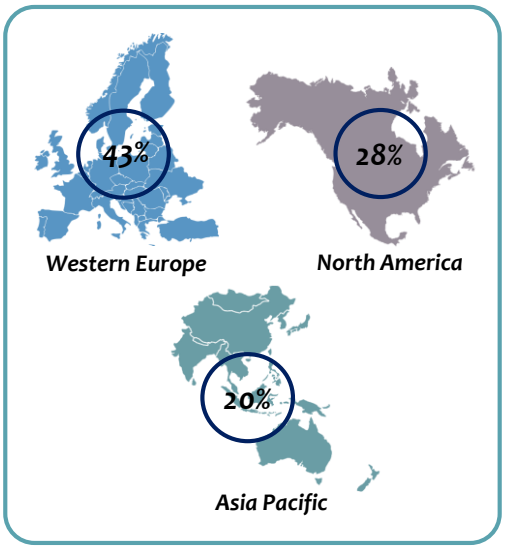
FDI In the Global Pharma Industry

- Globally, in 2014, there were ~200 pharma projects with numbers increasing to 287 by 2019. Capital investment and the number of jobs created as a result increased by ~16% and ~12% respectively, during this period.
- Western Europe was the key *source* of pharma investment from 2014 to 2019, accounting for 43%, followed by North America at 28%, and Asia Pacific at 20%.
- Western Europe also *received* the bulk of the investment, at ~36% of all global pharma FDI during the period—of which, the UK was the key recipient, attracting 22%, followed by Germany (17%) and France (~12%).



Notable Investments in the APAC, ME & Africa

- GSK was the largest investing company (2014-19 period), with $1.9B invested into 34 projects, creating ~4,000 jobs.
- GSK invested $1.05B in 2014 in its Indian unit to increase its stake from 50.7% to 75%.
- Invested $45M in 2017 to expand a production line at GSK's Cairo facility to manufacture low cost generics.

- AstraZeneca had the second highest number of projects in this period, with 24.
- Astra Zeneca invested $230M in a new facility in Taizhou, China to produce intravenous & oral solid medicines for the Chinese market.
- Invested $100M to expand its manufacturing facility in North Ryde, Sydney, to develop inhaler products for the treatment of asthma and COPD.

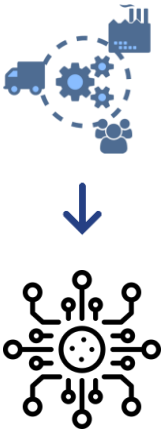
- US-based Pfizer ranked third, investing in 22 pharma projects globally.
- In 2014, Pfizer invested $3.5M to expand operations in its Indonesian solid oral dose plant, with the objective of increasing capacity by 76%.
- Invested $50M in 2017 to set up a new plant in Saudi Arabia, to develop 16 medicines in 5 therapeutic areas: cardiovascular, pain, anti-infective, urology, & neurology.

Source: Company News Articles; Global pharmaceutical FDI on an upward trend, FDIintelligence.com, March 2020; Glaxo completes $1B open offer to raise stake in Indian pharma arm to 75%, vccircle.com, March 2014; GSK reportedly to invest US$45m in Egypt by 2017, eiu.com, July 2016; AstraZeneca's New Manufacturing Facility, Taizhou, pharmaceutical-technology.com, 2014; Pharma giant Pfizer opens new $50m Saudi manufacturing hub, chemdiv.com, 2017.

Industry Challenges—Some Leading to Opportunities

Complexity of Supply Chains

- Pharma companies that embrace digital supply chains are able to boost revenue by >9%, market valuation by >12%, and profitability by >26%, but adopting such a model is no easy task.
- In pharma, the supply chain is highly complex and more regulated than in other industries.
- Shifting to digital SCM, with end-to-end transparency, is a key challenge. Thus, pharma manufacturers look out for tools that not only provide a comprehensive view of the supply chain, but also for those that provide insights on cost saving opportunities and inventory optimization.
- There is opportunity for specialized providers of technology who address the specific SCM needs of pharma manufacturers.



'Patent Cliffs' in Emerging Markets

- The end of drug exclusivity in mature markets, and also in recent years, emerging markets, has put a significant share of sales at risk.
- Between 2012 and 2016, patent cliffs in the pharma industry put sales worth a total of ~21B in the APAC region at risk, corresponding to ~10% of the whole APAC market.
- Pfizer's Lipitor, regarded as the best-selling prescription drug in history, went off-patent in 2011, and sales were believed to have declined from ~$11B in 2009/10 to ~$3B in 2015.
- The flip side of this loss in sales for Big Pharma is the increasing opportunity for generics manufacturers.

Threat of Counterfeit Drugs

- The WHO estimates that counterfeit drugs make up 10-30% of the global pharmaceutical supply:
  - A WHO study revealed that nearly 50% of the documented cases of drug counterfeiting were reported in developing countries of the Western Pacific (China, the Philippines, and Vietnam).
  - While it is estimated that ~1% of counterfeit medications are sold in the US at present, the numbers are increasing annually with most US counterfeit medicines being purchased online.
- High demand, expensive medications—such as various chemotherapeutic drugs, antibiotics, vaccines and erectile dysfunction drugs, weight loss acids, hormones, analgesics, steroids, and antihistamines—are the most common counterfeiting targets.
- The opportunity, once again, is for digital application providers in pharma to introduce technologies such as Blockchain to combat the challenge of counterfeit medicines.

Source: The Real Impact of Counterfeit Medications, uspharmacist.com, June 2014; How emerging markets are driving the transformation of the pharmaceutical industry, pwc.ru, 2013; Challenges and Opportunities in Pharmaceutical Manufacturing, blog.thomasnet.com, 2020.

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The Challenge of De-Risking API Supply

- China has notably emerged as a key provider of APIs to the world. Even the largest manufacturers in the world – the US and India – are heavily reliant on Chinese APIs.
- After the manufacturing slowdown in China and the disruptions in global trade with COVID-19, many countries will try to focus on diversifying their supply chains away from China.
- However, most manufacturing nations will still be forced to rely on other countries, as they are unwilling to take on the high environmental costs that come with API manufacturing.

Indian Reliance on Chinese APIs

India annually produces drugs worth ~$39 Billion

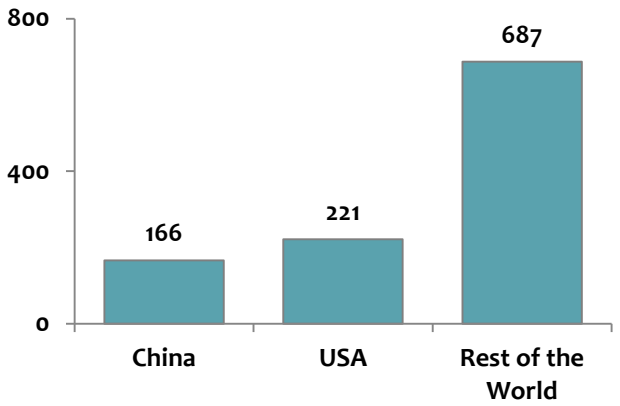
FY19 API imports from China ₹17,400 crore

53 key API's of India have nearly 80%–90% reliance on imports from China

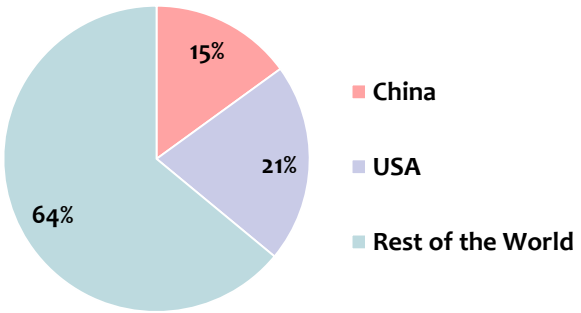
Year	Pharma Imports from China (₹ lakh)	Growth % over Last Year
2015–16	94,789.79	-
2016–17	89,892.90	-5.2%
2017–18	81,873.39	-8.9%
2018–19	1,03,861.93	26.9%
2019–20	1,14,927.31	10.7%
Growth from 2016–17 to 2019–20		28%

US Reliance on Chinese APIs

Number of API facilities for All 370 U.S. Marketed Drugs on the 2019 WHO EML



Percent of API Facilities for All 370 US Marketed Drugs on the 2019 WHO EML



Source: US FDA; Ministry of Commerce India; Pharmexcil; European Pharmaceutical Review; Economic Times India.

Challenges in Attracting FDI

Sri Lanka's pharmaceutical industry requires further support in the form of capital infusion, and there needs to be favorable conditions for global pharma firms to consider JVs with local partners, which will promote growth and facilitate crucial technology transfers.

- 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.
- However, inviting foreign pharmaceutical manufacturers could also be seen as a negative by some. The effort by the Sri Lankan government to invite Indian pharmaceutical companies to manufacture in Sri Lanka in 2015/16 created concerns regarding a loss of market share for local manufacturers in an already small share of market.
- The promotion of local drug production and its long-term development potential will be hampered by challenging regulatory and operating environment conditions. The current requirements for setting up are cumbersome, time consuming, and provide limited incentives for MNCs to invest in Sri Lanka.
- 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.

Critical Factors for Creating Favorable Conditions for Technology Transfers in Pharma

Source: Pharma sector needs a level playing field-Astron MD, Sunday Observer, Sep. 2019; Regulatory & market profile of SL, Pharmexcil, 2018; Sri Lanka woos Indian pharma companies to set up operations in the country, Economic Times India, July 2016; IFPMA; Stax Primary Research, June 2020.

Global Pharma Exports

Global Export Value of Pharmaceutical Products for Select Countries

(in USD millions, 2017)

Country	Value
Germany	$83.77M
Switzerland	$70.37M
USA	$44.93M
Belgium	$42.62M
Ireland	$38.41M
Netherlands	$33.63M
United Kingdom	$32.71M
France	$31.52M
Italy	$25.52M
Denmark	$12.94M
India	$12.89M
Spain	$11.35M
Austria	$9.08M
Sweden	$7.77M
China	$7.36M
Israel	$7.30M
Canada	$6.27M
Singapore	$5.89M
Hungary	$5.21M
Japan	$4.56M
Poland	$4.34M
Slovenia	$3.06M
Korea	$2.90M
Australia	$2.53M

Country	Value
Panama	$1.61M
Mexico	$1.36M
Brazil	$1.25M
UAE	$0.89M
Turkey	$0.88M
Argentina	$0.74M
Russia	$0.73M
Jordan	$0.67M
Indonesia	$0.56M
Taiwan	$0.52M
Thailand	$0.51M
Saudi Arabia	$0.46M
South Africa	$0.45M
Dominican Republic	$0.45M
Colombia	$0.35M
Cyprus	$0.31M
Costa Rica	$0.28M
Egypt	$0.28M
Malaysia	$0.24M
Guatemala	$0.22M
Pakistan	$0.21M
Iran	$0.19M
Vietnam	$0.15M
Chile	$0.15M

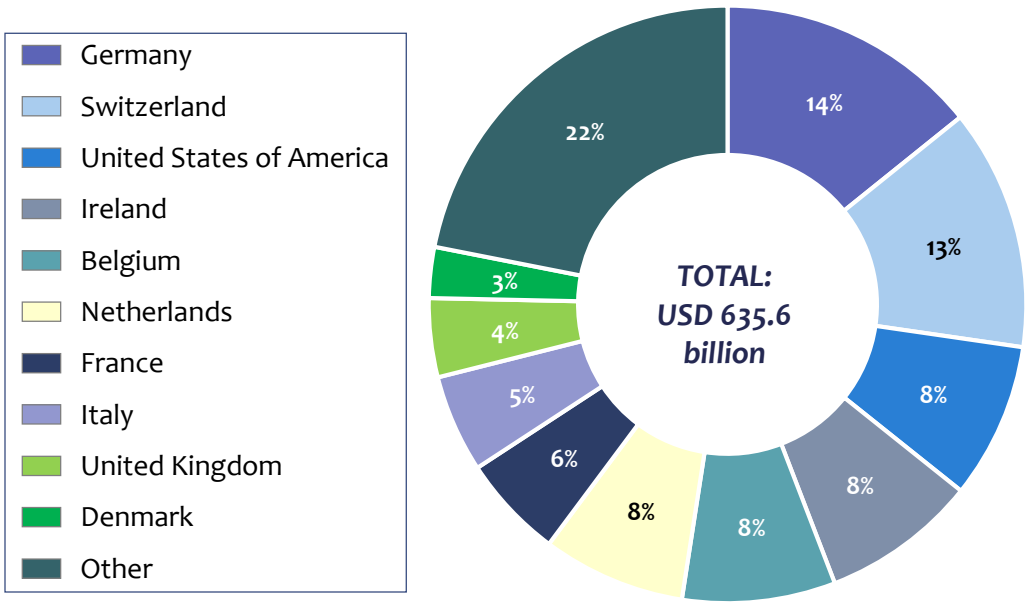
Country	Value
El Salvador	$0.14M
Kenya	$0.12M
Uruguay	$0.12M
Bangladesh	$0.11M
Morocco	$0.10M
Oman	$0.08M
Tunisia	$0.05M
Peru	$0.05M
Lebanon	$0.05M
Paraguay	$0.04M
Kuwait	$0.04M
Philippines	$0.04M
Ecuador	$0.04M
Barbados	$0.04M
Mauritius	$0.03M
Palestine	$0.02M
Uganda	$0.02M
Cambodia	$0.01M
Nicaragua	$0.01M
Honduras	$0.01M
Senegal	$0.01M
Nepal	$0.01M
Sri Lanka	$0.01M

Source: UN Comtrade (HS Code 30); ITC.

Top Global Exporters

The top 10 pharmaceutical products and medicine exporting countries in the world are all European, with the exception of the USA. India and China rank at #11 and 15, respectively.

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



- Although India, China, Singapore and Israel comprise a small share of total exports in terms of value, they are increasingly providing a high volume of pharmaceuticals to low-income countries, especially generic drugs.
  - For example, India is the world's third largest drug producer by volume and manufactures ~60% of vaccines globally.
- MNCs are engaged in all stages of manufacturing and are able to generate new molecular entities (NMEs) and distribute through subsidiaries and licensees. They are highly concentrated in a handful of developed countries.
- Manufacturers in other countries typically produce patent-expired drugs, although they may be capable of discovering and developing NMEs, they usually lack in-house research capacity. They typically buy active ingredients through international tenders or from the original innovator. They sell the medicines either under brand names or under international nonproprietary names (INN) as generics.
- Some developing countries have a pharmaceutical industry of the innovative type, which can produce active ingredients, but in a majority of developing countries, the industry does only the final, technologically simple stages of FPPs, and relies on importing APIs from other countries.

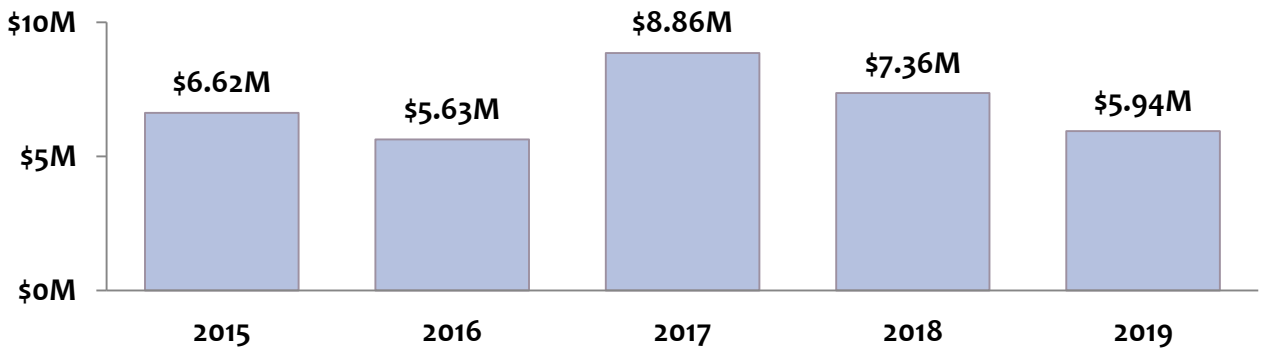
Source: UN Comtrade; ITC; World Bank; WHO.

Exporting Pharmaceuticals from SL

- There has been some level of local pharmaceutical manufacturing in Sri Lanka since the late fifties. But with no consistent policies or strategies to stimulate growth, there has only been a small measure of progress in the intervening years.
- To put the country's pharmaceutical export status into perspective—in 2017, Sri Lanka was ranked at 99 in the list of pharmaceutical exporter nations (in terms of total value of exports).*
- While there are pockets of export potential to be explored, becoming an attractive pharma manufacturing hub will require sustained effort and resources by public and private sector players working together toward a clear strategic roadmap.

SL Exports of Pharmaceutical Products, 2015–19

(in USD millions)



"For this country to go forward, I see a couple of sectors that need to be worth a billion or multi-billion dollars [in exports]. One sector is pharma. We're heavily dependent on getting our pharmaceuticals from foreign countries. We have the capability, we have the know-how. There are some good, successful local companies. We're trying to build a pharma zone, looking at a billion dollars over time. It'll be a 5-7 year journey. Unless you try now, you won't get a chance, and it is a good time to start because the whole ecosystem is getting moved around."

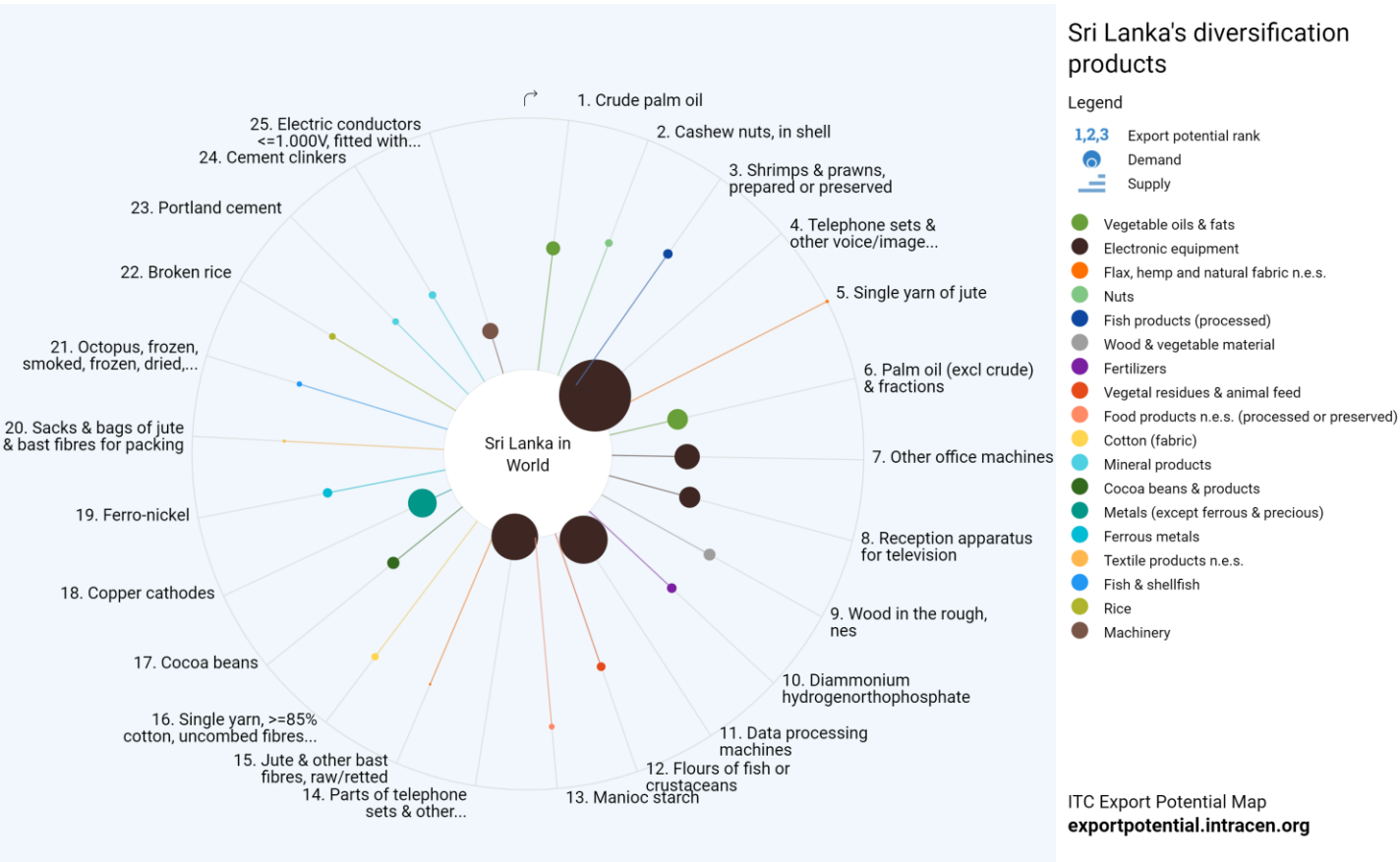
—Sanjaya Mohottala, Director General, BOI of Sri Lanka, June 2020

* Based on ITC data. Official government export data from CBSL put export figures even lower.

Source: ITC trade database; Astron website; Stax Primary Research, June 2020; Sanjaya Mohottala's Address at the 23rd AGM of the MBA Alumni Association, University of Colombo, YouTube, June 2020.

ITC's Product Diversification Map for SL

- The International Trade Center's (ITC) market analysis tools are used globally by companies and government institutions (including the EDB) when formulating trade strategies. The ITC's Product Diversification Indicator (PDI) identifies products that the exporting country does not yet competitively export, but which seem feasible given the country's current export basket and that of similar countries.
- The PDI does not list pharmaceuticals within the top 25 products to be considered for diversification of exports from Sri Lanka. In the graphic below, the numbers refer to the ranking, the bubble size to the extent of global demand, and the colored radial line to SL's ability to supply (the closer the radial line is to the outer circle, the easier for SL to supply).
- According to the PDI, currently, Sri Lanka's best options for diversification in global export are in crude palm oil, cashew nuts (in shell), and shrimps & prawns (prepared or preserved). The easiest product for SL to supply is jute (single yarn). Of the products ranked, telephone sets & other voice/image transmission apparatus has the strongest global demand potential.



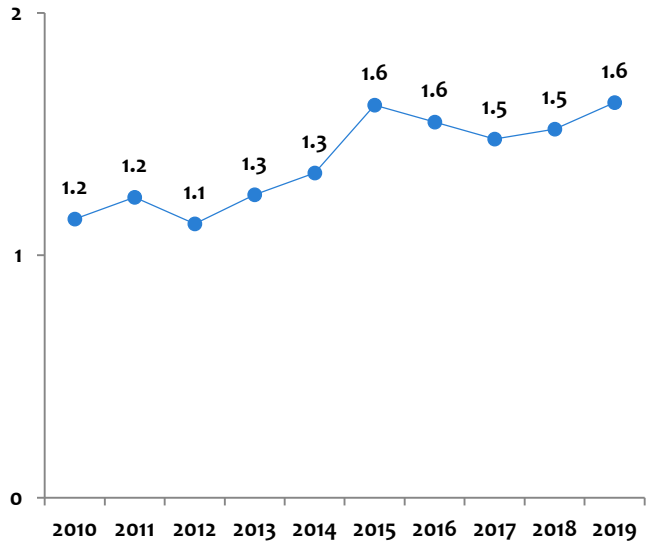
- However, the ITC itself points out that there are factors outside their estimations (such as FDI) that would affect export potential, and that the PDI should be seen as a starting point, which needs to be followed up with further research and consultations with public and private sector stakeholders in the country.

Source: ITC product diversification tool and trade database, accessed June 2020; Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine, World Bank, 2005.

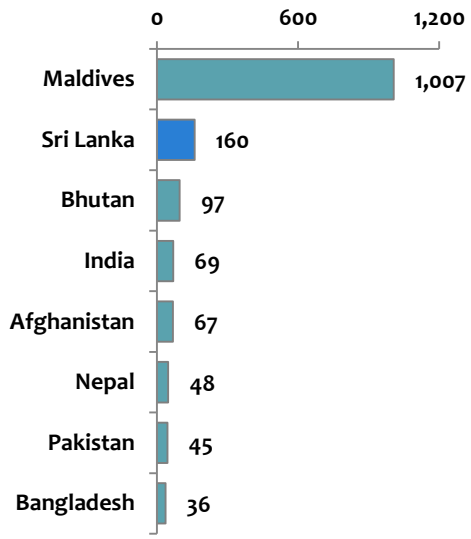
Success Factors Related to Pharma Exports

- A World Bank study found that there is strong positive correlation between successful pharmaceutical production and a country's:
    1. domestic market size being large,
    2. total governmental health expenditure being high, and
    3. Competitive Industrial Performance Index (CIP) score being high.
- The first two factors are partly why import substitution has come to be considered a crucial factor in laying the groundwork for pharmaceutical exports—many of the countries that have succeeded have started by catering to a large local market, in terms of absolute size in number of domestic consumers and also high demand from the public sector. However, since SL cannot claim such a population, other avenues will need to be explored.
- In comparison to regional neighbors who are large pharma exporters, SL spends more on health per capita. Sri Lanka's health expenditure as a percentage of GDP has remained at a fairly constant rate over the past decade, despite the country's elevation to upper middle income status.

Sri Lanka Total Health Expenditure, 2010–2019 **(as a % of GDP)**



CHE per Capita, South Asia by Country **(Current USD, 2017)**

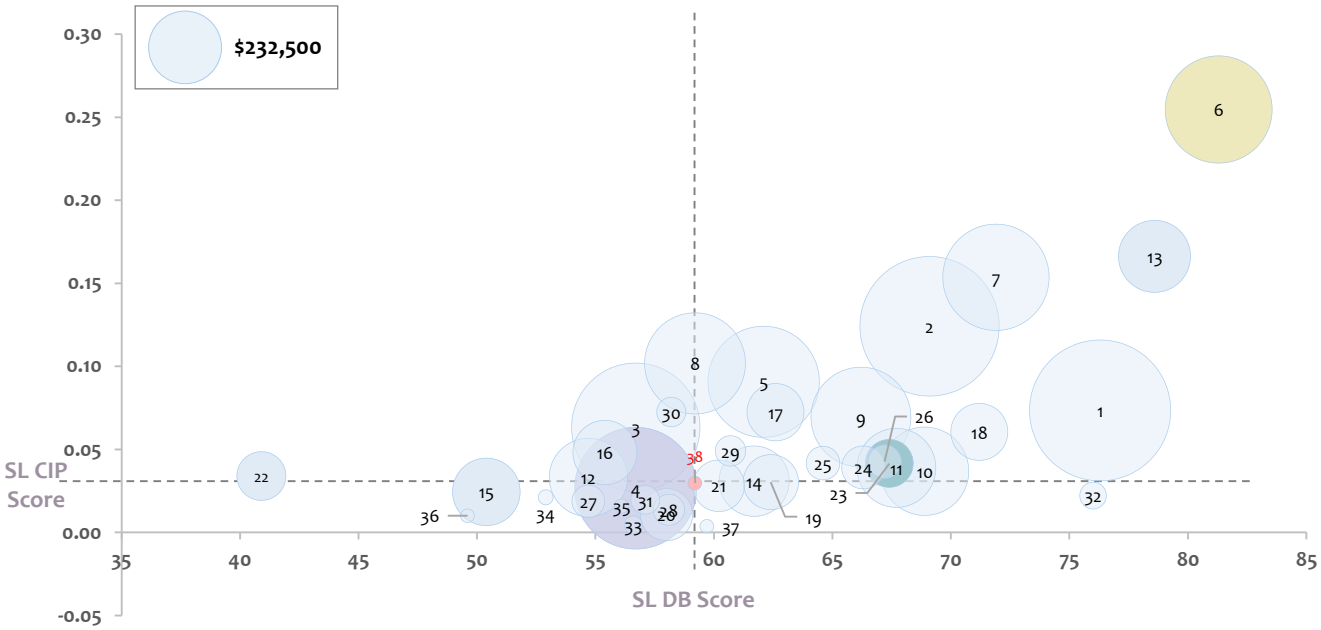


Note: Estimates of current health expenditures include healthcare goods and services consumed during each year. This indicator does not include capital health expenditures such as buildings, machinery, IT and stocks of vaccines for emergency or outbreaks.

Source: World Bank Databank; CBSL Annual Reports & Statistical Appendices; Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine, World Bank, 2005; SLHA, MOH, 2014-2016.

Comparing SL to Low- to Mid-tier Exporters

- A country highlighted in the aforementioned WB study, which succeeded despite not having a large population, was Jordan. In 2017, Jordan's pharma exports value was more than 75x greater than Sri Lanka's despite having lower scores on both the World Bank's Ease of Doing Business (DB) Ranking and the UNIDO's Competitive Industrial Performance (CIP) Index.
- The following chart depicts the DB and CIP scores of select low- to mid-tier exporting nations (with exports lower than USD 1 billion in value and greater than Sri Lanka's. 2017 export data is used here, as this was the year with the highest export value reported for SL by the ITC).



	Economy	Ease of DB Score 2017	CIP Score 2018	Pharma Exports value 2017 (USD Thousands)
1	UAE	76.3	0.0735	$ 893,795
2	Turkey	69.1	0.1242	$ 875,310
3	Argentina	56.7	0.0633	$ 743,308
4	Jordan	56.7	0.0267	$ 668,150
5	Indonesia	62.1	0.0907	$ 557,699
6	Taiwan	81.3	0.2547	$ 517,540
7	Thailand	71.9	0.1536	$ 508,827
8	Saudi Arabia	59.2	0.1018	$ 460,116
9	South Africa	66.2	0.0694	$ 450,912
10	Colombia	68.9	0.0369	$ 351,731
11	Costa Rica	67.7	0.0389	$ 281,354
12	Egypt	54.7	0.0331	$ 279,542
13	Malaysia	78.6	0.1662	$ 235,108
14	Guatemala	61.7	0.0309	$ 223,476
15	Pakistan	50.4	0.0245	$ 207,673
16	Iran	55.4	0.0482	$ 187,846
17	Vietnam	62.6	0.0724	$ 148,379
18	Chile	71.2	0.0606	$ 147,210
19	El Salvador	62.4	0.0303	$ 139,149

	Economy	Ease of DB Score 2017	CIP Score 2018	Pharma Exports value 2017 (USD Thousands)
20	Kenya	58	0.0108	$ 124,186
21	Uruguay	60.2	0.0281	$ 121,270
22	Bangladesh	40.9	0.034	$ 109,069
23	Morocco	67.4	0.0415	$ 104,091
24	Oman	66.3	0.0392	$ 84,962
25	Tunisia	64.6	0.0418	$ 52,741
26	Peru	67.2	0.0426	$ 51,455
27	Lebanon	54.7	0.0188	$ 48,884
28	Paraguay	58.1	0.0136	$ 44,999
29	Kuwait	60.7	0.0491	$ 42,247
30	Philippines	58.2	0.0725	$ 39,952
31	Ecuador	57.1	0.0196	$ 38,411
32	Mauritius	76	0.0222	$ 33,472
33	Uganda	56.6	0.0045	$ 15,029
34	Cambodia	52.9	0.0212	$ 10,688
35	Honduras	56.1	0.0159	$ 9,466
36	Senegal	49.6	0.0101	$ 9,144
37	Nepal	59.7	0.0037	$ 8,940
38	Sri Lanka	59.2	0.0298	$ 8,860

Source: ITC trade database, accessed June 2020; doingbusiness.org; UNIDO.org; Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine, World Bank, 2005.

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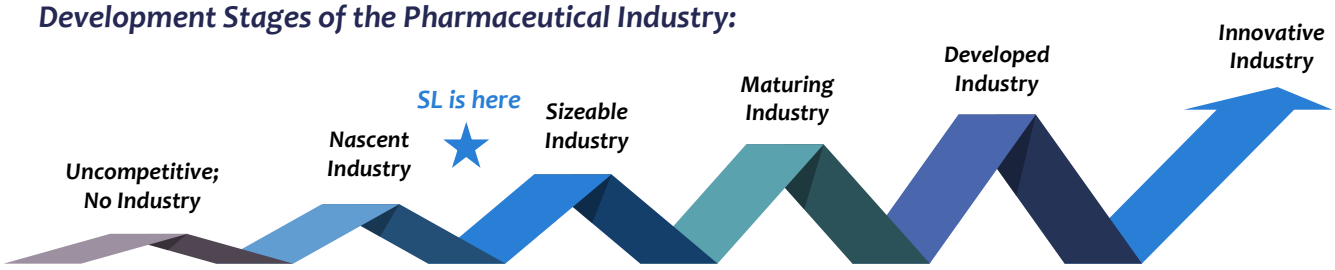
Key Takeaway #2: Clear, Consistent, Comprehensive Strategy for Exports

- As highlighted previously, and detailed in Chapter 5 of this report, currently leading pharma export nations have taken varying routes to success. What they all have in common however is a long-term, consistent commitment by the government and other stakeholders to lay the groundwork and procure the investments necessary to grow their exports in this sector.
- Many of the reference countries have been steadily investing into the ecosystem necessary for pharma exports since the 1960s. They also have not rested on their laurels but kept moving the bar higher in order to remain competitive. Those who failed to do so, are seeing some declines.
  - ❖ For example, Jordan implemented new ideas in the sixties and seventies, like setting up the first Free Zone in the region. However, they have not kept innovating and in recent years have lost some ground to competing nations.
  - ❖ Conversely, Taiwan has consistently invested into the sector and also kept innovating. E.g., its biomedical firms are experimenting on emerging areas such as e-health, cell therapy, precision robotics and AI applications within pharma.

The Plan should take into account a realistic assessment of the current market status as well as the unique factors that SL can use to differentiate.

Development Stages of the Pharmaceutical Industry:



Uncompetitive; No Industry	Nascent Industry	Sizeable Industry	Maturing Industry	Developed Industry	Innovative Industry
• Few, if any, local manufacturers • Heavily import-reliant with local players involved in import distribution only	• Growing number of local producers • Import substitution occurs at low to moderate levels	• Many producers with possibility of oversaturation • Emerging export base, even if import-reliant for certain products	• Stabilizing number of producers as consolidation occurs • Maturing export base, with imports still necessary for some items	• Stable number of producers following industry consolidation • Well-established export base with some imports still necessary	• Stable number of producers, with some moving into innovative R&D • Well-established export base with new, innovative products

Excerpts from the 'Island of Ingenuity' SL Investment Positioning Document:

"Sri Lanka has among the most rigorous intellectual property (IP) protection regimes in the region."

A.T. Kearney

Sri Lanka's budding island economy comes complete with an enabling environment for R&D, SMEs, financing and more. More than 75% of entrepreneurs are between 20–35 years old and 48% are IT/software engineers.

Source: Pharma Boardroom; UNIDO; World Bank; McKinsey; Island of Ingenuity.

For Example, the Government of Ethiopia has a 10-year strategy plan to develop its pharma sector

The Plan includes clear strategic objectives and set KPIs to monitor progress:

National strategy for pharmaceutical manufacturing development In Ethiopia, 2015–2025

Strategic Objective 1	***Improve access to medicines through quality local production - implement the GMP Roadmap***
Strategic Objective 2	***Strengthen the national medicine regulatory system***
Strategic Objective 3	***Create incentives designed to move companies along the value chain***
Strategic Objective 4	***Develop human resources through relevant education and training***
Strategic Objective 5	***Encourage cluster development and production of active pharmaceutical ingredients***
Strategic Objective 6	***Create a research and development platform***
Strategic Objective 7	***Attract foreign direct investment into the pharmaceutical sector***

Indicator	*Current*	*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)	—	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: National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015–2025), July 2015.

5. Reference Markets

Comparing SL to Select 'Success Stories'

- Taiwan has a population that is only slightly bigger than Sri Lanka's, but is one of the most successful APAC regional pharma manufacturers. They are not competing due to the development of a large domestic market but on the strength of their technology and innovation.
- Jordan's per capita GDP is very similar to that of SL, as is Morocco's. Further Morocco's CHE per capita is almost identical to that of SL. These are not particularly wealthy nations nor do they have high CHE spend (like Ireland), but Morocco's CIP is higher than Sri Lanka's.
- The successes of Taiwan, Morocco and Jordan will be examined in detail in this report, along with other select markets for context.

	Country	Population 2020 (M)	GDP p.c. (current USD) 2019	CHE p.c. (Current USD) 2017	CIP Score 2018	Pharma Exports Value (USD M) 2019
0	Sri Lanka	21.8	3,853	160	0.0298	5.9
1	India	**1,380.0**	2,104	69	0.0830	16,264.0
2	Bangladesh	164.7	1,856	36	0.0340	71.6
3	Pakistan	220.9	1,285	45	0.0245	217.6
4	Israel	9.0	43,641	3,145	0.1318	3,315.8
5	Jordan	10.2	4,330	341	0.0267	327.5
6	Egypt	102.3	3,020	106	0.0331	271.8
7	Morocco	36.9	3,204	161	0.0415	117.1
8	Cyprus	1.2	27,859	1,732	0.0159	372.6
9	Singapore	5.8	65,233	2,619	0.2573	8,107.0
10	Taiwan	23.8	27,131	945	0.2547	602.6
11	Ireland	4.9	**78,661**	**4,977**	**0.3172**	**53,555.3**

VARYING ROUTES TO EXPORT SUCCESS:

Dominating Domestic

Protect local market first and supply 70-90% of that need, which would help build scale. Also capitalize on cheap labor. Over time, keep improving unit economics.

BANGLADESH

PAKISTAN

INDIA EGYPT

Trading on Tech

Invest in talent & R&D though both government funds and FDI. Position country globally as a leader in innovation by using success in other tech areas too (e.g., Taiwan's semiconductor success. Keep moving the bar higher by investing further in latest tech.

SINGAPORE

ISRAEL TAIWAN

Continental Conduit

Build infrastructure to become gateway to broader region (e.g., Morocco to Sub-Saharan Africa). Hub strategy to reinforce that position (e.g., Jordan first-mover in free zones in Gulf). Keep positioning for FDI.

JORDAN MOROCCO

High-Income Haven

Use national high income to Invest into talent and infrastructure. Incentivize investment through tax haven status.

IRELAND

Source: World Bank Databank; National Statistical Bureau of Taiwan; Taiwan Ministry of Health & Welfare; Worldometers.info; UNIDO; Pharma Boardroom country profiles.

Bangladesh —A Right Timing Success Story

Macro Indicators

Population	GDP P.C.	CHE P.C.	Pharma Exports
~165M	$2,104	$36	$71.6M

Keys to Success

- Exemptions from 'TRIPS'
- Thrust Sector for Exports

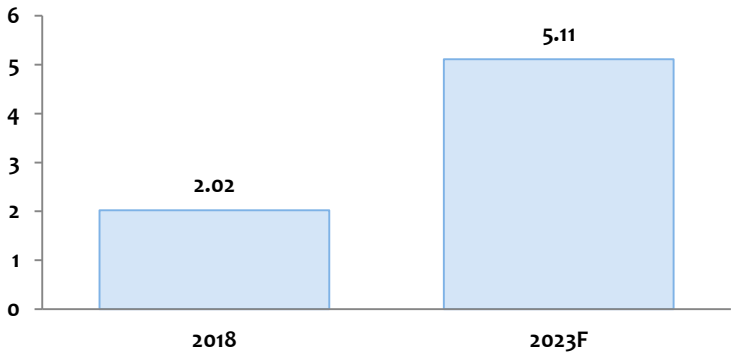
A Silent & Self-Sufficient Contender

Current Market

- In 1981, there were ~166 licensed pharmaceutical manufacturers in Bangladesh with local production dominated by 8 international companies manufacturing ~75% of the products.
  - All of the companies were mainly engaged in formulation through imported raw materials involving an expenditure of ~$700K (TK 60M) in foreign exchange.
- However, the landscape has significantly evolved over the last 40 years, from being import-dependent to becoming a self reliant, export-oriented sector, with ~260 licensed pharmaceutical companies in total. Of these, national companies now account for more than 75% of the pharmaceutical business in the country.
- Bangladesh is now nearly self-sufficient with ~98% of the demand met by local production, while the remaining constitutes imports of specialized products such as vaccines, anti-cancer products & biologics.
- The country's pharmaceutical sector is expected to reach ~$5.11B by 2023, from ~$2.0B in 2018, propelled by high investments by local companies seeking to grab a bigger share of the global market.

Bangladesh Pharmaceuticals Market, 2018–2023F

(In USD Billions)



Source: Local pharma market set to hit $5.11b by 2023, thedailystar.net, Aug. 2018; Pharmaceutical Industry, en.banglapedia.org, accessed July 2020; Pharmaceutical Opportunities in Bangladesh, UK Trade & Inv., accessed July 2020; Pharmaceutical industry is growing rapidly in Bangladesh, newvision-bd.com, 2019.

Bangladesh —A Right Timing Success Story Cont'd

Keys to Success— *Exemptions from 'TRIPS'*

- In 2002, the WTO's TRIPS agreement allowed Bangladesh and 49 other least developed countries to reverse engineer any patented medicines without taking prior permission from the innovator and to also export to any country (except the country where the patent exists) between 2006 and 2016.
  - This agreement was later extended to January 2033, allowing Bangladesh to be exempt from the obligations to implement patents and date protection for pharmaceutical products until this period.
- While the TRIPS agreement expires in 2033, Bangladesh is expected to exit the LDC category by 2024. Thus, the sector has set its sights on the opportunity arising from products nearing patent expiration.
  - Drugs worth ~$250B are nearing patent end in 2022, which will allow Bangladesh to target their manufacture.

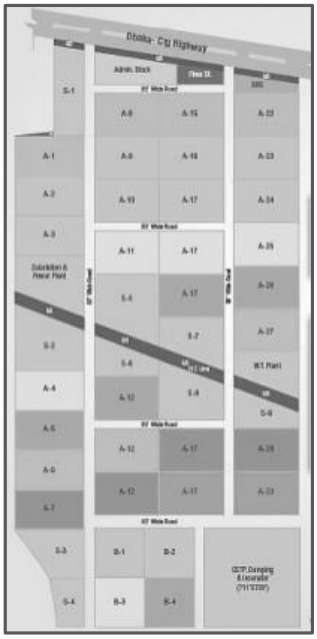
WORLD TRADE ORGANIZATION

TRIPS
Trade Related Intellectual Property Rights

Keys to Success— *Thrust Sector for Exports*

- The Bangladesh government declared its pharmaceutical industry as a 'thrust sector' owing to its huge export potential, and as such, has given it prominence, specifically encouraging the export of medicinal products.
- As a result of the emphasis and drive for the export of pharma, 1,200 products received registration for export between 2017-2019, according to the Bangladesh Association of Pharmaceutical Industries.
- Currently, Bangladesh exports to ~150 countries with other developing countries such as Myanmar, Sri Lanka, and the Philippines, being the largest importers.
- Further, as a key % APIs are imported, the Government has also initiated the setting up of an API park, of 81 Hectares, in Munshiganj (37 km from Dhaka):
  - Bangladesh believes that it can save ~70% of expenditure on raw materials when the API park is fully functional.
  - While the project is estimated to cost ~$31M, local pharma companies have already pledged ~$245M in investments in the Park.
  - In addition to making pharmaceutical products cheaper to manufacture, and as a result, more competitive in overseas markets, Bangladesh is also expected to earn more by exporting APIs to other countries.

Layout Plan of the API Industrial Park— Munshiganj



Source: Bright future for Bangladeshi pharmaceuticals", ukessays.com, Accessed July 2020; Bangladesh Pharmaceuticals Industry: An Emerging Generic Drug Hub in Asia, Blukonsult.com, Sept 2019; Bangladesh. Pharmaceutical Industry Overview, cispharma.blogspot.com, April 2015; Bangladesh pharmaceutical industry blooms bigger, dhakatribune.com, Aug 2019; Bangladesh Pharma Industry: Opportunities in Global Generics, jetro.go.jp, 2016.

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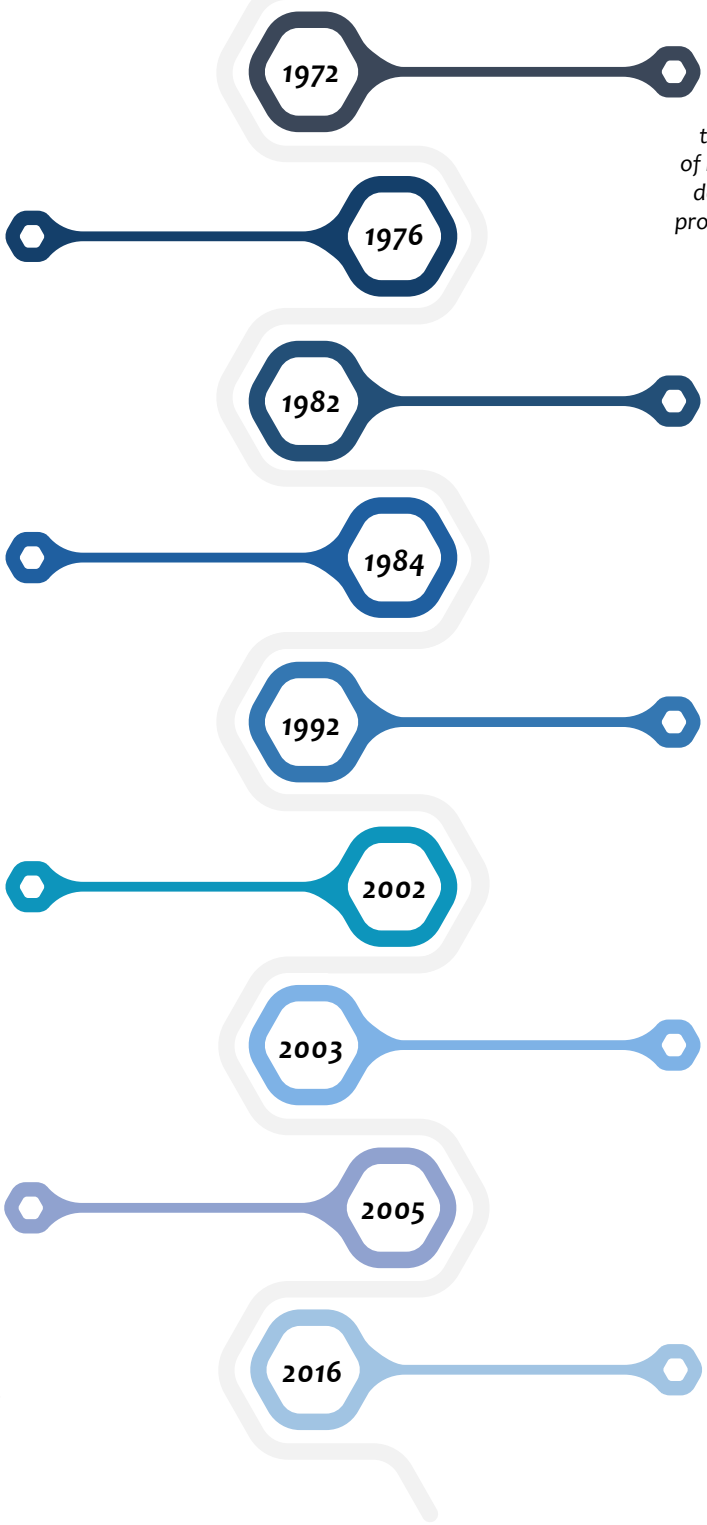
Bangladesh —A Right Timing Success Story Cont'd

Key Milestones



1972

Bangladesh Association of Pharmaceutical Industries (BAPI) established with 23 member companies

The apex body representing the pharmaceutical companies of Bangladesh with an objective of developing its pharma sector to promote access to affordable drugs

1976

The Directorate General of Drug Administration (DGDA), the national regulatory authority for drugs established

Entrusted with the responsibility of ensuring the quality, efficacy & safety of pharmaceutical products though the implementation of relevant legislation

1982

The Drugs (Control) Ordinance enacted

Promulgated by the Ministry of Law & Land Reforms to control manufacturing, importing, distribution, and the sale of drugs

1984

Drugs (Control) (Amendment) Ordinance legislated

Defined the process to appeal against an order or decision made by the regulatory authority

1992

First edition of the National Formulary published

A comprehensive initial list of all the drugs available in the market at the time

2002

WTO's TRIPS Declaration in Doha

Established to protect public health and, in particular, to promote access to medicines for all

2003

Second edition of the National Formulary published

Updated list of all the drugs available in the market

2005

National Drug Policy legislated

Aimed at supporting quality and availability of drugs, controlling pricing, eliminating non-essential and harmful drugs from the market, promoting local production of finished drugs, and developing a drug monitoring & information system

2016

Revised New Drug Policy approved & legislated

Addressed new areas— achieving self-sufficiency in drugs & raw material manufacturing, expanding the export of drugs, and establishing an effective surveillance system of medicines

Source: A Review on Revolution of Pharmaceutical Sector in Bangladesh after Liberation War and Future Prospects and Challenges, jpionline.org, 2019; Pharmaceutical industry, bangladesh.uz, accessed July 2020.

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Ireland —An Incentivization Success Story

Macro Indicators

Population	GDP P.C.	CHE P.C.	Pharma Exports
5M	$78,661	$4,977	$53,555M

Keys to Success

- Incentivized Investment Climate
- Advanced R&D Hub
- Large Talent Pool

A Sought-after Manufacturing Hub

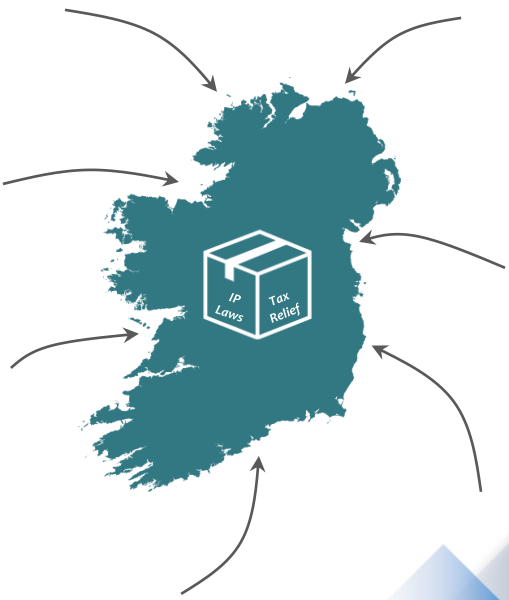
Current Market

- Starting with the creation of bulk ingredients, over the years, Ireland's pharma sector has grown to comprise of medicines, biotechnology, and medical devices.
- Currently, Ireland is home to 24 of the 25 largest global biotech & pharma companies (such as Johnson & Johnson, Roche, Pfizer, Novartis, MSD etc.).
- These companies are involved in all value chain activities, ranging from early-stage R&D to manufacturing and delivery of FPPs, within the country.
- 7 of the world's top-selling 10 drugs are also manufactured in the country.
- Pharmaceuticals account for 50% of all exports from Ireland, and the country is the largest exporter of pharmaceuticals in the EU.
- Within the last 10 years, the biopharmaceutical industry has invested ~$8B in new facilities across Ireland.

Johnson & Johnson, Roche, Pfizer, Novartis, MSD, AMGEN

Keys to Success— *Incentivized Investment Climate*

- At 12.5%, Ireland currently has one of the lowest corporate tax rates in the world, making it a highly attractive location for businesses to invest in and set up regional headquarters.
- Additionally, Ireland's IP laws have provided businesses with significant incentives to innovate.
  - The tax system supports the transformation of generated ideas into finished products, with no tax paid on earnings from IP where the underlying R&D work was carried out in Ireland.
  - Ireland also introduced a 25% R&D tax credit in 2014, designed to encourage companies to undertake new or additional R&D activity in the country—covering wages, overheads, plant/ machinery, and buildings. Stamp duty on IP rights were also abolished.
  - The 'Knowledge Development Box' introduced in 2016 was initiated to further reduce the rate of Irish corporation tax to 6.25% for profits derived from certain IP assets, where qualifying R&D activity is carried on in Ireland. This incentive can be claimed in conjunction with the R&D tax credit and 12.5% corporate tax rate.



Source: Why Ireland Is Attracting The World's Top Pharmaceutical Companies and How You Can Benefit, innopharmaeducation.com; Trends in the pharmaceutical sector, gradireland.com; Ireland is a home for 24 of the world's top biotech and pharma companies, siliconrepublic.com, 2017; Ireland Key For Pharma Companies, smartmbs.ie, 2019.

Ireland —An Incentivization Success Story Cont'd

Keys to Success— *Advanced R&D Hub*

- Over the years, Ireland has built a significant track record of clinical and academic research excellence. The Irish government also committed ~$9B (€8B) for research funding to bolster the country's reputation as a growing hub for R&D:
  - The Science Foundation Ireland (SFI), which generally funds research in the biopharmaceutical sector—especially focused on cancer, autoimmune diseases and Alzheimer's—signed a deal with Pfizer to help support drug discovery efforts in Ireland and globally.
- Over the years, Ireland has gained prominence in clinical and academic research excellence, particularly in the areas of Oncology, Immunology, & Neuroscience.

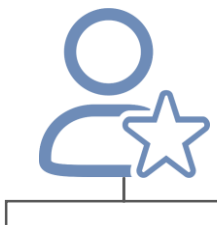
~$9B

Committed by the Irish Government for R&D

Keys to Success— *Large Talent Pool*

- Ireland has one of the youngest and most highly educated populations in Europe, providing a strong pool of talent for its pharma sector:
  - As international companies began setting up operations in Ireland during the 1950s & 60s, the Irish government instituted education system reforms to meet the needs of such firms, including the establishment of the Regional Technical College (RTC) system, supplemented by 2 National Institutes of Higher Education.
  - As a result, Ireland now produces a high volume of highly skilled graduates. The country has a participation rate of 98% in the education system, ranking it 6th in the world.
- Ireland's universities in Engineering, Chemistry, Bio-chemistry, and Bio-technology have had strong cooperative links with the pharma sector:
  - Feedback from the industry with regard to skills needed feeds directly into universities and drives the country's pursuit of Biopharma academic excellence.
- Currently, there are ~25K people directly employed within Ireland's pharma sector, with an additional ~25K indirectly employed providing support services.
  - Year-on-year job growth in the sector has been increasing by ~1K annually. E.g., the German Pharma company Allergen set up operations in Ireland in 1977, in Westport, employing 25 people. Today, the company employs over 1,700 staff across Ireland.

Skilled Pharma Workforce



25k

Directly Employed in the Sector

25k

Indirectly Employed Providing Support

Source: Bio-pharmaceutical Industry Ireland, idaireland.com; Ireland Key For Pharma Companies With an International Expansion Strategy, smartmbs.ie, 2019; Pharmaceutical industry: collaborating for health, eolasmagazine.ie, 2014.

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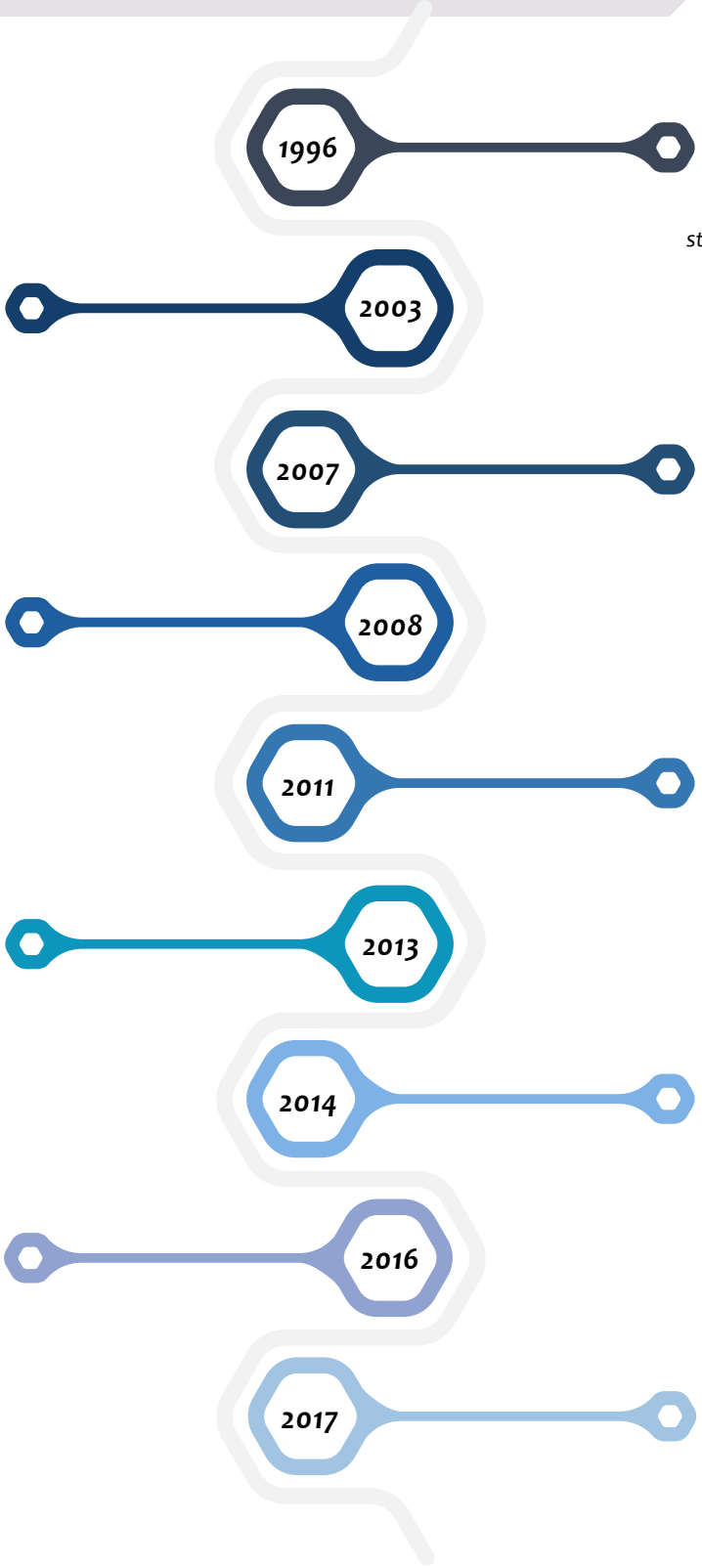
Ireland —An Incentivization Success Story Cont'd

Key Milestones



1996

Irish Medicines Board (IMB), established, replacing the National Drugs Advisory Board

Established as a safeguard to protect the public from sub-standard medical products, monitor all clinical trials, and ensure advertisers do not make false medical claims for their products

2003

Science Foundation Ireland (SFI) established

Responsible for funding applied research in the areas of science, technology, engineering & mathematics with a strategic focus

2007

Ireland Pharmacy Act legislated

Established the Pharmaceutical Society of Ireland (PSI) as the statutory regulator of pharma in Ireland

2008

Regulation of Retail Pharmacies

Specified requirements to be complied with on the sourcing, storage, sale, supply and keeping of records, in respect of medicinal products at retail pharmacies

2011

The National Institute for Bioprocess Research & Training (NIBRT) inaugurated

To serve the needs of the Irish bioprocessing industry by providing a world-class platform for research and training

2013

The Health (Pricing and Supply of Medical Goods) Act 2013 legislated

Allowed pharmacists to substitute prescribed non-generic medicines with less expensive generic alternatives

2014

The IMB renamed the Health Products Regulatory Authority (HPRA)

The objectives of the HPRA remained the same as those of the IMB

2016

The 'Knowledge Development Box' established

Reduced the Irish corporation tax to 6.25% for profits derived from certain IP assets, where R&D activity is carried out in Ireland

2017

Misuse of Drugs Regulations

Designed to prevent the abuse of certain substances that are considered to be dangerous, with a strong potential for abuse

Source: "legislation", thepsi.ie, Accessed, July 2020; "Health Products Regulatory Authority", hpra.ie, Accessed July 2020.

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Israel—The 'Start-up Nation' Success Story

Macro Indicators

Population	GDP P.C.	CHE P.C.	Pharma Exports
9M	$43,641	$3,145	$3,316M

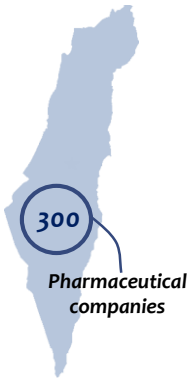
Keys to Success

- Teva— The Israeli Generic Drug Titan
- Leading Innovation Hub

Current Market

A Prominent Generic Drug Producer

- Israel's reputation in business has been built on the image of the start-up nation, as it hosts more NASDAQ-listed companies per citizen than any other country.
- Renowned globally for its technological prowess in fields like AgTech, Cybersecurity, and AI, the country has also made significant headway in the pharmaceutical arena.
  - The country has ~1,400+ companies in the Life Sciences sphere, which includes ~300 companies operating in the pharmaceutical space.
- There has been a strong focus on generics in Israel's pharma sector, and the growth of generic drug companies has driven much of the disproportionate export volumes that the country achieves every year.
  - In 2014, ~ 50% of all pharmaceutical companies in Israel, including Teva, Dexcel, Perrigo Corporation, and Unipharm, manufactured generic drugs. Teva is considered to be the largest generics manufacturer in the world.



Keys to Success— *Teva (The Israeli Generic Drug Titan)*

- Israel's pharma story starts with Teva, the undisputed colossus of the industry, which is one of the 15 largest pharma companies in the world today. Its revenue was ~$17B in 2019.
- Teva was originally set up as a distribution warehouse in Jerusalem for imported drugs, but after merging with a group of small drug companies in 1974, Teva Pharmaceutical Industries was formed.
- While Teva has expanded into the innovative space, generics still represent the central pillar of the company's business, as evidenced by its ~$41B acquisition of Allergan's generic activity in July 2015.
- In recent times however, management missteps & tectonic shifts in the pharmaceutical business have battered Teva, which faces declining prices for generic drugs and the loss of a patent on a major branded drug. More than $20B has been shorn from the company's market capitalization, cutting Teva's value roughly in half.

Source: How Israel Became a World Leader in Biotechnology, blogs.timesofisrael.com, June 2018; Israel's Life Sciences Industry IATI Report, 2019, iati.co.il, 2019; Pharma in Israel: building a global industry, pharmaceutical-technology.com, May 2016.

Israel—The 'Start-up Nation' Success Story Cont'd

Keys to Success— *Leading Innovation Hub*

- The Israeli government has provided significant incentives, both of a tax- and non-tax-based nature, to encourage international companies to set up R&D facilities in the country.
- Israel's scientific potential is well regarded globally, as the activities in various segments of the Life Sciences industry represent ~50% of the civilian research conducted at Israel's 7 universities, 10 research centers, and 5 schools of medicine.
  - The country has one of the world's highest concentrations of scientists per capita (145 for every 10K citizens), and 1 in 3 Israeli scientists specialize in some aspect of Life Sciences.
  - The country's biotech industry also boasts a high percentage of female innovators, with women accounting for 65% of the country's workforce and ~13% occupying top management positions in Tel Aviv's biomed index listed companies.
- Through its incentivized innovation climate, research centers such as the Weizmann Institute, the Hebrew University of Jerusalem, Tel Aviv University, and the Technion- Israel Institute of Technology have made significant medical discoveries, including the following:
  - The world's first nano medicine for treating various types of cancer, Doxil (known as Caelyx in the EU and Canada), was developed by researchers at the Hebrew University of Jerusalem.
  - The Weizmann Institute of Science incubated the ground-breaking multiple sclerosis drug 'Copaxone', which was one of the first Israeli produced drugs to receive approval from the US FDA.
- Additionally, advanced pharma & biotech companies in Israel have also made significant strides in innovation and R&D:
  - CytoReason developed the world's first and only machine learning-based model of the human immune system and the cells that power it, with an eye towards understanding how immune cells function in disease, tissue, and treatment contexts.
  - The National Institute of Biotechnology of Negev (NIBN)—the first independent, R&D-based entity founded as a company under the umbrella of a university (Ben-Gurion University of Negev)—focuses on treatments for cancer, infectious diseases, autoimmune and metabolic diseases, human genetic disorders, and neurogenerative diseases.
  - The company's technology has led to measurable real-world impact, including a 30% reduction in infant mortality among Israel's Bedouin population in the Negev Desert.

THE HEBREW UNIVERSITY OF JERUSALEM

TEL AVIV UNIVERSITY

WEIZMANN SCIENCE

TECHNION Israel Institute of Technology

אוניברסיטת בן-גוריון בנגב
Ben-Gurion University of the Negev
جامعة بن-غوريون في النقب

Source: Israel's R&D Prowess Is Fueling Pharmaceutical Innovation, itrade.gov.il,2019; Innovative Israel Creates Pharma Opportunity, pharmavoice.com, 2013; Pharmaceutical and Homeopathic Markets of Israel, integritas.co.il, 2017.

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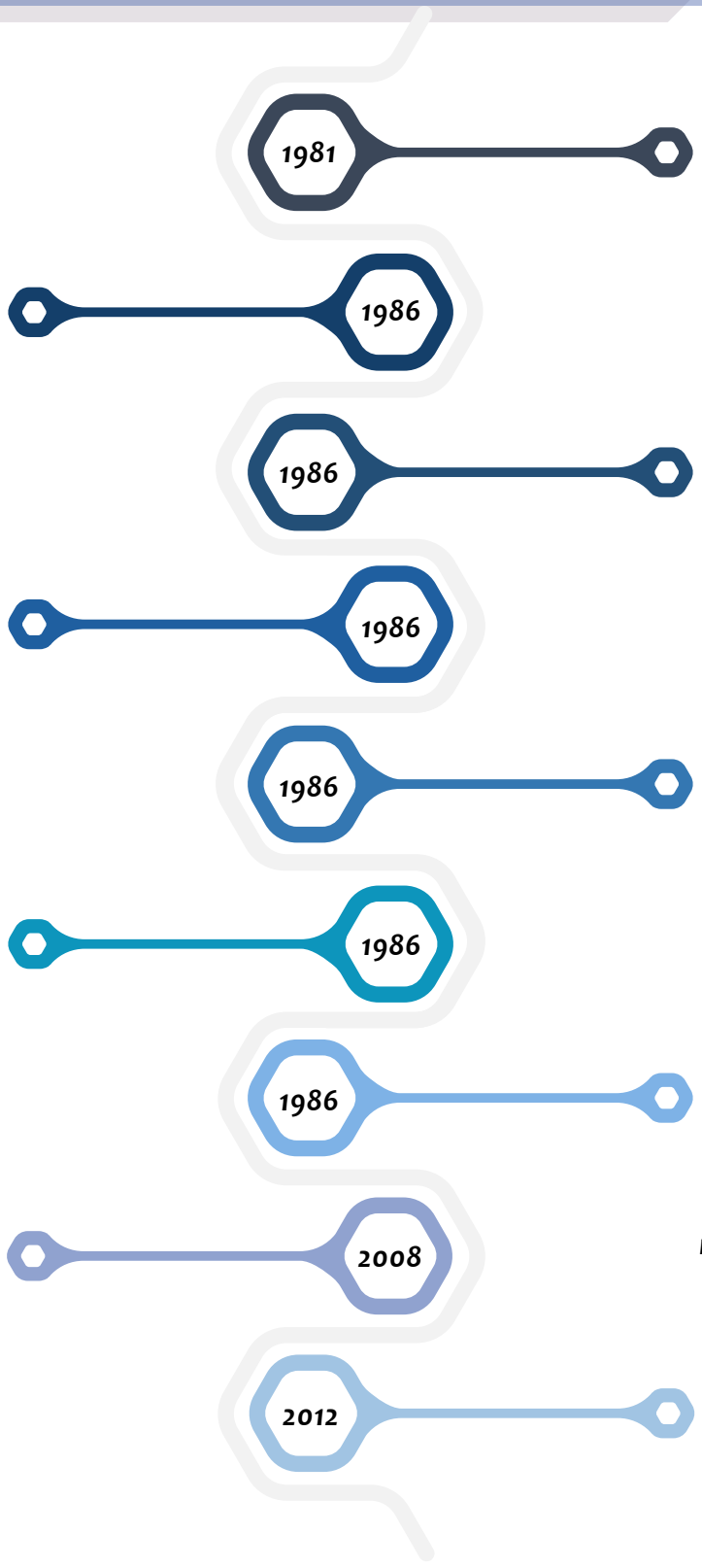
Israel—The 'Start-up Nation' Success Story Cont'd

Key Milestones



1981

The Pharmacists Ordinance

Regulates the manufacture, marketing, prescribing, importation and registration of medicinal products and also contains provisions relating to data exclusivity

1986

The Pharmacist Regulations (Preparations)

Established to regulate the marketing, prescribing, importation and registration of medicinal products and also contains provisions relating to pharmacovigilance and recall

1986

Pharmaceutical Department, established under the MoH

Authority responsible for controlling medical and pharmaceutical products, cosmetics, clinical experimentation on humans, prevention of pharmaceutical crime, and pharmaceutical services in Israel

1986

The Institute for Standardization and Control of Pharmaceuticals

Responsible for ensuring the quality of medicines marketed in Israel

1986

The Pharmaceutical Monitoring Section established

Responsible for the approval of labels and packages for medicinal products

1986

Registration Department established

Controlling body that deals with the registration of medicines in Israel

1986

Institute for Standardization and Control of Pharmaceuticals

Tasked with the responsibility of ensuring the quality of medicines marketed in Israel

2008

The Pharmacist Regulations (Good Manufacturing Practice) established

Enacted to further regulate the manufacture, importation and recall of medicinal products

2012

Pharmacovigilance and Drug Information Department, established under the MoH

Tasked with identifying, monitoring, and initiating activities aimed at minimizing risks associated with medication utilization

Source: Medicinal product regulation and product liability in Israel: overview, uk.practicallaw.thomsonreuters.com, accessed July 2020.

Singapore —A 'David vs. Goliath' Success Story

Macro Indicators

Population	GDP P.C.	CHE P.C.	Pharma Exports
~6M	$65,233	$2,619	$8,107M

Keys to Success

- Best-in-Class Infrastructure
- High Quality Workforce Development
- Innovation Ecosystem

Current Market

An Alluring Pharma Hub

- Singapore is a relatively young entrant into the global pharma space, given that the Singaporean government launched a national initiative to become a global hub for biomedical sciences in June 2000.
  - Within a mere span of a decade, the country emerged as one of the fastest growing bio clusters in Asia, with ~16k skilled workers, 30 research institutes, and manufacturing of ~$14B worth of medicines & devices for global markets.
- Singapore is also one of the few countries in the world that is net exporter with exports to leading destinations such as Switzerland, the Netherlands and Japan.
  - The country has more than 50 pharmaceutical manufacturing facilities, including plants owned by 8 of the world's 10 biggest pharma firms— GlaxoSmithKline, Merck Sharp & Dohme, Pfizer, Novartis, Roche, Sanofi, AbbVie, and Amgen.
- Singapore also offers excellent opportunities for biomedical science companies thanks to its pro-business environment, low corporate tax rate, and strong government support.

Keys to Success— *Best-in-Class Infrastructure*

- Singapore is home to many top-notch manufacturing facilities where a wide range of products across small molecules, biologics, cell therapy and medical nutrition are produced.
- The country has invested heavily in building up the relevant infrastructure to support global pharma companies to set up their manufacturing activities in Singapore through ready-built facilities and innovative partnerships.
  - Ready-built facilities such as the 'JTC Space' at the Tuas Biomedical park (TBP), provides industrial and lab space for pharma companies, which can be fitted out for single-use technology manufacturing platforms, allowing firms to set up production lines quickly and at a lower upfront capital cost. Today, TBP houses ~30 manufacturing plants in its vicinity.
  - Additionally, the government partnered with CMOs such as Lonza, Cellvec and ESCO Aster to develop and expand capacity options for commercial and clinical-scale production, as well as for new modalities, such as cell and gene therapy.

JTC Space & the Tuas Biomedical Park

Source: Singapore pharma sector an 'increasingly important' part of manufacturing: Fitch, straitstimes.com, 2019; Singapore a Pharma Hub for Asia, pharmavoice.com; Overview of the Singapore PharmBio Sector, pharmbiosingapore.com, accessed July 2020.

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Singapore —A 'David vs. Goliath' Success Story Cont'd

Keys to Success—*High Quality Workforce Development*

- Singapore has continued to prioritize the development of a workforce with high relevant skills for the pharmaceutical sector, which includes a strong pipeline of fresh graduates with industry-ready experience and capabilities.
  - As part of achieving this objective, the Government introduced the 'Professional Conversion Programme' (PCP), which provides Professionals, Managers, Executives, and Technicians with the opportunity to be re-skilled to potentially take on a new career in the pharma sector.
  - In 2019, Singapore's Economic Development Board, in collaboration with the Biopharmaceutical Manufacturers' Advisory Council (BMAC), launched a leadership training workshop for middle and senior managers in the Biomed Sciences industry, known as Project Zodiac, aimed at helping them develop self-awareness and leadership skills.
  - Moreover, Singapore established the 'Attach & Train Programme,' a talent development program aimed at building a pipeline of skilled manpower for the sector. Trainees in this program undergo on-the-job training with leading pharmaceutical companies.

Professional Conversion Programmes (PCP)
Reskill your competencies to take on new jobs

Keys to Success—*Innovation Ecosystem*

- The Singaporean Government committed ~$13B for research, innovation, and enterprise activities between 2011 and 2015.
- Additionally, the Government has invested heavily in building its biomedical & clinical research capabilities, and is home to several research institutes and consortia in key fields, such as Clinical Sciences, Bio-engineering, Molecular/Cell Biology, Genomics, Bio-imaging, and Immunology.
  - One such initiative was the 'Experimental Drug Development Centre,' set up by through the Agency for Science, Technology and Research, to advance and accelerate drug discovery in the island nation.
  - The 'Competitive Research Programme' (CRP) identifies strategic research areas where Singapore may want to invest and develop core capabilities.
  - The BMAC—made up of local pharmaceutical plant site directors and government agencies—was established to ensure that Singapore stays as a leader in R&D, manufacturing, and quality through the power of its workforce. It facilitates this by upgrading employees' skills, training new workers, and promoting best practices.
- To support Singapore-based biotech firms in their commercialization efforts, the Government set up the National Research Fund (NRF)-Temasek IP commercialization vehicle in 2018, committing ~$36M, to co-invest in start-ups (including biotech start-ups), whose business models are underpinned by IP generated from publicly-funded research.

A*STAR Experimental Drug Development Centre

National Research Foundation
Prime Minister's Office
Singapore

Singapore Government
Integrity Service Excellence
Competitive Research Programme

Source: Singapore Pharmaceutical Output up 86% this Year, gmpnews.net, 2020; Overview of the Singapore PharmBio Sector, pharmbiosingapore.com; Singapore Strengthens Position as Leading Site for Biopharmaceutical R&D, ddw-online.com, accessed July 2020.

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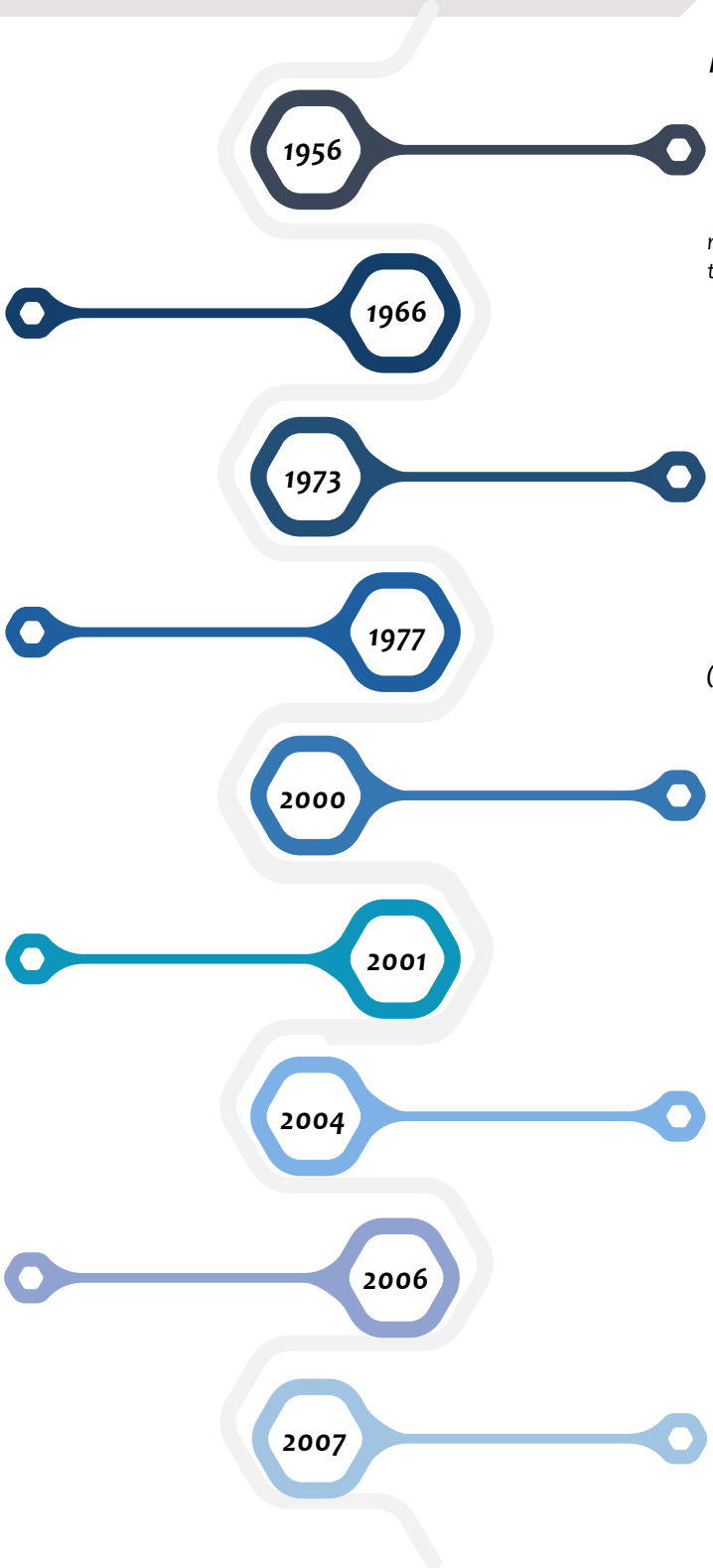
Singapore —A 'David vs. Goliath' Success Story Cont'd

Key Milestones



1956

Medicines (Advertisement and Sale) Act gazetted

Legislation to curb the proliferation of spurious and misleading advertisements for medicines & medical services, and to regulate the sale of substances recommended as a medicine

1966

The Health Sciences Authority, established under the Ministry of Health of Singapore

Established to highlight issues and support legislation that seeks to improve the pharmaceutical industry in Singapore.

1973

Sale of Drugs Act

Legislation to ensure that consumers are supplied with the quantity and quality of drugs demanded by them

1977

Medicines Act gazetted

The Act provides the main framework for the legal control of the importation, manufacture, distribution and advertising of medicinal products

2000

National Biomedical Science (BMS) Initiative, launched by the Singapore Government

An investment of $2.1B to develop the BMS industry into one of the key pillars of Singapore's economy

2001

The Health Sciences Authority, established under the Ministry of Health

The regulatory agency functioning as the national regulator for drugs, innovative therapeutics, medical devices & health-related products, ensuring they are regulated to high standards of safety, quality and efficacy

2004

Center for Drug Administration established

Rationalize and streamline the systems and processes for the evaluation and registration of western medicinal products in Singapore

2006

2nd Investment Tranche in the BMS initiative

Investment of $1B by the Singaporean government to build up clinical sciences capabilities

2007

The Health Products Act

Categorization of health products in accordance with their different characteristics & uses. Prescribes the standards for such products in relation to their formulation, composition, design, quality, safety, efficacy & presentation

Source: Singapore legal aspects of the health care system, rflegal.com, 2010; Singapore's Pharmaceutical and Medical Device Regulatory Environment: 2005 Update, pacificbridgemedical.com, 2005; Industry Organisations, dpseng.com.sg, accessed July 2020.

Jordan —An Old-School Success Story

Macro Indicators

Population	GDP P.C.	CHE P.C.	Pharma Exports
~10M	~$4,300	~$340	~$330M

Keys to Success

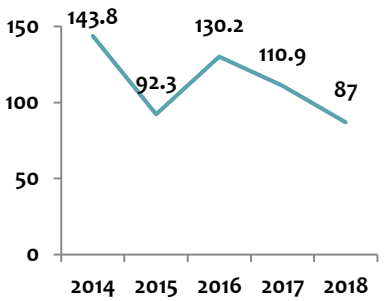
- First Mover & Regional Hub
- Center for Excellence
- Sustained Investment

Current Market

- Jordan is the only Arab country with higher pharmaceutical exports than imports, with 25-30% of manufactured drugs consumed locally, and the remaining 70-75%, exported to 60+ countries within MENA, the US, & Europe.
- It is the largest exporter of medicines to the Arab world, with the Gulf Cooperation Council markets fetching significantly higher drug prices than the world average.
- However, growth has fallen somewhat in the past few years as its traditional importers like Iraq, Saudi Arabia, Algeria, and Lebanon are building up their own production.

Net Exporter

Jordan Pharmaceutical Products Trade Balance, 2014-18
(in USD millions)



Keys to Success— *First Mover and Regional Hub*

- Jordan enjoyed first-mover advantage in the lucrative Gulf region by setting up manufacturing in the 1960's, and used a regional hub model to fuel success.
- Many Jordanian pharmaceutical manufacturers also got USFDA certifications, started extensive research on production of drugs nearing patent expiration, and began exploiting loopholes in Free Trade Agreements signed with the US and the EU in the early 2000's to build on its first mover advantage in marketing generics.
- Jordan was one of the first countries in the region to set up Free Zones.
- Its place as regional hub for overall healthcare quality is cemented by its booming medical tourism market as well.

Gulf Region

Source: ITC trade database, accessed June 2020; Pharma Boardroom country profiles; Worldometers.info; Pharma Move Forward, Venture Magazine, 2019.

Jordan —An Old-School Success Story Cont'd

Keys to Success— *Center for Excellence*

- The Country has ~18 providers of pharmaceutical qualifications (5 public; 13 private) with all providers offering a Bachelor of Pharmacy program, and two public schools (JU & JUST) offering a PharmD program.
- The language of instruction for all pharmacy teaching in Jordan is English, and the Faculty of Pharmacy at Jordan University (JU) in recent years has been taking serious steps in the direction of being internationally accredited with the Quality Assurance Agency (QAA) in the UK.
- In 2008, the industry had ~5K direct employees and ~8K indirect employees, which grew to ~10K direct employees & ~16K indirect employees by 2018. Nearly 40% of the workforce is female & two-thirds are highly skilled.

University of Jordan (JU)

Jordan University of Science & Technology (JUST)

Keys to Success— *Sustained Investment*

- The Govt. has always supported the development of the pharmaceutical industry, which the Kingdom built over half a century through specific capital infusions. In 2011, the Govt. invested $1.5B with the aim of taking the industry to broader international horizons.
- In 2018, Jordan's Government signed MOUs with the European Bank for Reconstruction & Development (EBRD) for the provision of technical assistance funds for eligible projects. Through this scheme, EBRD invested ~$5M into an equity stake in 'MS Pharma', based in Jordan and operating across the Middle East and North Africa, to be used in R&D, and commercialization of new drugs.
- Further, the Jordan Association of Pharmaceutical Manufacturers (JAPM), in collaboration with the USAID's 'Jordan Competitiveness Program,' has worked on several initiatives which have directly improved Jordan's pharmaceutical industry:
  - Automated drug registration to accelerate reviews of new drug submissions, especially locally manufactured generics.
  - Cleared a backlog of drugs awaiting registration.
  - Strengthened Jordan Food & Drug Administration (JFDA) through capacity building, workshops, coaching, & technical assistance.
  - Reformed regulations and processes to support drug manufacture and export.
  - Introduced an eCTD system that allows companies to register their drugs in foreign markets using internationally recognized standards, enabling faster and more competitive delivery.

European Bank for Reconstruction and Development

MS Pharma

JAPM The Jordanian Association of Pharmaceutical Manufacturers

Jordan Food & Drug Administration

USAID FROM THE AMERICAN PEOPLE

USAID Jordan Competitiveness Program

Source: ITC trade database, accessed June 2020; Pharma Boardroom country profiles; Worldometers.info; Pharma Move Forward, Venture Magazine, 2019; JAPM website, accessed June 2020.

Stax

Jordan —An Old-School Success Story Cont'd

Key Milestones

1972

Jordanian Practicing of Pharmacy Law gazetted

Regulations issued highlighting the role of retail pharmacists, and to a lesser degree, the role of importers, wholesales, and the manufacturing sector

1996

Jordanian Association of Pharmaceutical Manufacturers established

Established to support, develop & upgrade the Jordanian pharma industry to world-class standards through technology transfer, industry integration & the implementation of GMP

2003

Jordan Food & Drug Administration (JFDA) established

An independent national authority tasked with ensuring the safety and quality of food, and the efficacy, quality, and safety of medicines and related materials

2006

National Essential Medicines List (EML) initiated

Contains medicines & drugs considered to be effective and safe to meet the most important needs in Jordan's health system

2011

Law No 2 of 2011 on Clinical Studies gazetted

Provides regulations that govern drug related therapeutic and non-therapeutic clinical studies on human subjects

2013

Drug and Pharmacy Law No. 12 gazetted

Legislation that provides the framework for the legal control of the importation, manufacture, and distribution of medicinal products

2013

USAID Jordan Competitiveness Program (JCP) initiated

Supports the JFDA in streamlining & fully automating the drug registration process in Jordan, and increasing the competitiveness of Jordanian pharmaceutical companies exporting to regional markets

2015

Drug Registration Guidelines established

Specifies the guidelines and requirements for the registration of medicines

2018

MOUs with the European Bank for Reconstruction & Development (EBRD) signed

MOUs with the EBRD for the provision of technical assistance and funds for several sectors including pharma

Source: Industry Websites; Jordan's Regulatory Environment, ebrary.net, accessed July 2020; Jordan Pharmaceutical Country Profile, who.int/, 2011; Life Sciences 2020, Jordan, practiceguides.chambers.com, March 2020.

Stax

Morocco—An Unlikely Success Story

Macro Indicators

Population	GDP P.C.	CHE P.C.	Pharma Exports
37M	$3,204	$161	$117M

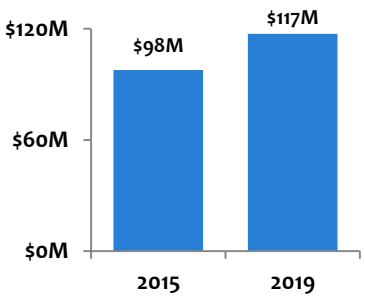
Keys to Success

A Sub-Saharan Platform for Pharmaceutical Generics

Current Market

- Morocco's domestic pharmaceutical market is currently the 4th largest in Africa (after Algeria, Egypt and South Africa) with a market worth ~$1.17B.
- With ~36 operational factories, the Moroccan market is a mature one with ~65% of drugs manufactured locally.
- In early 2013, the government launched new plans to boost the technology transfer of imported generics to manufacture them in Morocco instead.
- The country targets to reach a local market worth $2B billion & exports of ~$1.1B by 2023.
- Currently, Moroccan laboratories invest ~$30M per year in equipment, machineries and technology transfer.

Morocco Pharmaceutical Exports, 2015–19
(in USD millions)



> "We find the following characteristics: an industry of small batches, heavily dependent on imports of APIs, with high manufacturing costs and limited economies of scale. With a situation like this, one might have doubted the future of our pharmaceutical industry, but no such thing happened for the manufacturers, who never lost confidence and faith in their industry. The infrastructure is there, and this is what has made the country successful: I have personally received representatives from other countries, who were amazed with what we managed to put in place in the country."
>
> — *General Manager, Iberma*

IBERMA
Depuis 1993

Source: 7th International Exhibition for the Pharmaceutical Industry in North Afric, easyfairs.com, 2018; Morocco's Pharmaceutical Sector Took Key Step Forward, moroccoonthemove.com, 2016; ITC trade database, accessed June 2020.

Morocco—An Unlikely Success Story Cont'd

Keys to Success— *Active Governance & Control*

- The Moroccan government has played an active role in both encouraging and regulating local pharmaceutical producers, under the tutelage of the Health Ministry.
- Morocco actively monitors and assesses product quality at several levels. Upstream, the National Laboratory for the Control of Medical Products (Laboratoire National de Controle de Medicaments or LNCM) is the controlling laboratory, while downstream, the Health Ministry initiates controls at the pharmacy outlet level on an ad hoc basis.
- According to the pharmaceutical association, on an aggregate basis, Moroccan pharmaceutical manufacturers spend ~$34M annually on quality control measures. This is validated by the World Health Organization, which has classified Morocco as 'Europe-zone', implying that the quality controls are at European levels.
- The distribution of medical products in Morocco is done mainly via a network of 40 wholesalers that reach the country's pharmacies and hospitals. Wholesalers account for 80% of the flow, while 20% goes directly from manufacturers to pharmacies/ hospitals. State hospitals are supplied via the state run 'Pharmacie Centrale de Berrechid.'

World Health Organization

'Europe-zone' quality control classification

LNCM المختبر الوطني لمراقبة الأدوية
Laboratoire National de Contrôle des Médicaments

وزارة الصحة
Ministère de la Santé

Keys to Success— *Pharma-clusters*

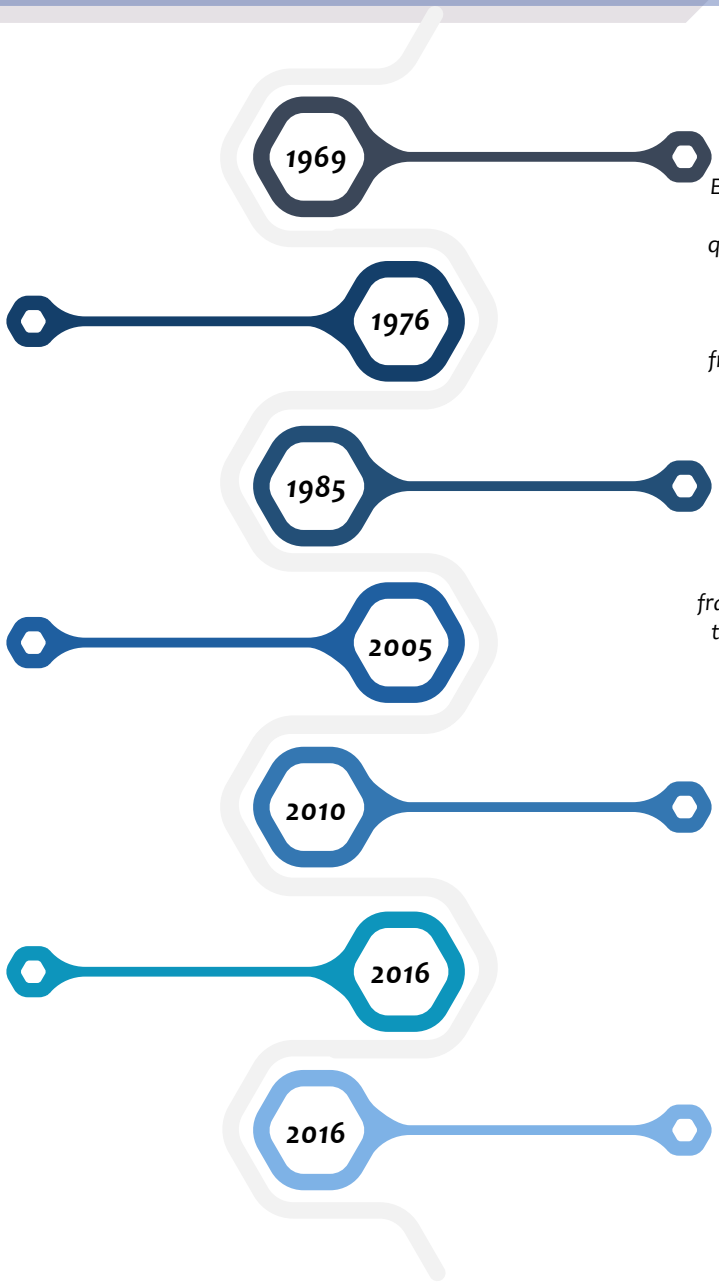
- In order to strengthen Morocco's pharmaceutical sector and boost value-added production, the Moroccan government signed a series of agreements with local pharmaceutical associations in 2016, paving the way for the implementation of the country's first pharma-clusters (ecosystems).
- With these agreements, Morocco planned to expand the manufacturing of both drugs and medical devices to bring the industry's contribution to GDP from 14% in 2016 to 23% by 2020, and create 500K new jobs.
- The government earmarked ~$45M in funding for the clusters, with specific segments – including medical devices, anti-cancer drugs and biosimilars– targeted to receive the bulk of the incentives.
- 2 ecosystems were planned to be developed on ~7 hectares of land, with one cluster specializing in the production of medical devices & the other focused on drug manufacturing, including R&D.

Pharma-clusters

Source: Pharma eyes export market, doingbusinessin.fr; How Morocco has forged new business frontiers, the-report.com; Morocco: The opportunities for the pharmaceutical industry, pharmaworldmagazine.com, 2018.

Morocco—An Unlikely Success Story Cont'd

Key Milestones



1969

Moroccan National Laboratory for the Control of Medicines (LNCM) established

Established to refer to and apply for international technical quality control standards, as well as for National Standards applicable to medicines and health products within the framework of the National Policy of the Ministry of Health

1976

Conseil de l'Ordre des Pharmaciens Fabricants et Répartiteurs (COPFR) established

Enacted to provide support to pharmacists and distributors by setting up training plans and scientific seminars

1985

Moroccan Association of Pharmaceutical Industry (AMIP)

Established to provide the pharmaceutical industry with a framework to represent and defend the interests of the profession, in consultation with all partners

2005

Les Enterprises Du Médicament Au Maroc (LEMM)

A professional association with the objective of providing patients, medical professionals & all healthcare providers, with innovative solutions, abiding to the strictest international standards

2010

Moroccan Association of Generic Medicines (AMMG) established

Representing manufacturers of generic pharmaceuticals, AMMG plays a key role in Morocco's health system by providing safe alternatives to the Moroccan patient

2016

Decree No. 2-14-841 on Marketing Authorization of Medicinal Products for Human Use

Introduced to improve the overall registration process, including issuing a marketing authorization of a reference product or biosimilar within 10 months, and for a generic within 9 months

2016

Morocco's First Pharma Clusters implemented

Under the agreements, Morocco plans to expand the manufacturing of both drugs and medical devices via the Industrial Acceleration Plan, which aims to increase the industry's contribution to GDP from 14% to 23% by 2020, and create 500K new jobs

Source: Industry Websites; "Morocco: The opportunities for the pharmaceutical industry", pharmaworldmagazine.com, Apr 2018; "Algeria, Morocco and Tunisia changing their regulatory landscape?", clarivate.com, Accessed July 2020; "Morocco focuses on special economic zones and investing in aeronautics", oxfordbusinessgroup.com, Accessed July 2020.

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Taiwan—A Next-Gen Success Story

Macro Indicators

Population	*GDP P.C.*	*CHE P.C.*	*Pharma Exports*
24M	$27,131	$945	$603M

Keys to Success

- *Open & Transparent Drug Policies*
- *Center for Research & Innovation*
- *Digital Nation & Smart Island*

The Next Regional Bio-Tech Powerhouse

Current Market

- Over the last few decades, Taiwan has been actively promoting biotechnology. In 1984, no Taiwanese biotech company was listed on a stock exchange; today, Taiwan boasts more than 100 listed firms with a combined value of ~$25B.
- Whereas 20 years ago, Taiwan had no lab with capabilities in toxicology, biosafety, & drug metabolism & pharmacokinetics (DMPK), several private companies now offer these services.
- Taiwanese biotech firms now have drug candidates in late stages of clinical trials in the US and other countries. The island has also not rested on its laurels but kept innovating—it now appears to be on the cusp of blending biotechnology with its considerable knowledge of electronics to create a new generation of innovative medical devices.
- The pharma market in Taiwan is estimated to reach $2.44B by 2021.

$1.77B

investment into Taiwan's biomedical industry in 2018

Keys to Success— *Open & Transparent Drug Policies*

- Taiwan's regulatory framework for medicinal products has been approved and accredited by the PIC/S: TFDA.
- With membership in PIC/S, Taiwan has demonstrated that its regulatory framework of manufacturing medicinal products—including legislation, GMP standards, inspection resources and quality management systems—meets international standards and norms.
- By being a full PIC/S Participating Authority, the GMP certificates and inspection results issued by TFDA are recognized globally.
- All pharmaceutical manufacturers in Taiwan have fully complied with PIC/S GMP.

PIC/S

Source: "Taiwan's biotech industry stands at a crossroads", cen.acs.org, June 2018; "Taiwan's Pharmaceutical Market Value to Reach $2.44 billion in 2021", globaldata.com, Oct 2017; "Taiwan Regulatory Framework for Medicinal Products has been Accredited by The PIC/S: TFDA", taiwan-healthcare.org, Aug 2017.

Taiwan—A Next-Gen Success Story Cont'd

Keys to Success— *Center for Research & Innovation*

- In line with the Taiwanese government's strategy of focusing on biotechnology, there has been public, stable funding of research for the past 20 years.
- Every year, the government has provided between $100M-$170M in funding to the Industrial Technology Research Institute, a large government lab that employs 6K people, 1.2K of whom have Ph.D.s., and the Development Center for Biotechnology (DCB)—a government lab created to boost Taiwan's drug development capabilities.
- In 2015, the Taiwanese government reduced income tax for the pharmaceutical industry in order to induce foreign multinational pharma companies to invest and set up in the country.
- In addition, Taiwan promoted its northern city of Hsinchu as a global manufacturing and R&D center.

$100M–$170M

ITRI Industrial Technology Research Institute

財團法人生物技術開發中心 Development Center for Biotechnology

Keys to Success— *Digital Nation & Smart Island*

- Due to its focus on innovation, Taiwan is sometimes referred to as 'The Israel of the East.' Aligning with the national policy of "Digital Nation, Smart Island," the government has promoted the "Digital Nation & Innovative Economic Development Program (DIGI+) 2017-2025," which sets out a clear framework for becoming a 'smart' island—alongside pillars such as AI and IoT, Biomedical is a industry.
- Since 2008, investment in Taiwan's biomedical industry has been growing steadily. The investment in 2018 reached $1.77B – 710M in the pharmaceutical sector, $560M in medical devices, and $510M in applied biotechnology. Taiwan is successfully applying its success in ICT, to replicate a similar ecosystem for the biomedical industry.
- The focus is on emerging areas such as e-health, cell therapy, and precision robotics and AI applications. Insilico Medicine – ranked within the top 100 AI companies worldwide – set up their R&D base in Taiwan in 2018 to strengthen their deep learning capacity in pharmaceutical chemistry and work with the Development Center for Biotechnology to develop new drugs.
- Taiwan is a global leader in semiconductor technology and that expertise is now being applied to facilitate the development of similar supply and manufacturing chains in regenerative medicine. Hitachi is expected to establish a cell manufacturing facility to develop innovative technologies for autologous cell manufacturing, allogenic cell manufacturing, analysis and detection.

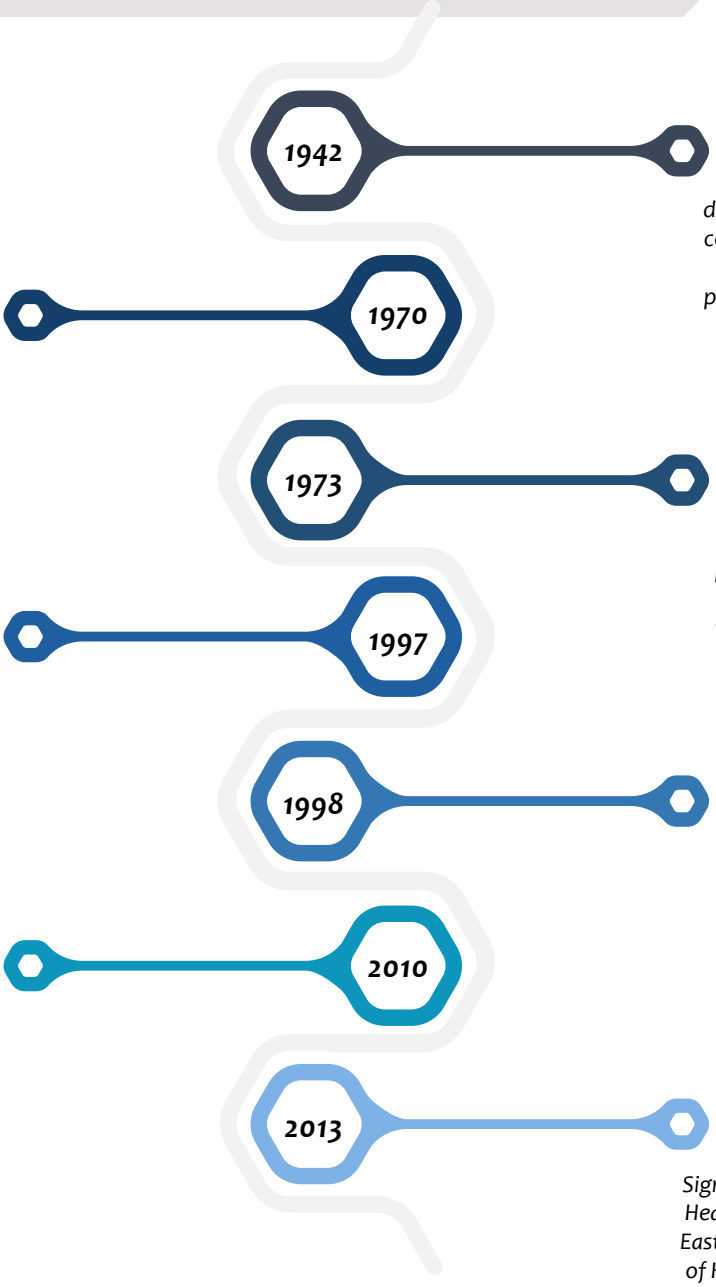
Insilico Medicine

HITACHI
Inspire the Next

Source: "Taiwan pharma market to hit $8bn but regs may limit homegrown R&D", outsourcing-pharma.com, Aug 2015; "Taiwan Regulatory Framework for Medicinal Products has been Accredited by The PIC/S: TFDA", taiwan-healthcare.org, Aug 2017; "Healthcare & Lifesciences Review", Pharma Board Room, Accessed July 2020.

Taiwan—A Next-Gen Success Story Cont'd

Key Milestones



1942

Pharmaceutical Society of Taiwan (PST) established

Focuses on the development of different phases in pharmacy— the committee of pharmacy education, pharmacy profession, industrial pharmacy, international affairs and the development of community pharmacy

1970

Pharmaceutical Affairs Law legislated

Regulates the manufacturing, importation, and sale of drugs and medical devices

1973

National Development Fund established

Initiated to accelerate industrial innovation & value addition, promote economic transformation & national development. Through the fund, $400M has been invested in the development & promotion of the pharma and biotech industry of Taiwan

1997

Taiwan Generic Pharmaceutical Association (TGPA) established

Part of the International Generic Pharmaceutical Alliance (IGPA), the TGPA is committed to promoting generic & biosimilar medicines, and exchanging information worldwide

1998

Center for Drug Evaluation (CDE) established

Set up to play the pivotal role of enhancing the efficiency and quality of drug evaluation, thus promoting public health and welfare, including timely access to innovative medicines

2010

Taiwan Food and Drug Administration (TFDA), established

Authority established to oversee food, drug, and medical device safety and quality. The TFDA deals with risk assessment, inspections, and market approvals for foods, drugs, biotech products, cosmetics, and medical devices

2013

Taiwan-Japan Cooperation Agreement on Pharmaceutical Regulations

Signed between Taiwan's Ministry of Health & Welfare, the Association of East Asian Relations, Japan's Ministry of Health, Labor, & Welfare, and the Interchange Association Japan as a response to the globalization of Taiwan's pharma industry with an aim to expand cooperation in bilateral pharma regulations between Taiwan & Japan

Source: Drug Approval System of Chinese Taipei, nifds.go.kr, 2015; Taiwan's TFDA, globalregulatorypartners.com; Pharmaceutical Affairs Act, law.moj.gov.tw; International Participation, cde.org.tw; Taiwan Pharmaceutical Association, omicsonline.org,; Pharmaceutical Society of Taiwan, fapa.asia, accessed July 2020.

APPENDICES

APPENDICES

Appendix 1—Varying Market Sizing Sources and Methodologies

Methodology 1

Calculation based on SPC Annual Reports + 2019 IMS data + Private Hospital Annual Reports

Pharma Market: Public Sector

Description	LKR	USD [e]	Imports	Source/ Notes
DHS (SPC Sales to Public Hospitals)	42,959,659,808	239,998,099	78%	SPC Financial Statements 2019; Import % - based on past SPC Financial Statements
Public Market 2019	*42,959,659,808*	*239,998,099*		
Value of Imports	*33,688,478,657*	*188,203,791*		

Pharma Market: Private Sector (also referred to as the Open Market)

Description	LKR	USD [e]	Imports	Source/ Notes
Retail Pharmacy Sales (incl. SPC) [a]	48,592,737,802	271,467,809	96% [b]	Value -IQVIA 2019; Import % based on SLPMA presentation, April 2020
SPC – Other Open Market [c]	8,591,569,594	47,997,595	33% [b]	Value -SPC Financial Statement 2019; Import % based on past SPC Financial Statements
Pvt. Hospital Pharmacy Sales [d]	6,927,546,259	40,670,122	96%	2018/19 Hospital Annual Reports; Import % based on SLPMA presentation, April 2020
Pvt. Practitioners [d]	692,754,626	3,870,138	50%	Stocking Doc. Sales = 10% of Pvt. Hospital Sales (based on IHP market segmentation, 2015); Import % based on SLPMA presentation, April 2020
Total Private Market 2019	*64,804,608,281*	*364,005,664*		
Value of Imports	*56,647,148,548*	*316,464,517*		

***N.B.* Methodology 1 is used when referring to market size throughout this report, as it uses as many direct sources as possible and appears to be the most robust when triangulated. Other methodologies are provided in the appendix for reference only.**

a. IQVIA data includes sales of 2,215 A Grade retail pharmacies (out of a total in the country of ~2,300). Only sales of certain molecules manufactured by SPC, that could be specifically identified on IQVIA, were considered inclusive in the value of retail pharmacy sales (accounts only for ~4% of overall SPC sales in the open market). This figure excludes sales made by Private Practitioners and Private Hospitals.
b. 96% of retail pharmacy sales and 33% of SPC sales are from import supplies.
c. The rest of SPC sales on the open market (~96% of LKR 8.9bn) have been segmented separately to avoid the underestimation of market size.
d. This is a conservative figure that includes only the largest private hospitals providing sales data in their latest annual reports. Being derived from this figure, the value for stocking doctors is also a conservative figure.
e. Avg. 2018 XR: 1 USD = LKR 162.5 ; Avg. 2019 XR: 1 USD = LKR 179

Appendix 1—Varying Market Sizing Sources and Methodologies

Methodology 2

Calculation based on 2017-19 Import Data

CBSL/OEC/ITC Data

Calculation	*USD*
• Imports of Medical and Pharmaceutical Products— 2019	*553,000,000*
• Pharma Imports Excl. Medical Devices	*376,040,000*[a]
• **Total Market 2019**	***442,400,000***[b]

Methodology 3

Calculating based on Imports— SLPMA Figure

Calculation	*USD*
• Imports of Pharmaceutical Products	*430,000,000*
• **Total Market—2019** [b]	***505,882,353***

a. Of total import expenditure on medical and pharmaceutical products, on average, ~68% is on pharma only, when ratios from 2017 -18 are taken into consideration.

b. ~85% of market is imports.

Appendix 1—Varying Market Sizing Sources and Methodologies

Methodology 4

Calculation based on 2019 IMS data

Calculation	*USD*
• IMS Sales (Open Market) 2019	*271,467,809*
• **Total Market 2019 (assuming IMS is 40%)**	***678,669,523***
• Value of Imports [a]	*576,869,094*

Methodology 5

Calculation based on 2018 Pharmexcil Report

Calculation	*USD*
• Total Pharma Market— 2018	*664,000,000*
• Total Pharma Market Forecasted—2022	*787,000,000*
• CAGR - 4.1%	—
• **Total Market— 2019**	***691,224,000***

a ~85% of market is imports

Appendix 1—Varying Market Sizing Sources and Methodologies

Methodology 6

Calculation based on 2015/16 HH Expenditure Survey - per HH

Calculation	*LKR*	*USD**
• Monthly HH Spend on Medical/ Pharmacy Products	*452*	*3.2*
• **Annual HH Spend on Medical/ Pharmacy Products**	***5,424***	***38***
• Number of Households = 5,400,000	—	—
• **Total Market 2015**	***29,289,600,000***	***204,822,378***

Methodology 7

Calculation based on HH Expenditure Survey - Per Person

Calculation	*LKR*	*USD**
• Monthly Spend on Medical/ Pharmacy Products— Per Person	*119*	*0.8*
• **Annual Spend Per Person on Medical/ Pharmacy Products**	***1,428***	***10***
• Number of People = 20,700,000	—	—
• **Total Market 2015**	***29,559,600,000***	***206,710,490***

Appendix 2—SLPMA Calculation of FX Saving

N.B. The information in the following box has been quoted verbatim, as provided to Stax by the SLPMA.

Following is a real comparison made between an imported branded generic product and a locally manufactured product of the same antibiotic. Two dosage forms are considered: an injectable antibiotic and a tablet form. This calculation compares forex savings in comparison with the local market leader.

Table 1:

Complex Product	USD, Mn (Total Spend)	Calculation
1. Value of Imported medicine CIF price	9.6	-
2. Value of locally manufactured medicine ex-factory price	3.9	-
3. Value of Imported Raw Materials for local manufacturing with applicable taxes + CESS	2.2	-
4. Forex Saving	7.4	(1 minus 3)
5. Forex Saving as Percentage of Import Value	77%	(4/1)*100

Notes for Table 1:

i. USD 9.6 Mn is the CIF value for 2019, all values in the table are for the year 2019 based on the assumption if the same number supplied to MSD was imported for the private market.
ii. Value of imported raw materials for manufacture are subject to duty and CESS where applicable.
iii. All values are calculated based on MSD supply figures since IMS data is not available for injectables, same methodology of calculation can be used for private market quantities.
iv. If applied to private market the same forex savings of 77% can be demonstrated. The value of total savings will change as per the quantity.

Table 2:

Basic Tablets Pack (50 Tablets)	USD, (Per 50 tablet pack)	Calculation
1. Value Of Imported Medicine CIF price	1.37	-
2. Value Of Locally Manufactured Medicine ex-factory price	0.92	-
3. Value Of Imported Raw Materials For Local Manufacturing	0.45	-
4. Forex Saving	0.92	(1 minus 3)
5. Forex Saving As Percentage Of Import Value	67%	(4/1)*100

Appendix 3—APIs Temporarily Restricted For Export By India

No.	Restricted APIs	IT HS Codes	Treatments
1	Paracetamol and formulations made of it	29222933, 30049099	drug used to treat fever, moderate pain
2	Tinidazole and formulations made of it	29332910, 30049023	drug used to treat amoebic and parasitic infections
3	Metronidazole and formulations made of it	29332920, 30049022	antibiotic to treat bacterial and protozoal infections
4	Acyclovir and formulations made of it	29335990, 30049099	antiviral medication to treat infections caused by viruses
5	Vitamin B1 and formulations made of it	29362210, 30045032	vitamin to treat or prevent thiamine deficiency
6	Vitamin B6 and formulations made of it	29362500, 30045039	vitamin to treat or prevent pyridoxine deficiency
7	Vitamin B12 and formulations made of it	29362610, 30045034	vitamin to treat or prevent cobalamin deficiency
8	Progesterone and formulations made of it	29372300, 30043919	used in hormonal therapy
9	Chloramphenicol and formulations made of it	29414000, 30042050	antibiotic to treat a number of bacterial infections
10	Erythromycin Salts and formulations made of it	29415000, 30042061	antibiotic to treat a number of bacterial infections
11	Neomycin and formulations made of it	20419050, 30049015	antibiotic to fight bacteria in the body
12	Clindamycin Salts and formulations made of it	29419090, 30042095	antibiotic used to treat a variety of serious infections
13	Omidazole and formulations made of it	29420090, 30049021	antibiotic used to treat protozoan infections

Source: India Ministry of Commerce and Industry, March 2020.

Appendix 4—Pharmacist Education Offerings in SL

University/ Institute	*Course*
National Institute of Health Sciences	Certificate of Proficiency as Pharmacist (awarded by the Ceylon Medical College Council)
University of Colombo	B.Sc. in Pharmacy
University of Peradeniya	B. Pharm
University of Sri Jayewardenepura	Pharmacy (Special) Degree course (04 years)
University of Sri Jayewardenepura	Pharmacy (General) Degree course (03 years)
University of Jaffna	B.Sc. Pharmacology
University of Ruhuna	B.Sc. Pharmacology
University of Kelaniya	Diploma in Ayurveda Pharmaceuticals
University of Kelaniya	B.Sc. Pharmacology
Open University of Sri Lanka	Bachelor of Pharmacy
KDU	B.Sc. Pharmacy
Sri Lanka Technological Campus	Diploma in Pharmacy Practice
Aquinas College Colombo	Diploma in Pharmacy Management & Practice
PATHE academy	Higher National Diploma (HND) in Pharmacy
Pharmaceutical Society of Sri Lanka	Diploma in Community Pharmacy
CINEC Campus	B.Sc. (Hons) Industrial Pharmaceutical Sciences
Flamingo Academy	Pharmacist (external) Training Course (examination by Ceylon Medical College Council)

State-run or -affiliated
Private

Source: University and other educational institution websites, accessed July 2020.

Appendix 5—Local Manufacturer Profiles

1 Aithra Pharmaceuticals (Pvt.) Ltd.

Aithra pharmaceuticals specializes in the manufacturing of creams, ointments, gels and lotions for the private and tender market of Sri Lanka.

FTEs: 5

Capacity – Current & Planned

- **CURRENT:** 1 facility in Palliyawatta, Wattala encompassing 5,000 sq. ft., with a capacity (dermatological products) of 80kg/ ltrs per day
- **PLANNED:** Additional plant within next 2–3 years in Horana/ Homagama to increase production by 50%

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- Derma Soft- 100g
- Drapocare- 30g
- Mycotin – 15g
- Sterosone- 15g
- Uriderm -100g, 50g

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

2

Astron Limited

Incorporated in 1956, Astron Limited specializes in pharmaceuticals, nutritional supplements, nutraceuticals, cosmeceuticals, herbals and animal healthcare. Currently exports to Maldives, Seychelles, Cambodia, Myanmar, and Singapore.

FTEs: 500

Capacity – Current & Planned

- **CURRENT:** 1 factory in Ratmalana
- **PLANNED:** Additional factory to be built in the Western Province over the next 2-3 years

Certifications/ Standards

- cGMP under WHO-GMP certification
- ISO/IEC 17025, ISO/IEC 17025: 2005 certified by Sri Lanka Accreditation Board for Conformity Assessment
- Best Supplier (SPC Private Sector) for 2016, 2017 and 1st Runner-up for 2018 at the State Pharmaceuticals Corporation (SPC) Supplier Convention

Registered Product List

- ALBENDAZOLE TABLETS IP 400MG
- AMLODIPINE TABLETS USP 5MG
- ATORVASTATIN TABLETS 10MG
- AZITHROMYCIN CAPSULES 250MG
- CHELINE SALICYLATE 8.714% & CETALKONIUM CHLORIDE 0.01% GEL
- CHLORPHENAMINE MALEATE 2MG & DEXTROMETHORPHAN HYDROBROMIDE 5MG/ 5ML SYRUP
- CODEINE PHOSPHATE BPC SYRUP 25MG/5ML
- FRAMYCETIN SKIN CREAM 1% W/W
- FUSIDIC ACID CREAM BP 2% W/W
- GLIPIZIDE TABLETS BP 5MG
- HYDROCORTISONE CREAM USP 1% W/W
- IRON WITH FOLIC ACID VIT.C & VIT. B COMPLEX
- KETOTIFEN FUMARATE SYRUP 1MG/5ML
- LORATADINE TABLETS USP 10MG
- METFORMIN HYDROCHLORIDE EXTE. RELE TABLETS USP 500MG
- MULTIVITAMIN & MINERALS CAPSULES FOR PREGNANCY
- OXYTETRACYCLINE 30mg &
- PARACETAMOL TABLETS BP 500MG
- PYRANTEL PAMOATE SUSPENSION USP 50MG/1ML
- SILDENAFIL CITRATE TABLETS 50MG
- TISOCONAZOLE 1% DERMAL CREAM
- VITAMIN & MINERAL SUPPLEMENT

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

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

Established as a family business in 1896, CDDEF is engaged in the manufacturing of pharmaceutical products including the antiseptic liquid 'DETTOL' brand, on behalf Reckit Benkiser (RB) Lanka Ltd.

FTEs: 33

Capacity – Current & Planned

- **CURRENT:** 1 production plant in Panadura with a capacity of ~200K ltrs per month. Sister company (SRND Pharma), also in Panadura, manufactures medicated plasters.
- **PLANNED:** New facility under discussion with RB to be developed within 2 years. Plans to manufacture new product range as well.

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

Contract Manufacturing of Dettol for RB

Medicated plasters

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

4 Celogen Lanka (Pvt.) Ltd.

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

FTEs: 172

Capacity – Current & Planned

- **CURRENT:** 1 Manufacturing facility in Pallekele, constructed at an investment of $18.5M (LKR 1.4B), and established as a JV between India & SL, with production capacity of 5B tablets/ capsules per year.
- **PLANNED:** Additional facility in development (90% completed) to be opened in Pallekele for the production of saline products.

Certifications/ Standards

- cGMP under WHO-GMP certification
- EU-GMP certification (to be obtained this year)

Registered Product List

- AMLODIPINE BESYLATE TABLETS USP 2.5MG
- ATORVASTATIN TABLETS IP 10MG
- BACLOFEN TABLET BP 10MG
- CALCIUM CARBONATE TABLETS USP 1.25g
- CAPTOPRIL TABLETS USP 12.5MG
- DEFERASIROX DIPERSIBLE TABLETS 100MG
- DOMPERIDONE TABLETS BP 10MG
- DOXEPIN CAPSULES BP 50MG
- FERROUS FUMARATE 182.4MG+ FOLIC ACID 0.4MG BP TABLETS
- HYDRALAZINE TABLETS BP 50MG
- HYDROXYCHLOROQUINE SULPHATE TABLETS USP 200MG
- LABETALOL TABLETS BP 100MG
- LEVAMISOLE HYDROCHLORIDE TABLETS USP 40MG
- LOSARTAN POTASSIUM TABLETS USP 50MG BIPILO 50
- METFORMIN TABLETS 500MG GLUMIN 500
- MYCOPHENOLATE MOFETIL TABLETS USP 500MG
- NALIDIXIC ACID TABLETS BP 250MG
- OMEPRAZOLE CAPSULES GASTRO RESISTANT 20MG
- PYRIMETHAMINE TABLETS BP 25MG
- SODIUM BICARBONATE TABLETS USP 600MG
- SULFADIAZINE TABLETS USP 500MG
- VALGANCICLOVIR TABLETS USP 450MG
- WARFARIN SODIUM TABLETS 1MG IP
- ZINC SULPHATE TABLETS USP 10MG

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

5 CIC Life Sciences (Pvt.) Ltd.

A manufacturer of oral solid dose medication (own brand and generics) and importer of analgesics, anti-ulcer drugs, drugs for diabetes control, and cough medicines (including expectorants) from India.

FTEs: 60

Capacity – Current & Planned

- **CURRENT:** 1 manufacturing plant in Welisara.
- **PLANNED:** Technical upgrade of factory to increase production, to execute the company's commitment to produce and deliver a combination of 7 products under a buy-back arrangement with the government. Additional facility also in the pipeline to manufacture and export existing & new product range.

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- ASPIRIN DELAYED RELEASE TABLETS USP 75MG
- ATENOLOL TABLETS BP 50MG TENOL-50
- ATORVASTATIN TABLETS IP 10MG
- AZITHROMYCIN TABLETS 250MG
- CLOPIDOGREL TABLETS USP 75MG
- GLICLAZIDE TABLETS 80MG
- METFORMIN TABLETS BP 500MG
- OMEPRAZOLE CAPSULES BP 20MG
- PRAZOSIN TABLLETS BP IMG

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

6 Diyatha Pharmaceutical and Healthcare (Pvt) Ltd

Established in 2013, Diyatha Pharmaceuticals, a subsidiary of Diyatha Holdings (Pvt) Ltd., specializes in pharmaceuticals and nutraceuticals.

FTEs: 100

Capacity – Current & Planned

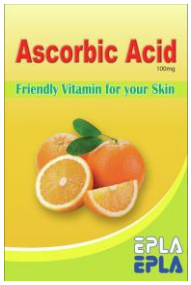
- **CURRENT:** 1 liquid medicine local product manufacturing plant in Ja-Ela opened in 2019, as a JV between Diyatha Pharma & SPMC. Current production capacity of 100K bottles each containing 100ml of medicine.
- **PLANNED:** N/A

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- CETIRIZINE ORAL SOLUTION BP 5MG/5ML
- CHLORPHENAMINE ORAL SOLUTION USP 2ML/5ML
- PARACETAMOL (PAEDRIATIC) ORAL SOLUTION B.P 120MG/5ML
- SALBUTAMOL ORAL SOLUTION 2MG/5ML



Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

7

Emergen Life Sciences (Pvt.) Ltd.

Established in 2012, Emergen specializes in the manufacturing of products covering the entire range of dry powder inhalation preparations (DPIs) to treat asthma and COPD.

FTEs:
150

Capacity – Current & Planned

- **CURRENT:** : One 40,000 sq. ft. facility in Kelaniya with manufacturing capacity of 1M capsules per day.
- **PLANNED:** Addition of expanded 'Clean Room' compliant to PIC/S standards & R&D lab for the manufacture of slow release tablets for local & export markets.

Certifications/ Awards

- GMP certification (NMRA)
- Silver medals at the 'Presidential Awards' for innovation, under the category of Medicine (2016)
- Awarded silver medal at the 'Salon International Des Inventions' in Switzerland, under the category of Medicine (2016)

Registered Product List

- ECLOMETHASONE AQUEOUS NASAL SPRAY BP 50MCG
- BECLOMETHASONE DIPROPIONATE DRY POWDER INHALA 200MCG
- BUDESONIDE NASAL SPRAY 64MCG/DOSE
- FORMETEROL FUMARATE 12MCG+BUDESONIDE 400MCG
- IPRATROPIUM BROMIDE BP 40MCG DRY POWDER FOR INHALAT
- LEVOCETIRIZINE CAPSULES 5MG
- PANTOPRAZOLE DELAYED RELEASE CAPSULES 20MG
- SALBUTAMOL SULPHATE DRY POWDER INHALATION CAPSULES
- SALMETEROL 50MCG & FLUTICASONE PROPRONATE 100MCG
- TAMSULOSIN HYDROCHLORIDE CAPSULES USP 0.4M
- TIOTROPIUM BROMIDE DRY POWDER INHALATION CAPSULES

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

8 Flexus Pharma (Pvt.) Ltd.

A privately held pharmaceutical manufacturer and distributor to government hospitals, the SPC, the National Blood Bank, private hospitals, clinics, and medical laboratories.

***FTEs:* 15**

Capacity – Current & Planned

- **CURRENT:** One medium-scale manufacturing plant in Biyagama with production capacity of ~200K m^3 per week.
- **PLANNED:** 1 new factory to be set up. Location and capacity TBD.

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- Betamethasone ointment
- Miconazole Nitrate cream
- Betamathazone cream
- Emulsifying Oinment
- Silversulphadiazine cream
- Hydrocortisone cream and oinment
- Fusidic acid cream
- Clotrimazole cream Benzyl Benzoate
- Diclofenac gel–cream
- Calamine lotion
- Methyl salicylate cream

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

9

Glaxo Wellcome Ceylon Ltd.

Manufacturing and marketing under the Glaxo Wellcome banner, the company offers several products including anti-ulcerants, respiratory products, systemic antibiotics, anti-virals, dermatologicals and anti-emetics.

FTEs: **225**

Capacity – Current & Planned

- **CURRENT:** 1 production plant in Kaldemulla, Moratuwa, with capacity to manufacture 2.5M 'Panadol' tablets per day, 1M 'Panadeine' tablets per month, & 50K ltrs of medicinal syrups per month.
- **PLANNED:** Additional facility for the manufacturing of 'Panadeine' to be commissioned in 2020.

Certifications/ Standards

- GMP certification (NMRA)
- ISO 9001: 2008
- PIC/S Certification (In progress)

Registered Product List

- CHLORHEXIDINE DIAGLUCONATE MOUTHWASH 0.2% W/V
- CHLORPHENIRAMINE MALEATE 2.5MG
- IRON & B COMPLEX
- PARACETAMOL (PAEDRIATIC) ORAL SOLUTION B.P
- PANADOL SYRUP
- SALBUTAMOL SYRUP BP 2MG/5ML

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

10

Himata (Pvt.) Ltd.

HIMATA
(PVT) LTD.

Specializes in the production of Povidone Iodine Solution.

FTEs: **15**

Capacity – Current & Planned

- **CURRENT:** 1 factory in Homagama. Production capacity for Povidone Iodine 500ml (80K bottles) & hand sanitizer (5L— *50K bottles*; 500ml— *100K bottles*) per month.
- **PLANNED:** New factory to be set up within the next 2-3 years to increase capacity by 50%.

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- Surgical Pharmaceutical Products:
  - Povidone Iodine Solution (Betadine)
  - Hand Sanitizer

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

11

Interpharm (Pvt.) Ltd.

Incorporated in 1990, Interpharm specializes in the manufacturing and marketing of liquid oral dosages, and generic drugs including antihistamines, multivitamins, and antacids for the state and private sector in Sri Lanka.

FTEs: **62**

Capacity – Current & Planned

- **CURRENT:** 1 manufacturing facility in Piliyandala, which includes a 3,000 sq. ft. laboratory for product analysis, quality control and quality assurance.
- In 2013, the company won a tender to supply 105M tablets to Government hospitals.
- **PLANNED:** N/A

Certifications/ Standards

- cGMP under WHO-GMP certification
- Products comply with the standards set by the British pharmacopoeia & US pharmacopoeia

Registered Product List

- CLINDAMYCIN HYDROCHLORIDE CAPSULES USP 300MG
- GLICLAZIDE TABLETS B.P 80MG
- METRONIDAZOLE TABLETS BP 200
- OMEPRAZOLE DELAYED RELEASE CAPSULES 20MG
- THEOPHLLINE PROLONGED RELEASE TABLETS BP 125MG

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

12

Gamma Pharmaceuticals (Pvt.) Ltd.

Was incorporated as Warner Hudnut Lanka (Pvt.) Ltd., before being rebranded as Gamma Pharmaceuticals. Gamma specializes in the manufacturing of mouthwashes, pharmaceutical creams, and ointments. It is also the holding company of Interpharm (Pvt.) Ltd.

FTEs: **62**

Capacity – Current & Planned

- **CURRENT:** 1 facility in Piliyandala, with a fully-automated Italian-made IMA C960 cream & ointment tube filling machine (capacity of 3,600 tubes/ hour with high dosing accuracy).
- Full manufacturing capacity of plant—200K tubes/ month
- **PLANNED:** N/A

Certifications/ Standards

- cGMP under WHO-GMP certification
- Products comply with the standards set by the British pharmacopoeia & US pharmacopoeia

Registered Product List

- ALUMINA , MAGNESIA & SIMETHICONE ORAL SUSPENSION WITH OXETACAINE
- BISMUTH ZINC AND HYDROCORTISONE COMPOUND OINTMENT
- DIPHENHYDRAMINE HCL ORAL SOLUTION USP 13.5/5ML
- DOMPERIDONE ORAL SUSPENSION 5MG/5ML
- HYDROCORTISONE ACETATE CREAM USP 1%
- THEOPHYLLINE ORAL SOLUTION USP 25MG/5ML
- THYMOL 0.013% & BENZOIC ACID 0.018% & METHYL SALICYLATE 0.02% ALCOHAL 7.0% MOUTHWASH

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

13

Lina Manufacturing (Pvt.) Ltd.

A pharmaceutical manufacturer specializing in dry powder inhaler capsules, nasal sprays, tablets, and creams. The factory was acquired by Akbar Pharmaceuticals (Pvt.) Ltd. in 2010.

FTEs: ***80***

Capacity – Current & Planned

- **CURRENT:** 1 plant in Ratmalana with Italian IMA Capsule machinery. Production capacity for tablets— 50kg per day; creams— 200 ltrs per day
- **PLANNED:** N/A

Certifications/ Standards

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

Registered Product List

- CAPTOPRIL TABLETS B.P 25MG
- METHYL SALICYLATE COMPOUND GEL
- PRAZOSIN HYDROCHLORIDE TABLETS IMG
- SALBUTAMOL DRY POWDER INHALATION
- SALMETEROL 50MCG & FLUTICASONE PROPRONATE
- DERMAFIELD CREAM 20G
- NEOPOZINE 450G
- AQUEOUS CREAM 100G
- EMULSIFYING OINTMENT 750G
- MENTHOL 1G
- SACHETSVASLINE 100 G
- MENTHIL 5G
- WINTERPAN GEL 350 GR.
- VASLINE 1KG
- WINTERPAN 1KG
- DERMAFIELD 500G
- AQUEOUS CREAM 750G
- VASLINE 750G
- LIQUID HAND WASH 5L
- EMULSIFYING OINTMENT 1KG

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

14

Medicom (Pvt.) Ltd.

Established in 1998, Medicom specializes in the manufacturing and distribution of medicinal disinfectant & pharmaceutical syrup products.

FTEs: **20**

Capacity – Current & Planned

- **CURRENT: :** 1 manufacturing facility in Dehiwala, including subcontracted production of alcohol-based hand sanitizer products for the SPMC
- **PLANNED:** N/A

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- ALCOHOL BASED HAND SANITIZER (RUB IN HAND DISINFECTANT)
- POVIDONE IODINE SOLUTION BP 10%
- MEDILAC LACTULOSE SYRUP
- CRESOL 50% V/V WITH SOAP SOLUTION
- CETIRIZINE HYDROCHLORIDE ORAL SOLUTION B.P. 1 MG/ 1 ML


Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

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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.

FTEs: **200**

Capacity – Current & Planned

- **CURRENT: :** One $13.5M investment into a state-of-the-art research & manufacturing facility within the SLINTEC Park in Homagama with a production capacity of 3B tablets per annum.
- **PLANNED:** N/A

Certifications/ Standards

- EU GMP Compliant— European Medicines Agency (EMA)

Registered Product List

- AMITRIPTYLINE TABLETS BP 25MG
- ASCORBIC ACID TABLETS BP 100MG
- CETIRIZINE TABLETS BP 10MG
- CHLORHEXIDINE 1.5%+CETRIMID 15% ANTISEPTIC SOLUTION
- CHLORPHENIRAMINE TABLETS BP 4MG
- CIMETIDINE TABLETS BP 200MG
- CLONAZEPAM TABLETS USP 500MCG
- CO-TRIMOXAZOLE TABLET BP 480MG
- DEXAMETHASONE TABLETS BP 500MCG
- DIAZEPAM TABLETS BP 2MG
- FAMOTIDINE TABLETS USP 20MG
- FURAZOLIDONE 100MG USP
- HYDROCHLOROTHIAZIDE TAB BP 50MG
- HYOSCINE BUTYLBROMIDE TABLETS BP 10MG
- LOSARTAN POTASSIUM TABLETS BP 50MG
- MEBENDAZOLE 100MG TABLET U.S.P
- PARACETAMOL TABLETS BP 500MG
- PHENOBARBITAL TABLETS BP 15MG
- PROCHLORPERAZINE TABLETS BP 5MG
- PROPANTHELINE BP 15MG

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

16

Navesta Pharmaceuticals (Pvt.) Ltd.

Specialized manufacturer of injectable penicillin (dry powder injectable Beta Lactam antibiotics).

FTEs: 200

Capacity – Current & Planned

- **CURRENT:** One factory in operation in Horana. It is a 40,000 sq. ft., sterile facility that is currently running at ~35% capacity. The full production capacity of the plant is 50M vials.
- **PLANNED:** Two more factories to be built in the next five years to expand capacity and product lines.

Certifications/ Standards

- GMP certification (NMRA)
- In the process of obtaining EU-GMP and PIC/S
- Certified by the BOI of Sri Lanka

Registered Product List

- AMPICILLIN FOR INJECTION B.P 1G, 250MG
- BENZYL PENICILLIN FOR INJECTION BP 600MG
- CLOXACILLIN FOR INJECTION 250MG
- CO-AMOXICLAV FOR INJECTION BP 1.2G
- FLUCLOXACILLIN FOR INJECTION BP 1000MG
- PENICILLIN G BENZATHINE FOR INJECTION 1.2MIU
- PIPERACILLIN & TAZOBACTAM FOR INJECTTION USP 4.5G
- TICARCILLIN SODIUM 3G + CLAVULANIC ACID 200MG

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

17

State Pharmaceuticals Manufacturing Corporation

Incorporated in 1987 and funded by the Japanese Government, the SPMC is the only state sector corporation engaged in the manufacture of pharmaceuticals (72 drugs under generic names), covering a wide spectrum of pharmacological categories.

FTEs: 260

Capacity – Current & Planned

- **CURRENT:** A 75,000 sq. ft. manufacturing facility consisting of 2 separate manufacturing zones, is equipped with Japanese and German machinery, and has a production capacity of ~2K tablets/ capsules per annum.
- **PLANNED:** Set up a JV facility with the CINTEC cooperation to manufacture morphine.

Certifications/ Standards

- cGMP under WHO-GMP certification
- Products comply with the standards set by the British & US pharmacopoeia

Registered Product List

- AMOXICILLIN CAPSULES BP 250MG
- ATENOLOL TABLETS USP 50MG
- ATORVASTATIN TABLETS IP 10MG
- BENZHEXOL TAB BP 2MG
- CETIRIZINE TABLETS BP 10MG
- CIMETIDINE TABLETS 200MG
- CIPROFLOXACIN TABLETS USP 250MG
- CLARITHROMYCIN TABLETS USP 250MG
- CLOXACILLIN CAPSULES BP 250MG
- DILTIAZEM HYDROCHLORIDE 60MG TABLETS USP
- DOMPERIDONE TABLETS BP 10MG
- ENALAPRIL MALEATE TABLETS USP 5MG
- ERYTHROMYCIN STEARATE TABLETS BP 250MG
- FAMOTIDINE TABLETS USP 20MG
- FRUSEMIDE TABLETS B.P 40MG
- GLICLAZIDE TABLETS BP 80MG
- INDOMETHACIN CAPSULES B.P 25MG
- LOSARTAN POTASSIUM TABLETS BP 50MG
- MEBENDAZOLE TABLETS USP 100MG
- METFORMIN TABLETS BP 500MG
- PARACETAMOL TABLETS BP 500MG
- PHENOXYMETHYLPENICILLIN TABLETS BP
- PREDNISOLONE TABLETS BP 5MG
- PROPRANOLOL TABLETS BP 40MG
- SALBUTAMOL TABLET B.P 2MG
- THEOPHYLLINE EXTENDED RELEASE TABLETS
- TOLBUTAMIDE TABLETS BP 500MG
- TRIFLUOPERAZINE TABLETS BP 5MG
- VERAPAMIL TABLETS B.P 40MG
- VITAMIN B COMPOUND

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

18

Unical Ceylon Ltd.

Established in 1964, Unical Ceylon commenced operations as a JV with Calmic Limited UK, for the manufacturing of pharmaceuticals for the Sri Lankan market.

FTEs: **40**

Capacity – Current & Planned

- **CURRENT:** 1 manufacturing plant in Katubedda
- **PLANNED:** N/A

Certifications/ Standards

- GMP certification (NMRA)

Registered Product List

- Unbranded tablets— Contract manufacturing for the Sri Lankan Government
- Vitamin C tablets— Subcontracted by A. Baur & Co.

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

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Universal Lifeline Ceylon (Pvt.) Ltd.

Universal lifeline

A pharmaceutical manufacturer specializing in the production of hand sanitizer products to multinationals and embassies, as well as exporting to the Maldives and Seychelles.

FTEs: **25**

Capacity – Current & Planned

- **CURRENT:** 1 manufacturing plant in the Mirigama Industrial Area. Current production capacity is at 100K bottles per month.
- **PLANNED:** Additional facility to manufacture new range of dermatological products in.

Certifications/ Standards

- cGMP under WHO-GMP certification
- ISO 9001: 8000 certification (In progress within next 2 years)

Registered Product List

- Hand Sanitizer (Zero Brand)

Source: Company website and press releases; Stax primary research; NMRA.

Appendix 5—Local Manufacturer Profiles

20

ACE Healthcare (Pvt.) Ltd.

Specializes in the manufacturing of cosmetic, dermatological, and nutraceutical products for both the local and international markets.

FTEs: 95

Capacity – Current & Planned

- **CURRENT:** Phase 1 manufacturing plant in Horana, for an investment of ~$13.5M (LKR 2.5B) focusing on cosmeceutical products
- **PLANNED:** Phase 2 (to be completed in 2021) will include an additional factory for pharmaceutical products (tablets, capsules, & syrups) with a capacity of 200k tablets per hour

Certifications/ Standards

- GMP certification (NMRA)— currently for cosmeceutical factory
- GMP certification (NMRA)— by 2021
- cGMP under WHO-GMP certification— to be obtained within 6 month after local certification of GMP
- EU GMP Certification (Proposed)

Registered Product List

- Full range of ayurvedic cosmeceutical products (approved by the NMRA)

Source: Company website and press releases; Stax primary research; NMRA.

Since 1961

SLCPI

Sri Lanka Chamber of the Pharmaceutical Industry

This report has been privately commissioned by the Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI). The research herein has been conducted independently by Stax Inc., and the viewpoints expressed are those best supported by currently available data and inputs from multiple stakeholders across the industry.

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