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**Disease prevalence and Incidence**

Non-Communicable Diseases (NCDs) are on the rise and are a leading cause of morbidity and mortality – ~62% of total reported global deaths are caused by NCDs. Largely, 65% of total deaths (Figure 1) in Sri Lanka are due to cardiovascular, cancers, diabetes, and chronic respiratory diseases. Traumatic injuries continue to be the leading cause of hospitalization. The determinants and risk factors – tobacco use, unhealthy diet, raise in blood glucose and blood pressure, physical inactivity, and harmful use of alcohol – are shared by these diseases (Figure 2). As per the Ministry of Health (MOH), every day ~ 600 people succumb to NCDs, and further, over 21,000 individuals die annually due to smoking in the country. The government has, however, made significant progress in curbing tobacco use by imposing a ban on smoking in public spaces, increasing the tax levied on cigarettes, and implementing other measures.

As per WHO, proportion of the population aged above 65 years will increase from 6.3% to 12.3% in Sri Lanka by 2020. As the prevalence of NCDs increases with age, these progressively aging populations will result in a corresponding increase in NCD cases. Moreover, while unplanned urbanization reduces options for physical activity and increases exposure to air pollution; globalization and underlying social determinants are driving unhealthy lifestyle behaviors (Figure 2). The Government of Sri Lanka declared 2013 as the “Year for Prevention and Control of Non-communicable Diseases”.

Sri Lanka provides universal care to its citizens and has performed well in controlling communicable diseases. Although significant achievements have been made in nearly eradicating/eliminating vaccine preventable diseases, leprosy, malaria, Japanese encephalitis, congenital syphilis, neonatal tetanus, lymphatic filariasis, etc. diseases such as dengue and some of the neglected tropical diseases such as leptospirosis continue to be a threat. Due to the demographic and epidemiologic transitions in the country on account of the marked increase in life expectancy and decrease in fertility rates; the poor become particularly vulnerable as the incidence of NCDs rises, and to require essential drugs and health services, one has to do out-of-pocket payments. Thus, such challenges need a reform at the primary healthcare level.
Sri Lankan Healthcare Systems

Sri Lanka is providing cost effective healthcare, free of direct cost to the patient. The maternal mortality ratio, neonatal mortality rate, life expectancy at birth and many more health indices are comparable with those of the developed world. While the government’s commitment to health and education is commendable, demographic and epidemiologic transitions pose new challenges which require reform of the primary healthcare model of the country. Several international partners are active in the health sector in Sri Lanka, including UN Agencies (ILO, IOM, UNDP, UNFPA, UNICEF, WFP and WHO), international NGOs, multilateral and bi-lateral organizations (World Bank, ADB, JICA, AusAID, USAID etc).

Sri Lanka has an extensive network of public health units and hospitals spread across the island. Hospitals in general are well staffed and equipped to meet the growing curative health demands of the community. There are a few Specialized Hospitals for the treatment of chronic diseases like tuberculosis, leprosy, mental illnesses, cancer, chronic rheumatic diseases and infectious diseases. These Hospitals are included in another category. There are close to 5,000 beds in these hospitals. The National Hospital of Sri Lanka (NHSL), located in the city of Colombo is the largest hospital in the island and has more than 3,500 patient beds. This hospital provides for a number of specialties, including subspecialties like neurology, cardio-thoracic surgery, but excludes pediatrics, obstetrics, ophthalmology and dental surgery. Renal transplant service is also provided by a collaborative project with the University Surgical and Medical Units of the Hospital.

Despite having well trained Medical Officers, Dental Surgeons, Assistant Medical Officers, Nurses and other paramedical personnel; the public health sector has inadequate capacity, limited access to specialist treatment and inconsistent service standards. The availability of complex surgical procedures and specialist care in the public sector is limited to the National Hospital of Sri Lanka in Colombo and a few other large hospitals in major cities. The waiting list for this type of care is usually very long. In addition to a disparity in the available care between rural and urban areas, the health infrastructure in the north and east of the country is poor owing to damage caused during the country's civil war.
Synopsis of Sri Lankan Pharmaceutical Market

Pharmaceutical Market Size and Historical Data
A growing and ageing population will boost demand for pharmaceuticals. According to the UN Population Division, the number of people living in Sri Lanka will increase from 18.85mn in 2000 to 22.58mn in 2022 – a rise of nearly 20%. The percentage of the population over 65 years of age will jump from 9.4% in 2000 to 16.0% in 2020, which means that investment in healthcare facilities and treatment will be necessary.

The government's 2014 budget, outlined in November 2013, allocated as much as LKR2,000mn ($15mn) to tackle non-communicable diseases under a three-year plan focusing on improvements in infrastructure, this is more than double the LKR900mn that was earmarked in the 2011 budget when Mahinda Rajapaksa was sworn in for his second presidential term. The new budget allocated a total of LKR74.1bn ($562.4mn) to both healthcare and education spending, up from LKR46.1bn ($350.3mn) in the 2012 budget, although the authorities did not provide separate figures for the two sectors.

Spending on healthcare services accounted for 3.3% of Sri Lanka's GDP in 2012. This was below the regional and global averages, but above that of neighboring India. Although healthcare expenditure is forecast to increase in absolute terms over the next decade, we predict spending as a percentage of national wealth will decrease to xx% of GDP by 2017. Totaling LKRxxbn ($xxbn) in 2012, and accounting for xx% of total expenditure, the private sector accounts for the majority of healthcare spending. Out-of-pocket payments represent the primary channel. Private sector spending by both, Non-Government Organizations (NGOs) and insurance plans is minimal.

Leading Therapeutic Areas
The Sri Lankan pharmaceutical market was estimated to be ~$xxm in 2013, out of which, the market value of the private sector was ~$xx million (source: IMS 2013) with an annual growth of X%. Alimentary & Metabolism, Cardiovascular, Anti-infectives and Respiratory are among the main therapeutic categories wherein cardiovascular category shows the highest growth (Figure 3).
According to the WHO, in Sri Lanka, cardiovascular diseases account for ~xx% of the deaths, while cancer and respiratory diseases account for x% (each) followed by diabetes (x%). As compared with other geographies, NCDs are on the rise in Sri Lanka, and it accounts for ~xx% of diseases in the country (World Bank’s Human Development Network). The generics-driven market is majorly focused on alimentary and metabolism segments with the highest growth coming from the cardiovascular therapeutic area.

As per IMS 2013 data, top five therapy areas were -

, Respiratory, and CNS (Figure 4). Therapy areas, which either recorded flat or declined sales, were while

, and reported robust growth.
Basic resources such as water, electricity, and un-skilled human resources are available with ease in the country. Sri Lanka lacks skilled professionals for advance pharma manufacturing.

**Active Pharmaceutical Ingredients (APIs) and other supportive industry:** Sri Lanka does not have any local manufacturer of APIs and other input required for drug formulations.

**Future Growth**

Healthcare spending in Sri Lanka is expected to increase from LKR252.10bn (US$1.98bn) in 2012, to LKRxxxxbn (US$xxxxxbn) by 2017. The key driver of growth will be a strong economy, underpinned by newly established political stability, although inflation will also play a part.

Sri Lanka's patented drug market is expected to be worth US$xxxxmn, or in the region of xx-xx% of the total pharmaceutical market, which we define as combined sales of OTC medicines, generic drugs and patented drugs. Patented drugs are estimated to account for less than half of the prescription market. The demand for patented drugs will on one hand be stimulated by the strengthening private sector, but on the other, depressed by the government's focus on increasing the use and prescription of generic drugs. Additionally, the high contribution of out-of-pocket spending to healthcare expenditure will continue to focus patients' attention on cheaper products and the non-traditional segment, despite the government's warnings that 30,000 'quacks' are known to practice Western medicines, homeopathy and Ayurveda traditional medicine in Sri Lanka.

Based on our market analysis, we expect growth will come from the current leading therapy areas in future where newer medicines may be able to gain market share (Figure 5), and accordingly, we have designed the product portfolio.
**Medicine Supply and Accessibility**

The State Pharmaceuticals Corporation (SPC) is the sole importer of medicinal drugs for the state sector, and also imports a significant proportion of drugs for the private sector. Pharmaceuticals are purchased on a system of worldwide tenders, restricted quotations or monopoly quotations. Drugs imported for the state sector are distributed through the government’s Medical Supplies Division whereas those imported for the private sector are sold at SPC retail outlets (Raajya Osu Salas), Franchise Osu Salas and other private pharmacies.

**Government (MSD) purchase of hospital supplies through Medical Supplies**

The Medical supplies division (MSD) is managed directly by the Line Ministry who is responsible to ensure timely and smooth distribution of drugs and selected medical supplies. Though the Sri Lankan health system is decentralized, the countrywide requirement of drugs and medical supplies are purchased centrally by the MSD through the State Pharmaceutical Corporation (SPC). Depending on the demand and estimated requirements (provided by all provinces), quarterly requirement is distributed to 26 Regional Medical Drug Stores (RMDS) located in 26 health districts.

According to the Ministry of Health budget, the funds allocated to purchase medicine/devices for MSD have risen from LKR16.7bn ($127mn) in 2012 to LKR31bn ($237mn) in 2014. MSD would retain ~25% of the allocated budget for emergency purchase in case of shortages. MSD distributes nearly 1000 varieties of essential drugs to government hospitals and dispensaries. Health ministry Budget allocation to purchase drugs was LKR28bn in 2013 for SPC and SPMC.

Funds allocated for the purchase of pharmaceuticals in the past 4 years (Table 2)–
Current Status of Pharmaceutical Manufacturing in Sri Lanka

Local Manufacturing and its Current Status

Major generic pharmaceutical manufacturers in Sri Lanka are State Pharmaceuticals Manufacturing Corporation (SPMC), MSJ, Astron, GSK, and Interpharm. Annual capacity (one shift) of SPMC is xxx billion Units Tablets/Capsules and MSJ has capacity of xxx billion tablets and xxxKL liquid preparations. MSJ started operations in 19xx and Interpharm (gamma pharma) started in 19xx, with no new pharma company setting up mfg plant in the last xx years.

More than xxx different variations of products are manufactured locally which accounts for xx products (brands) registered by local pharma companies with CDDA. Out of this, registration of xx products has expired. Local manufacturers have the capability to manufacture tablets, capsules, syrup, cream, elixir, solution, lotion, gel, ointment formulations (Table 7). Currently, No local company is manufacturing injectable formulations in Sri Lanka. These products are generally supplied to SPC, MSD by participating in an open tender and directly in the private market through their own network.

Table 7

<table>
<thead>
<tr>
<th>Dosage forms</th>
<th>Astron</th>
<th>SPMC</th>
<th>MSJ</th>
<th>Interpharm/ Gamma pharma</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td></td>
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<td>Capsules</td>
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Source: CDDA-registered products; MP Advisors

Issues and challenges for local players:

- The Sri Lankan market size is very small for economies of scale to work for most of the drug products. Thus, the competition in price with bigger generic players of India and Bangladesh is very difficult, if the Country continues to import multi-brands for all the generic products.
- It also reduces the chances of the plant being utilized to its full capacity as portfolios of products need to be produced in the same place. This may also hamper the productivity of the plant due to several products’ change over (cleaning areas and change parts of the equipments for different drug products) during production.
Regulatory, Pricing, Insurance Framework

Regulatory Status in Sri Lanka

The drug regulatory authority of Sri Lanka is the Cosmetics, Devices, and Drug regulatory authority (CDDA) and there are no state controlled regulatory agencies. CDDA intends to provide a legislative framework to control the use of pharmaceutical drugs with respect to its Registration, Manufacture, Importation, Sale (wholesale and retail), Labeling, Transportation, Advertising, Distribution of samples, Testing (through NDQAL) and Disposal of expired /outdated products.

Local GMP compliance certificate is required to start manufacturing for the domestic market while WHO cGMP is required for export. For importer/ foreign suppliers - need to submit stability data of the real time; however, in the case of local manufacturers, six months stability data (accelerated) is required. ICH guidelines are well in place. The registered products will have an initial one year provisional license followed by 5 years validity which can be renewed.

All local pharmaceutical manufacturing facilities are inspected at least once in every two years to assess the compliance with GMP. Currently, foreign manufacturers are only required to provide attestation by the competent authority of that country that a given product has been manufactured in its premises and has used operating practices that conform to GMP.

Country is flooded with numerous brands of generic medicines that cause confusion in the market. Sri Lankan regulatory authority (CDDA) registered over 10,000 drug products and (Table 9) local producers manufacture around 300 products. More than xx% products registered are from Indian manufacturers. The registration of more than xx% of products registered with CDDA has expired.

Approval timeline (Table 10) – New molecule to Sri Lankan market – will take 12-18 months and subsequent entrants will get approval within a year. New molecule has to be evaluated by Drug Evaluating Sub Committee (DESC). Registration cost of new molecule – LKR xxxxx + VAT (3 batches stability data, 3 packs sample of the same batch, xxx tabs, labeling and carton samples while registering the product) and registration cost of subsequent entrants – LKR xxxxx + VAT.