Overview of Healthcare Environment – Singapore and Malaysia

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Project Background and Scope

An overview of the Healthcare Environment from Market Prognosis for Singapore and Malaysia, based on the following content

- Healthcare Provision (Healthcare System, Healthcare Policy, Healthcare Financing and Expenditure)
- Prescribing and Dispensing (Prescribing Influences and Trends, Drug Subsidies, Hospital Formularies, HTA and Dispensing)
- Pricing (Pricing System, Discounts and Margins)
- Regulatory Environment (Drug Registration, Clinical Trials, IPR)
- Pharmaceutical Business Environment (Industry structure, historical generics market, distribution, sales and Marketing)

- QuintilesIMS Market Prognosis reports are leveraged to produce this report

- Country covered: Singapore & Malaysia
- Time Period for Reports : Q1 2017

Healthcare System

Healthcare System

- Singapore's healthcare system is based on a mixed public/private model
- Government-owned providers including six acute general hospitals handle around 80% of inpatient care, with the private sector made up of 11 private hospitals catering for the remainder. The picture is reversed in the primary care setting
- Singapore's public healthcare system will undergo major reform during 2017, with the Ministry of Health (MoH) reorganizing the existing six regional health systems into three integrated clusters – National University Health System in the west, National Healthcare Group in central, and Singapore Health Services in the east

Healthcare Policy

- The MoH is progressing towards the three strategic objectives (accessibility, quality and affordability) laid out in its Healthcare 2020 Masterplan
- MoH has scheduled addition of 2,900 more beds in acute and community hospitals between 2016 and 2020
- MoH projected that medical manpower (including doctors, nurses, pharmacists and allied health professionals) will have to be increased by about 50% equivalent to an additional 20,000 staff by 2020, from 46,000 in 2011

Healthcare Financing and Expenditure

- Medisave, MediShield Life and Medifund (the 3Ms) are the main source of public healthcare financing
    - Medisave - a compulsory personal savings scheme, with fund withdrawal allowed for certain medical expenses
    - MediShield Life - a basic medical insurance plan
    - Medifund - an endowment fund set up by the government to help needy Singaporeans who are unable to pay for their medical expenses
    - 3Ms are financed by individual contributions and government subsidies
- Public healthcare spending had almost doubled between 2012 and 2015, driven by commitments to the implementation of initiatives laid out in the Healthcare 2020 Masterplan
- In 2014, the government spent S$7.3 billion on healthcare – equivalent to 1.9% of GDP and pledged to raise healthcare spending to S$8 billion by 2016, however surpassed the target in 2015 with actual health expenditure of S$9.2 billion

Prescribing and Dispensing (1/2)

Prescribing Influences and Trends

- Singapore is an out-of-pocket market, with patients bearing the major share of pharmaceutical expenses
- Government policy favors the use of generics in public facilities
- Purchasing by pharmacy departments in private hospitals is limited largely to inpatient

Drug Subsidies

- 'Subsidized' patients receive 50% off charges for subsidized drugs, while children and the elderly are entitled to 75% discounts in all public healthcare facilities
- Low-to-middle income patients are now entitled to 75% off their subsidized drugs bills, Pioneer Generation members receive an additional 50% discount on top of such benefits
- The MoH will gradually expand the number of subsidized drugs listed on the Standard Drug List (SDL) or (Medical Assistance Fund) MAF
- The list of subsidized drugs will remain dominated by generics, and originators of innovative products will continue to face obstacles in gaining access to the wider patient population in the public sector

Hospital Formularies

- The core formulary (or 'hospital drug list'), which is revised by the Pharmacy and Therapeutics Committee on an on-going basis, contains products that are stocked by hospitals on a regular basis
- Few private hospitals operate explicit formularies. Physicians in individual private clinics operating within hospitals decide independently on which drugs to stock
- Accessing hospital formularies will be increasingly difficult, however, as more hospitals have begun to operate 'one drug per class' or 'one-in/one-out' approaches to formulary listing
- To access unregistered products, physicians must apply to the Health Science Authority (HSA) for authorization to import the drug on a 'named-patient' basis

Prescribing and Dispensing (2/2)

Health Technology Assessment (HTA)

- The Agency for Care Effectiveness (ACE) – established in August 2015 – will play an increasing role in MoH decision making where the inclusion of drugs on its subsidy lists is concerned
- Assessment procedures are not regarded as very scientific, however, and decisions are influenced heavily by the outcome of analyses carried out elsewhere, particularly in the UK by the National Institute of Health and Care Excellence (NICE)

Dispensing

- With little prospect of a move towards the separation of prescribing and dispensing functions, hospital pharmacies and clinics will continue to dominate dispensing activity
- Generic substitution is only permitted if the pharmacist receives consent from the prescriber
- Physicians will be reluctant to give up their dispensing rights, since dispensing profits can account for as much as 50-60% of total income generated by private GPs

Pricing

Pricing System

- There is no formal price control system for pharmaceuticals in Singapore, with price dictated by purchasing practices, market competition and patient affordability
- Prices in the public sector are controlled indirectly by the tender system operated by the Government Procurement Office (GPO)
- Public hospitals and polyclinics procure around 90% of their drugs jointly through the GPO
- Patient affordability will continue to affect pricing strategies for innovative specialty products in the public sector

Discounts and Margins

- Discounts will remain widespread in both the public and private sectors
- In the public sector, discounting will be driven primarily by GPO purchasing strategies, while in the private sector offering bonus will be employed as an incentive for dispensing doctors to purchase a particular brand
- Mark-ups of up to 30% are imposed on the drugs prescribed and dispensed in both public facilities and private clinics

Regulatory Environment

Drug Registration

- Singapore's Health Science Authority (HSA) will continue to overhaul regulatory requirements and processes, realigning domestic regulations with international standards and enhancing regulatory efficiency
- While the registration process for new drugs is generally regarded as efficient, the HSA will continue to enhance regulatory procedures, improving the efficiency and transparency of regulatory reviews. The authority approved Singapore's first monoclonal antibody biosimilar, Celltrion's Remsima (infliximab), in March 2016
- A consolidated Health Product Act (HPA), regulating all health products in Singapore, became effective in November 2016

Clinical Trials

- Singapore will remain a leading regional hub for multinational clinical trials in Asia. The country will face competition for shares of the clinical research pie from neighboring markets, however, with Singapore's small patient population and clinical trial costs counting against it
- Major contract research organizations, including Quintiles, Covance, MDS Pharma, Pharmaceutical Product Development and Icon, have established a strong presence, and are ideally placed to address the growing Asian market for clinical trials

IPR

- Intellectual property protection (IPP) available to originators will remain comprehensive by regional standards, but multinationals will lobby for the provision of longer data protection periods
- The IP Office of Singapore (IPOS) invested S$65 million in 2013 to strengthen its manpower and technical capabilities, aiming to double its pool of some 2,000 IP professionals by 2022
- Singapore is a party to the ASEAN Intellectual Property Rights Action Plan 2011-2015. The ASEAN Patent Examination Co-operation program reduces the cost and time required to obtain a patent in the ten member countries

Pharmaceutical Business Environment

Industry structure

- The local industry comprises just four companies: Beacons Pharmaceuticals, ICM Pharma, Sunward Pharmaceutical and Leung Kai Fook (LKF) Medical. Presently, around 30 of the world's top pharmaceutical, biotechnology and medical technology companies have their regional and international headquarters in Singapore

Generics market

- Pro-generic policies and increased access to subsidized medicines will drive up demand for generics, but low prices will limit generics market value. Biosimilars will offer attractive cost-saving opportunities, but the market for follow-on products will be limited in volume terms
- According to QuintilesIMS audit data, branded generics and copy products are responsible together for almost 85% of sales by volume. Their share of the market by value currently stands at around 42%. Branded generics dominate, with products sold by (International Non-Proprietary Name) INN generating just 3% of sales through audited retail, clinic and hospital channels (4.7% by volume)

Distribution

- Without separation of prescribing and dispensing functions, the role played by most distributors will be limited largely to that of logistics providers – though some will expand their offerings to the provision of sales and marketing activities for key principals. The generics market will remain crowded, with some 20 domestic distributors chasing government tenders for the supply of generics to public health facilities

Sales and Marketing

- The promotion of medicines is regulated by the HSA under the Medicines Act 1975 and its subsidiary legislation, the Medicines (Medical Advertisements) Regulation 1977. Rules requiring pre-publication approval of promotional materials are being relaxed, with self-regulating industry codes expected to govern activity in future. Physician detailing will remain key to the promotion of individual brands, but companies will have to pursue a more client-centric approach to marketing

Glossary of local terms

Glossary	
ACE	Agency for Care Effectiveness
ASEAN	Association of South East Asian Nations
GPO	Group Purchasing Office
HPA	Health Product Act
HSA	Health Sciences Authority
IPOS	Intellectual Property Office of Singapore
IPP	Intellectual Property Protection
MAF	Medical Assistance Fund
MoH	Ministry of Health
SDL	Standard Drug List

Malaysia

Healthcare System

Healthcare System

- The Ministry of Health (MoH) maintains overall responsibility for public healthcare provision, although administrative powers have been devolved to regional, state and district-level bodies
- Private healthcare is available through private hospitals and clinics, with treatment largely paid for by patients on an out-of-pocket basis

Healthcare Policy

- A strategic plan for healthcare drawn up by the Ministry of Health (MOH) under the 11th Malaysia Plan for 2016-2020 includes several measures designed to improve healthcare delivery. The plan sets out to improve on the existing primary and secondary care delivery network by increasing coverage and efficiency. Efforts are underway to encourage investment in healthcare; build up the primary-care network; and to establish Malaysia as a favored destination for medical tourism
- Expansion of the public healthcare delivery network is underway as part of the Government Transformation Plan (GTP) for the period to 2020. Government investment in the clinics network, medicines, and the recruitment of health personnel will improve access to healthcare, helping to narrow the gap between the public and private sectors

Healthcare Financing and Expenditure

- The public and private sectors accounted for 55.2% and 44.8%, respectively, of total health expenditure in 2014, compared with 54.8% and 45.2% in 2013
- Public health expenditure rose by 13.2% to M$24.6 billion in 2014, while private health expenditure was 11.7% higher at M$19.9 billion
- Public spending in the sector is dominated by the MOH, which accounts for 87% of the total. Private spending is dominated by out-of-pocket payments, which accounted for 78% of all private health expenditure in 2014
- Government funds will continue to underpin the majority share of healthcare expenditure, with slow economic growth limiting increases in out-of-pocket spending

Prescribing and Dispensing (1/2)

Prescribing Influences and Trends

- Prescribing trends will continue to be differentiated by sources of funding
- Doctors employed in government facilities will prescribe widely by generic name, in accordance with MOH Drug Formulary or the 'Blue Book' listings and the National Essential Drug List (NEDL)
- The government's healthcare reform program (earlier known as '1Care for 1Malaysia'), if implemented, would drive major changes in prescribing and dispensing behavior in Malaysia – not only through the introduction of a common formulary and reimbursement schedule for patients under a national health insurance scheme, but by separating the two functions

Pharmaceutical Purchasing

- The MoH Drug Formulary includes 320 chemical entities within 30 therapeutic groups, covering around 13% of all scheduled medicines registered in Malaysia, or some 2,900 preparations. The latest edition of the MOH Drug Formulary lists 1,666 preparations by generic name
- The MoH sources most drugs through one of two purchasing methods:
    - Tenders – issued for the supply of multisource drugs
    - Contract purchases – applying to patented drugs and some other products
- Multisource drugs on the ministry's Approved Product Purchase List (APPL) are procured through Pharmaniaga. About 50% of the MoH's medical product requirements are met through Pharmaniaga
- Pharmaniaga will continue to supply public hospitals through to 2019, and its contract may be extended beyond that date

Prescribing and Dispensing (2/2)

Separation of Prescribing and Dispensing

- Plans for the separation of prescribing and dispensing (SPD) functions in Malaysia are the most anticipated element of a new Pharmacy Bill drawn up by the government, but have yet to reach Parliament. As of March 2017, the bill remained mired in contention, with strong resistance from the powerful medical lobby, and the government was seeking further input before finalizing a draft
- There are concerns that ministerial policy on SPD is being swayed by government-linked companies (GLCs) with an interest in expanding their retail pharmacy interests. There has been some speculation that a restrictive policy on drug reimbursement (e.g., a positive list of reimbursable medicines) might be implemented in pharmacies to favor GLCs, or that reimbursement for medicines might be limited by therapeutic class

Pricing

Pricing System

- There is no formal price control mechanism for either prescription pharmaceuticals or non-prescription drugs
- In the public sector, some indirect price control mechanisms are employed by MoH to ensure fair, reasonable, affordable and stable prices. Procurement strategies, which are the most prominent example, include:
    - Using Pharmaniaga as a conduit for the purchase of most multi-source drugs
    - Lengthy tender agreements, awarded to single suppliers and at fixed prices
    - Negotiated supply agreements for products not on the APPL
- Though manufacturers are free to set their own launch prices for new drugs, ex-manufacturer sale prices for products added to the Formulary must be submitted to the MoH. These prices are subject to monitoring by regulators, while prices offered to government facilities must not exceed the price quoted to the MoH at listing for a period of one year
- Drug prices in the private sector were impacted by the implementation of Goods and Service Tax (GST), ringgit depreciation and the challenging macroeconomic environment between 2015 and 2016. With 8,630 prescription medicines 'zero rated' for GST as a result of measures contained in the 2016 budget, the impact of the tax on prices has moderated, and it is not expected to have a significant impact on future price trends
- The MOH has published a consumer price guide (CPG) online, in line with the revised National Medicines Policy (NMP) of Malaysia, which serves as a guidance on the availability of medicines and their prices for consumers

Discounts and Margins

- Retail pharmacies and clinics purchase drugs at the wholesale price, receiving bonus offers of free goods depending on the purchase order volume. Guidelines limit the level of free goods provided to 30%
- A distribution-only model, or ‘the logistic model’, usually allows for a margin of 5-10%, while the distribution plus sales model, will allow for a margin of 25-35%
- Retailer margins vary from less than 20% to 30%, depending on levels of competition in individual market segments and the geographical area they serve
- Average wholesaler discounts are in the 5-10% range, while average retail pharmacy/clinic discounts are around 15-20%, depending on the purchase order volume
- Explicit regulation of discounts and bonuses may be considered, depending on how stakeholders in the drug distribution chain respond to GPTP guidelines and other measures aimed at improving price transparency and fair trade in the private sector

Regulatory Environment

Drug Registration

- The Drug Control Authority (DCA), which oversees the drug approval process, is part of the MOH's National Pharmaceutical Control Bureau (NPCB)
- Formal approval timelines are laid down in the DCA's client's charter. For prescription and OTC drugs, they are as follows:
  - New chemical entities (NCEs): 245 days
  - Other prescription and non-prescription drugs: 210 days
  - Abridged applications:60 days (80 days for fixed-dose combinations)
- Registrations are valid for fixed five-year periods, after which license holders have to apply for renewals. Registration fees charged by the DCA are M$2,200 for standard new drugs and M$4,000 for NCEs. Charges are higher for products containing multiple active ingredients, while companies entering the Malaysian market must also pay annual fees for import (M$500) and manufacturing (M$1,000) licenses
- Compliance with new standards and regulatory requirements will drive up local industry costs, while approval delays for new drugs and preferential treatment of locally-manufactured products will remain key areas of concern for multinationals

Clinical Trials

- In 2015, 128 clinical trials were conducted in MOH facilities – slightly ahead of the annual target, which was set at 120
- The MOH's own clinical research center, now known as Clinical Research Malaysia, has been corporatized. It acts as a clearing house for study funding and a center for business development, training and marketing
- Growth in the number of clinical trials conducted in Malaysia will be driven partly by government incentives under Economic Transformation Program (ETP). With pharmacoeconomic requirements becoming necessary to support MOH Drug Formulary listings, originator companies will step up the volume of clinical studies conducted in local populations

IPR

- Malaysia's membership in the Trans Pacific Partnership (TPP) agreement will strengthen intellectual property protection in the longer term, encouraging trade and investments from other TPP signatories that could enable it to enjoy a first mover advantage among the ASEAN nations, along with Singapore and Vietnam

Pharmaceutical Business Environment

Industry structure

- Multinationals will continue to dominate the top end of the corporate sales rankings. Partnership agreements between local and foreign players will be used to lever the entry of specialty products into the market
- Several multinationals have entered into or are negotiating technology-transfer agreements under the government's Pharmaceutical Off-Take Agreements
- Local manufacturers are partnering with new players pursuing entries into the Malaysian market through technology transfer agreements, manufacturing contracts and joint ventures

Generics market

- The MOH is the biggest buyer of generics, followed by GPs and private hospitals. Retail pharmacies account for only a minor share of the generics market
- Unbranded generics account for only 4.1% of sales by value (8.5% by volume) in audited retail and hospital channels. Demand for generics will continue to rise, driven by patent expiries and the government's desire to contain healthcare costs

Distribution

- The dynamics of pharmaceutical distribution are unlikely to change appreciably until major healthcare reforms are implemented in Malaysia. Separation of prescribing and dispensing, if introduced, would have an appreciable impact on patterns of ordering and delivery, as well as related issues such as electronic networking
- The distribution of imported generics is also undertaken by local wholesalers and distributors, among which Apex Pharma, Summit and the third-party logistics provider, IDS, are leading players

Sales and Marketing

- In a reformed healthcare system, pharmaceutical company promotional strategies will shift from transactional relationships with dispensing doctors to target pharmacists as more important arbiters of product choice. Promotions to doctors in the private sector will then place more emphasis on product information and education

Glossary of local terms

Glossary	
APPL	Approved Product Purchase List
ASEAN	Association of South East Asian Nations
DCA	Drug Control Authority
GLCs	Government Linked Companies
GPTP	Good Pharmaceutical Trade Practice
MoH	Ministry of Health
NCE	New Chemical Entity
NEDL	National Essential Drugs List
SPD	Separation of Prescribing And Dispensing
TPP	Trans Pacific Partnership

Interreg
Estonia-Latvia
European Regional Development Fund

EUROPEAN UNION

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