

Thai Pharmaceutical Market Analysis

Final Report

September 2015



Contents

- **Executive Summary**
- Pharmaceutical Market Overview in Thailand
- Regulation Aspects
- Key Stakeholder Mapping
- Summary & Recommendation

Innovative drugs and being listed in NLEM will benefit MNC Pharmacom to penetrate in Thailand market

Current market situation



Implications to MNC Pharma

- Healthcare market in Thailand is projected to present the good growth in usages due to aging population, higher incidence of Chronic diseases & Non-communicable diseases, together with the hospital expansion in term of hospital number and beds
 - Drugs of Antibiotics, Antineoplastics (oncology), Anti-cholesterol, and Diabetes together contribute the large portion in total market value
 - Being listed in NLEM is the key driver of market expansion due to the high usage at Medical schools and government hospitals under 3 healthcare schemes
 - There is the aggressive competition between Originators and Generics due to cost-containment policy implemented by CGD (Ministry of Finance). Some Originators' manufacturers have decided to launch a fighting brand to compete with local generics. Aggressive discount promotion is being offered to maintain its market share in the market
 - Even Pharmacy shows rapid growth as nationwide coverage with many locations (~16,000 pharmacies nationwide as of 2015), hospitals remain the main channel for drug dispense
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- Innovative drugs will advantage MNCs to compete in Thailand pharmaceutical market as local manufacturers do not have competency in this aspect.
 - If MNC pharmaceutical companies would like to capture the market share and be able to absorb the lower profitability, being listed in NLEM as soon as possible will give them the great potential due to government hospitals significantly dominate the drug dispense
 - In case that MNC pharmacoms have OTC drugs in their product portfolio, pharmacy channel is highly attractive due to its nationwide coverage with numerous outlet numbers. Together with the high influencer of pharmacist over patient's purchase decision making on brands and products.

Fighting brand (generics) or price positioning as premium generics can advantage MNC pharmacom in competition as well

Law & regulation



Implications to MNC Pharma

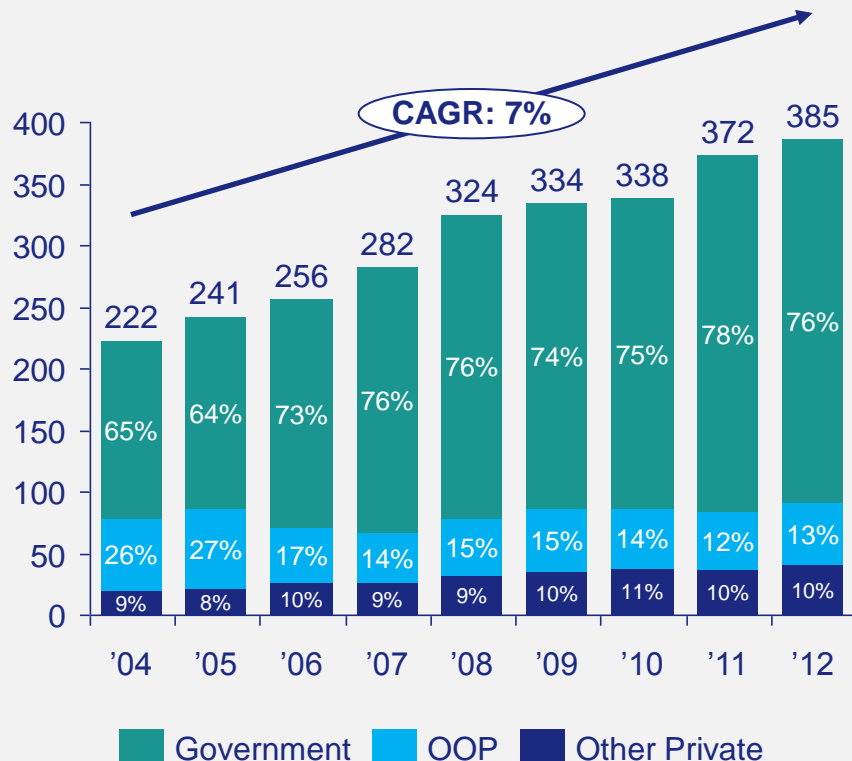
- Centralized procurement and Median price setting by CGD are the key pressure to Originators to sustain in Government hospitals as these policies benefit Generics producers (local) rather than MNCs
 - Restricted markup on CSMBS' reimbursement on Non-NLEM will encourage government hospitals to prescribe Originators over Generics thus current Originators' companies head toward to private hospital and Pharmacy market to substitute the decreasing usage in government hospital sector
 - If it is eventually approved, the 'Single Price Policy' will force private hospitals to push sales on Generics rather than Originators in order to maintain their business profitability due to the much lower cost of Generics which provide the large room for markup
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- The alternative of fighting brand offered by MNC pharmacom can assist the company in aggressive competition with generics and cost containment policies by government
 - Among all 3 healthcare schemes, CSMBS shows the highest potential for new MNC players to access Thailand market as this scheme has more flexibility in term of treatment budget approval on original drug prescription compared with the other 2 schemes (Universal Coverage and Social Security Scheme)
 - If MNC pharmacom can position their product price in between that of current original drug and generic drug (for each drug indication or drug class), there is the opportunity for company to seize the gap in private hospital market due to the single price policy as hospitals can gain higher profit from their offer on original drug (higher profit than current original but less profit than generics) but hospital can serve patients the better drug efficacy

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Government priority on healthcare accessibility and increase in private spending are the key drivers of Thai healthcare sector

Healthcare spend per capita evolution (USD)



Key facts about Healthcare industry in Thailand

- Thailand population of 67 million in 2014. By 2050, the number will be increased to 82.5 million
- There are 22,019 doctors and 17,476 specialists in Thailand
- Number of **hospitals** is 1,221 serving 122,347 beds
 - ✓ Government: 955 hospitals (96,889 beds)
 - ✓ State-enterprise: 6 hospitals (925 beds)
 - ✓ Municipality: 3 hospitals (44 beds)
 - ✓ Private: 257 hospitals (24,489 beds)
- Number of **pharmacy** is 16,566 Pharmacies
- 99% of the Thailand population has healthcare cover, funded by one of 3 payer schemes:
 - ✓ Universal Coverage (UC) for those not in government or formal employment
 - ✓ Civil Servants Medical Benefits Scheme (CSMBS) for all government employees
 - ✓ Social Security System (SSS) for those formally employed

Source: WHO; IMS Market Prognosis

There are 3 healthcare schemes playing an important role in healthcare accessibility to Thai nationals

Healthcare coverage in Thailand

Scheme/Detail	Universal Coverage Scheme (UCS)	Social Security Scheme (SSS)	Civil Servant Medical Benefit Scheme (CSMBS)	Private Insurance ^{1/}
Scheme nature; coverage	Citizen entitlement (those not covered by SSS or CSMBS); comprehensive	1.5% of salary equally by 3 parties; comprehensive	Non-contributory scheme; comprehensive , higher than UCS & SSS	Private contract
Beneficiaries	Thai citizens	Private sector employees, excl. dependents	Government employees, dependents ^{2/} (and retirees)	Those insured
% Population covered (est.)	75%	16%	9%	Est. 6-9 mill ^{3/}
Source of finance; Cap ^{4/}	General tax (US\$ 79/cap)	Pay-roll tax, Tri-party (employer-employee-govt); (US\$ 71/cap)	General tax, non-contributory scheme; (US\$ 367/cap)	Insurance buyers; as per contract
Management organization	NHSO, MOPH	Social Security Office, Ministry of Labor and Welfare	Controller General Department, Ministry of Finance	Private insurance companies

1/ Additional coverage by private contract

2/ Dependents include parents, spouse and up to 2 children under 20 years of age

3/ These beneficiaries are also covered under either UCS, or SSS

4/ Cap show average spending/capital/annum, paid by the government to a hospital (2010). Amount varies according to type of treatment

Source: Health System Research Institute, Ministry of Public Health; National Health Security Offices; Controller General Department, Ministry of Finance; World Bank Report

Cost-containment measures to address current healthcare financing difficulties will have strong impacts to original drugs

Description of current healthcare coverage

- The Thai healthcare system is based on the principle of universal access
- The government claims that over 99% of the population is now covered by public health insurance under one of three schemes:
 - ✓ **Universal Coverage, or UC, scheme**, also known as the 'gold card' scheme (THB 30 scheme), which covers the remaining majority of the population. This scheme is financed by National Health of Security Office (NHSO)
 - ✓ **Social Security Scheme, SSS**, which is mandatory for all formal-sector employees. The payer for this scheme is Social Security Office; however it is shown that this scheme is less reimbursed by private employees due to the lowest budget per head among all 3 schemes and complicated process of reimbursement thus employees are likely to apply their private insurance if they have
 - ✓ **Civil Servants Medical Benefits Scheme, CSMBS**, for government employees, pensioners and dependants; this scheme is supported by Controller General Department (Ministry of Finance) with the highest budget among all 3 schemes. This scheme is not limited to only NLEM drug but Non-NLEM can be reimbursed as well if needed and approved by CGD

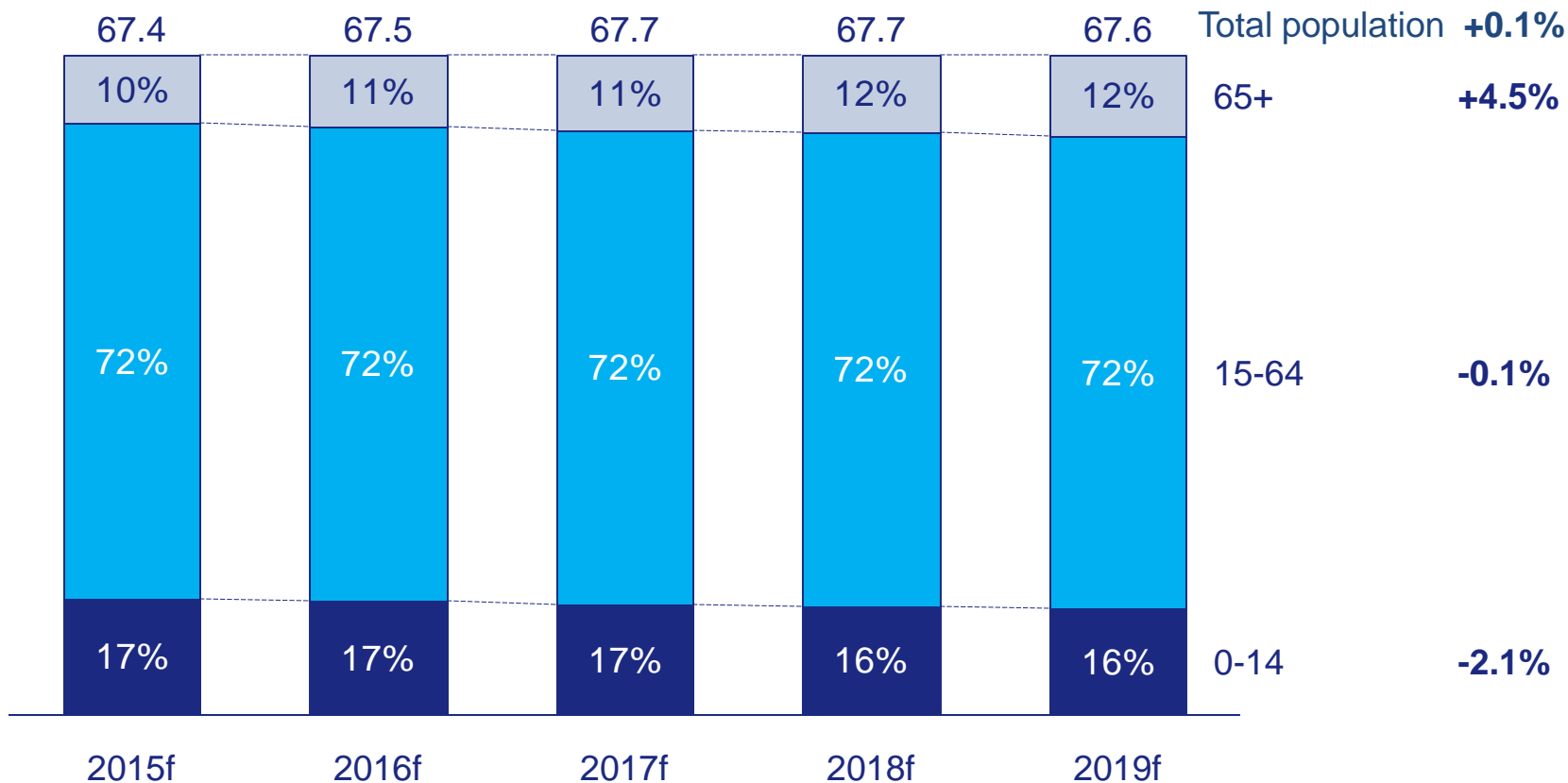
Source: Health System Research Institute, Ministry of Public Health; National Health Security Offices; Controller General Department, Ministry of Finance

Aging population will continue to increase implying more demand for health care services and increase in healthcare spending

Population by age distribution

Thailand (million)

CAGR (%)
2015-2019



Source: Economist Intelligence Unit, Q4 2014

There are several government's regulations that will impact healthcare industry during the next 5 years

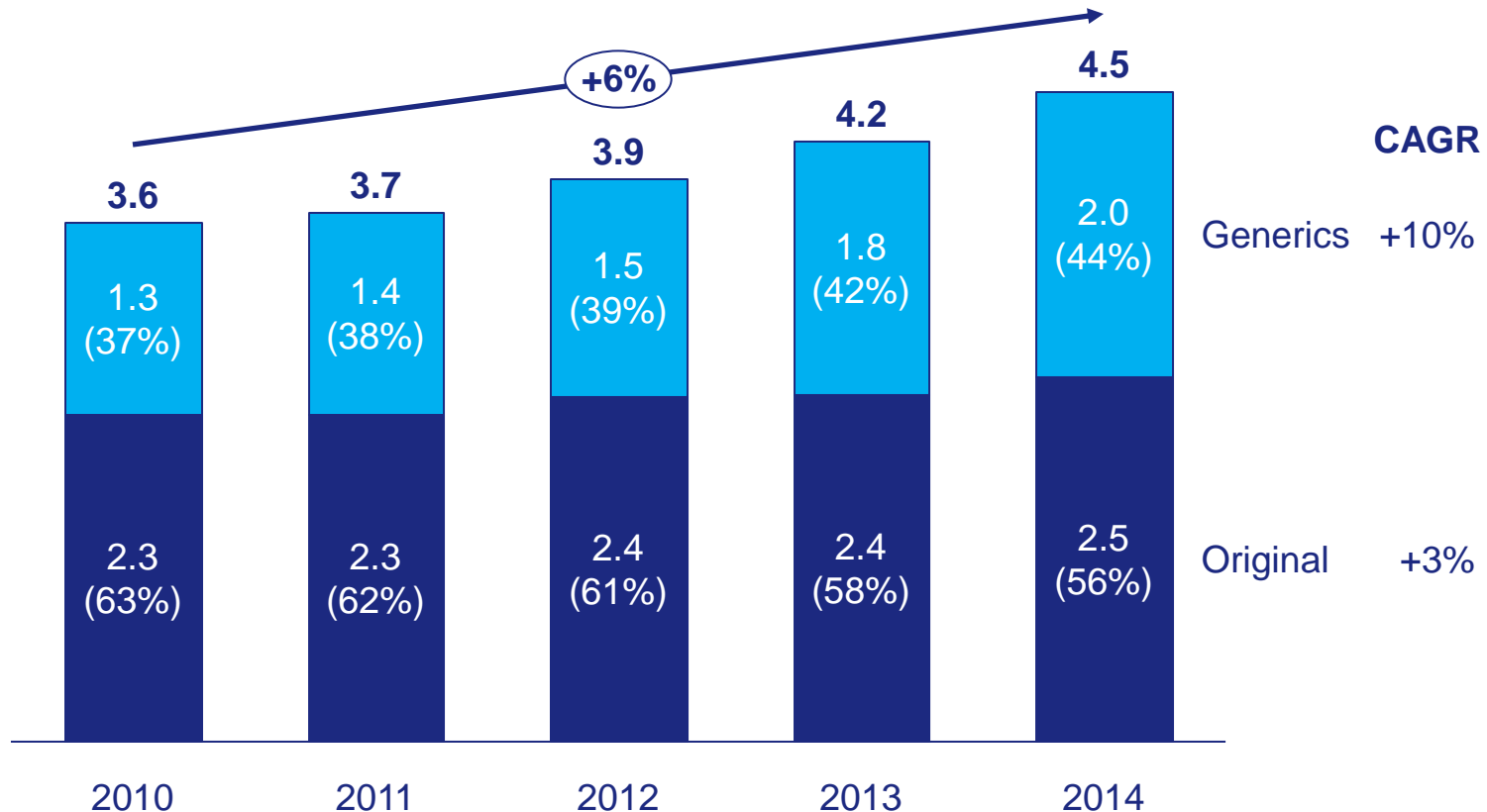
Key regulation affecting healthcare industry in Thailand

Regulation	Description
Medical tourism promotion	<ul style="list-style-type: none">Government is also promoting Thailand as a medical tourism hub in ASEAN. It is expected of growing investments in the private hospital market and resurgent growth in medical tourism
Increase in healthcare coverage scheme	<ul style="list-style-type: none">Expansion of the coverage of the Universal Coverage Scheme (UCS) with the additions of more drugs and ample population is likely to expand the market. Nevertheless, it will come with budgetary constraint that the government will attempt bring down the price from their suppliers
Diagnosis Related Groups policy	<ul style="list-style-type: none">Increasing prescribing controls in the public sector hospitals through auditing, promotion of generics drug usage and use of Diagnosis Related Groups (DRG) are likely to be key barriers for market expansion.
Price control for innovative drugs	<ul style="list-style-type: none">Increasing prescribing controls in the public sector hospitals through auditing, The Comptroller General's Department's (CGD) plan for government hospitals to limit the mark-up on expensive innovative products to no more than 3%
Median price policy	<ul style="list-style-type: none">The introduction of median pricing for highly-priced non-National List of Essential Medicines (non-NLEM) drugs is projected on the negative impact on the market by dropping off the expensive drug prices

Generics have shown rapid growth, while Originators have slowly expanded with diminishing market share

Pharmaceutical market size^{1/}

Total Thailand, Sales value (USD, bn)



Note: ^{1/} Data is excluded promotion and price discount

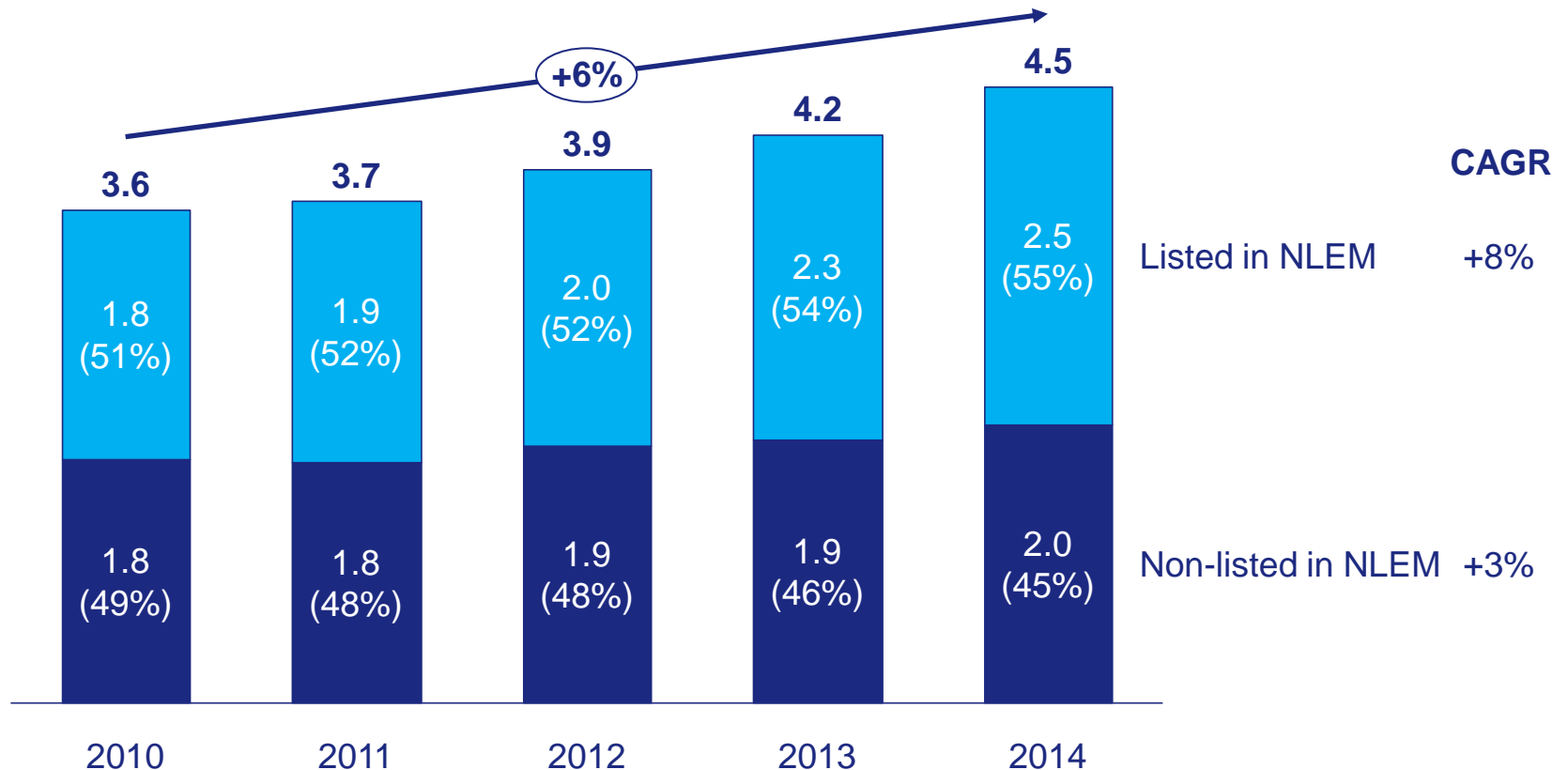
Assume constant exchange rate at THB 30/USD

Source: IMSPlus

NLEM drugs have raised in sales value, particularly in government hospitals; the majority of drugs listed are generics

Pharmaceutical market size compared to NLEM^{1/}

Total Thailand, Sales value (USD, bn)

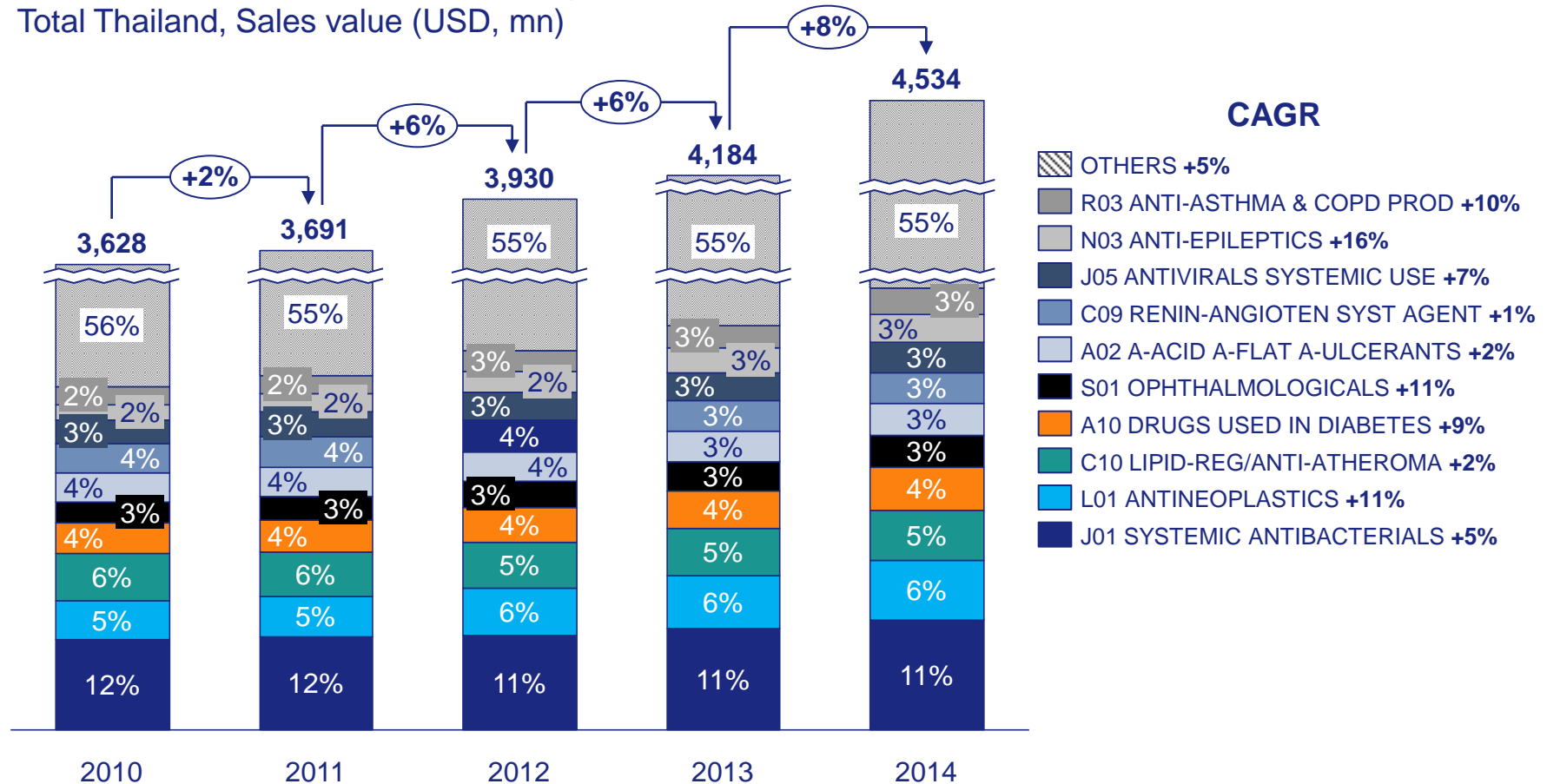


Note: ^{1/} National List of Essential Medicine
Assume constant exchange rate at THB 30/USD
Source: IMSPlus

Antibiotic drug is the largest category in Thailand, followed by oncology (L01), anti cholesterol (C10), and diabetes (A10) drugs

Pharmaceutical market size by categories

Total Thailand, Sales value (USD, mn)



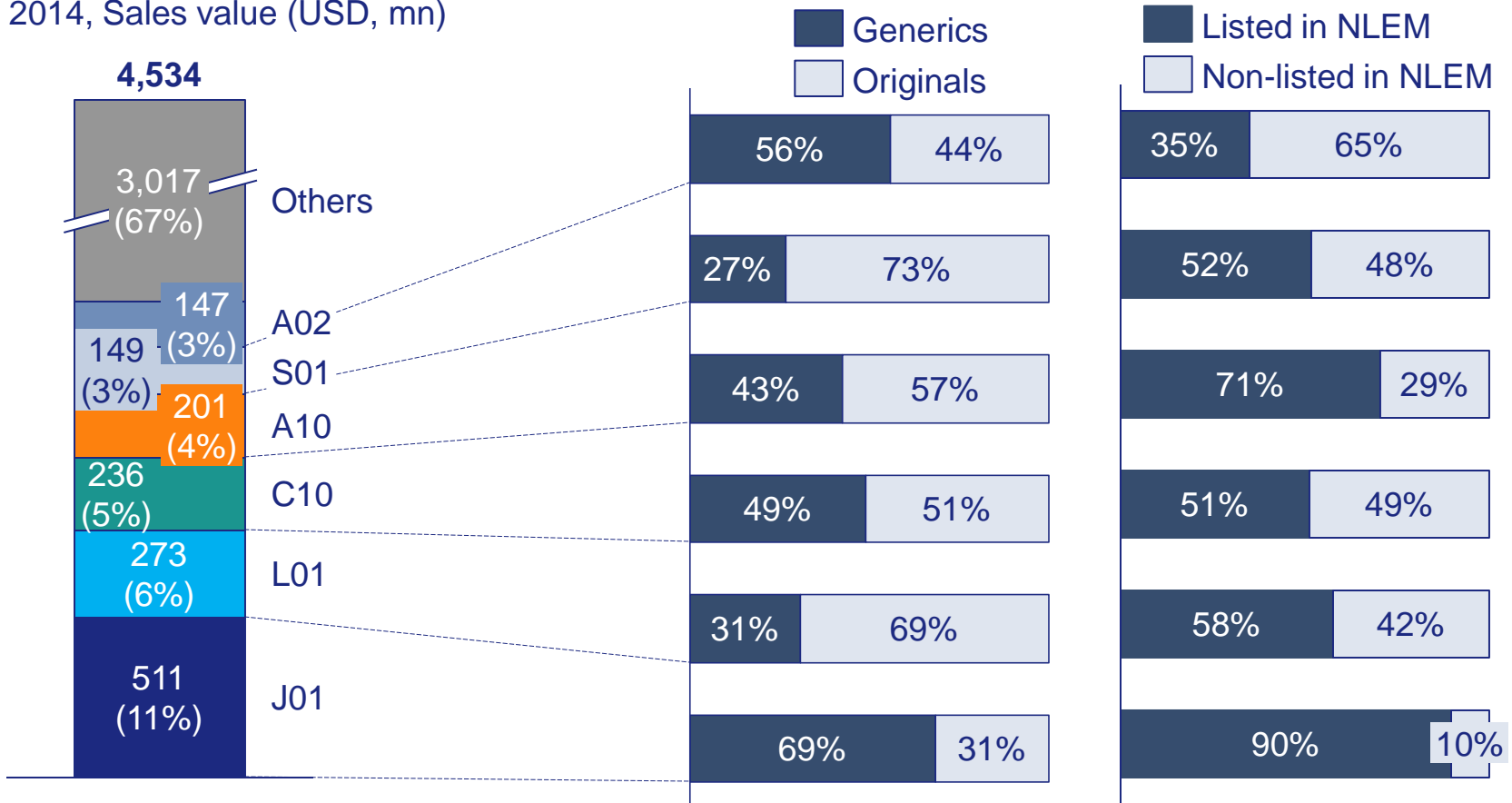
Note: Assume constant exchange rate at THB 30/USD

Source: IMSPlus

Antibiotics, diabetes, and oncology have high contribution from NLEM listing; Significant NLEM listing of original drugs in oncology

Market situation by key category, Original Vs. Generics and Re Vs. Non-reimbursement

2014, Sales value (USD, mn)



Sales value

Note: Assume constant exchange rate at THB 30/USD

Source: IMSPlus

A02: A-ACID A-FLAT A-ULCERANTS
 S01: OPHTHALMOLOGICALS
 A10: DRUGS USED IN DIABETES
 C10: LIPID-REG/ANTI-ATHEROMA
 L01: ANTINEOPLASTICS
 J01: SYSTEMIC ANTIBACTERIALS

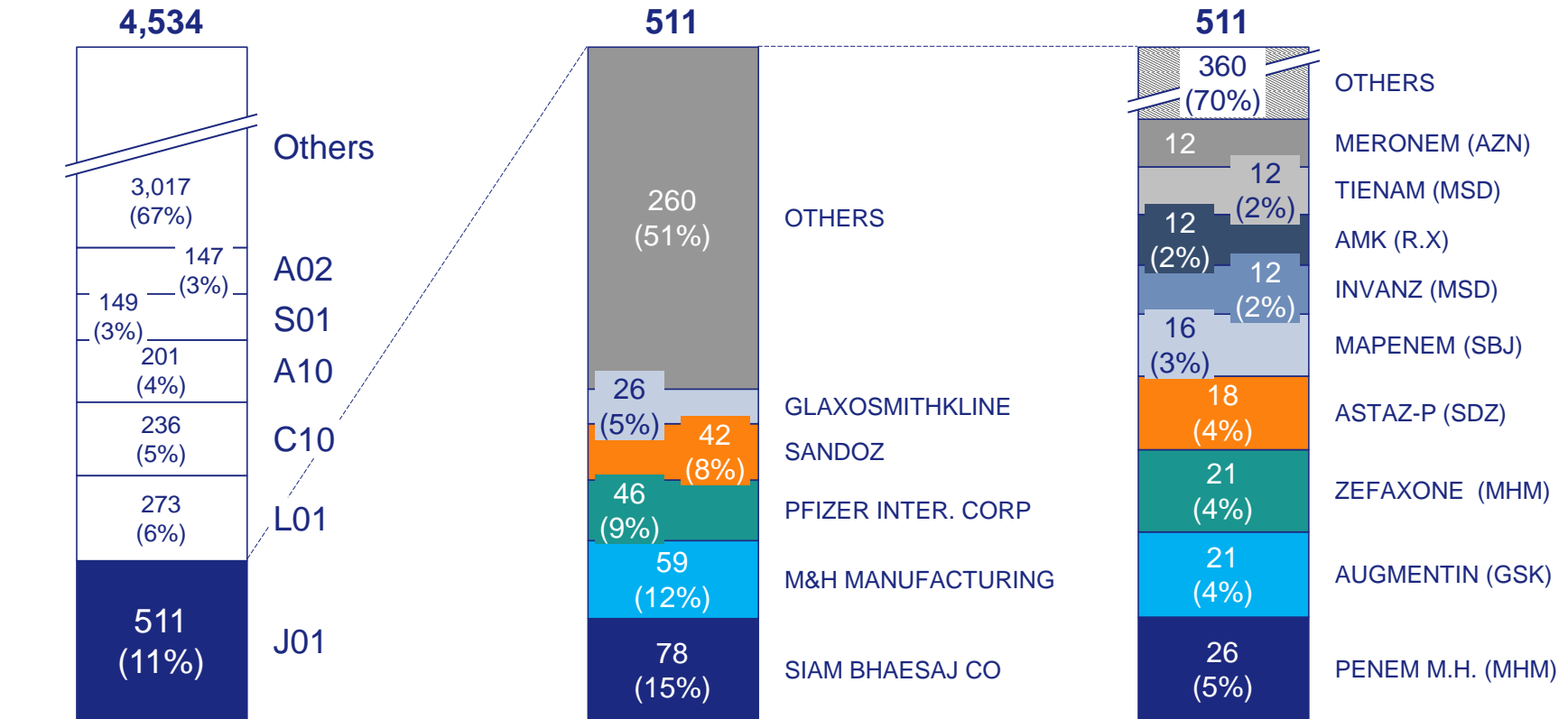
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Local companies - Siam Bhaesaj and M&H are the market leader in Antibiotics, followed by Pfizer and Sandoz

Market situation by key category

J01 SYSTEMIC ANTIBACTERIALS , 2014, Sales value (USD, mn)



Sales value

Leading companies

Leading products

Note: Assume constant exchange rate at THB 30/USD
Source: IMSPlus

A02: A-ACID A-FLAT A-ULCERANTS
S01: OPHTHALMOLOGICALS
A10: DRUGS USED IN DIABETES
C10: LIPID-REG/ANTI-ATHEROMA
L01: ANTINEOPLASTICS
J01: SYSTEMIC ANTIBACTERIALS

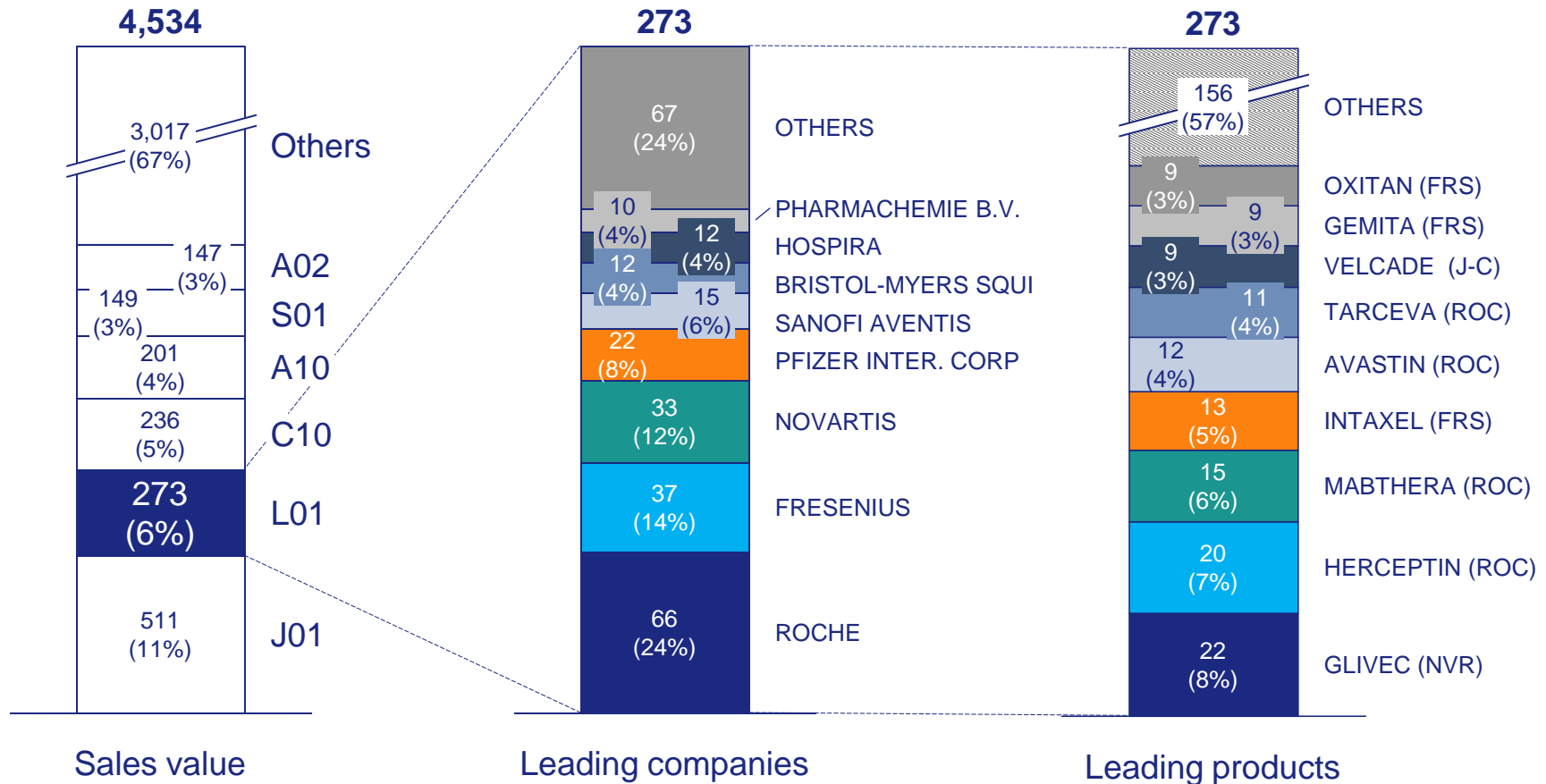
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All market leaders in oncology are MNCs; Roche, Fresenius, Novartis, and Pfizer accounting for 60% of total market

Market situation by key category

L01 ANTINEOPLASTICS, 2014, Sales value (USD, mn)



Note: Assume constant exchange rate at THB 30/USD
Source: IMSPlus

A02: A-ACID A-FLAT A-ULCERANTS
S01: OPHTHALMOLOGICALS
A10: DRUGS USED IN DIABETES
C10: LIPID-REG/ANTI-ATHEROMA
L01: ANTINEOPLASTICS
J01: SYSTEMIC ANTIBACTERIALS

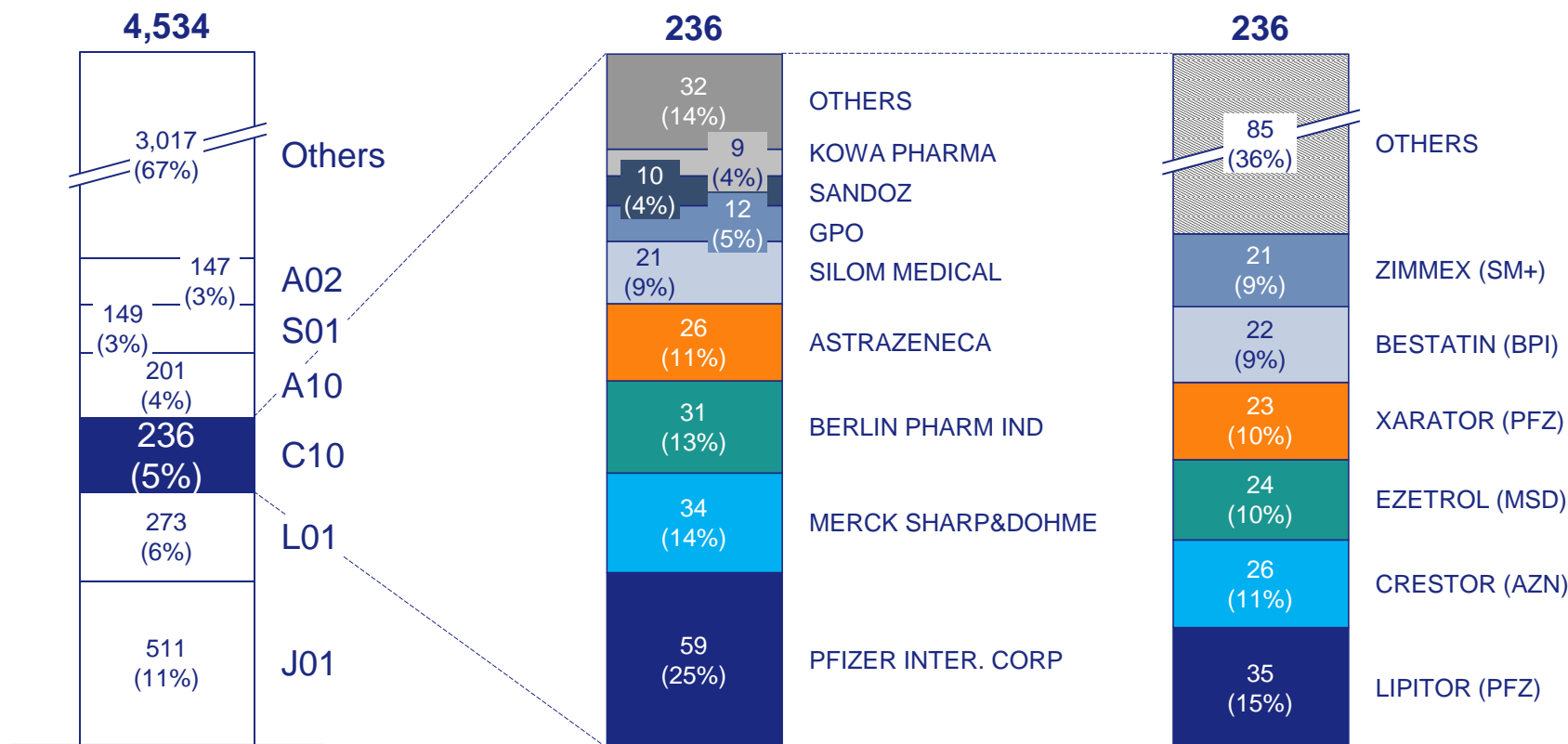
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Several products are outstanding in Lipid-regulating drugs which are Lipitor, Crestor, Ezetrol, and Xarator contributing ~50% of market

Market situation by key category

C10 LIPID-REG/ANTI-ATHEROMA, 2014, Sales value (USD, mn)



Note: Assume constant exchange rate at THB 30/USD
Source: IMSPlus

A02: A-ACID A-FLAT A-ULCERANTS
S01: OPHTHALMOLOGICALS
A10: DRUGS USED IN DIABETES
C10: LIPID-REG/ANTI-ATHEROMA
L01: ANTINEOPLASTICS
J01: SYSTEMIC ANTIBACTERIALS

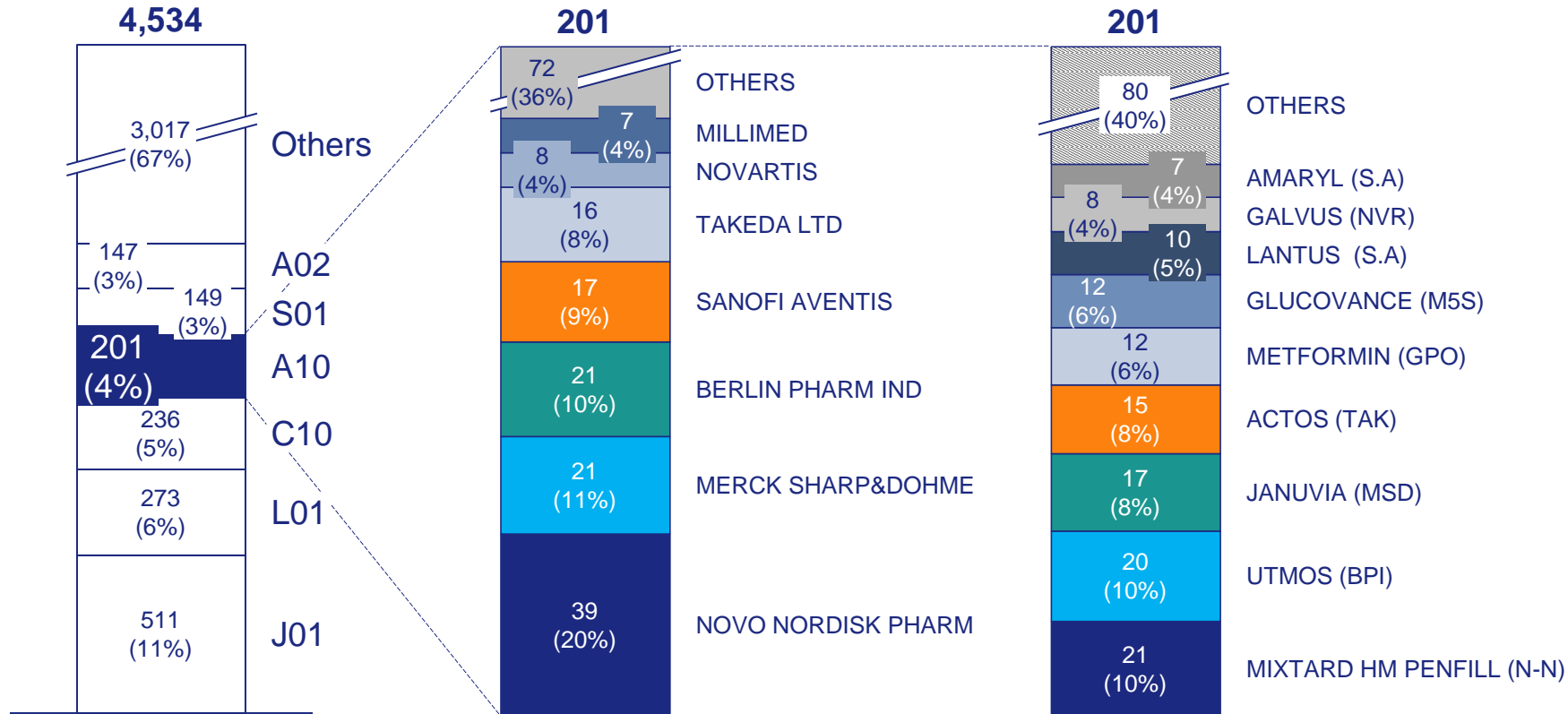
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Four market leaders dominate up to 50% of Diabetes drug market: Novo Nordisk, Merck, Berlin Pharm, and Sanofi

Market situation by key category

A10 DRUGS USED IN DIABETES, 2014, Sales value (USD, mn)



Sales value

Leading companies

Leading products

Note: Assume constant exchange rate at THB 30/USD

Source: IMSPlus

A02: A-ACID A-FLAT A-ULCERANTS
 S01: OPHTHALMOLOGICALS
 A10: DRUGS USED IN DIABETES
 C10: LIPID-REG/ANTI-ATHEROMA
 L01: ANTINEOPLASTICS
 J01: SYSTEMIC ANTIBACTERIALS

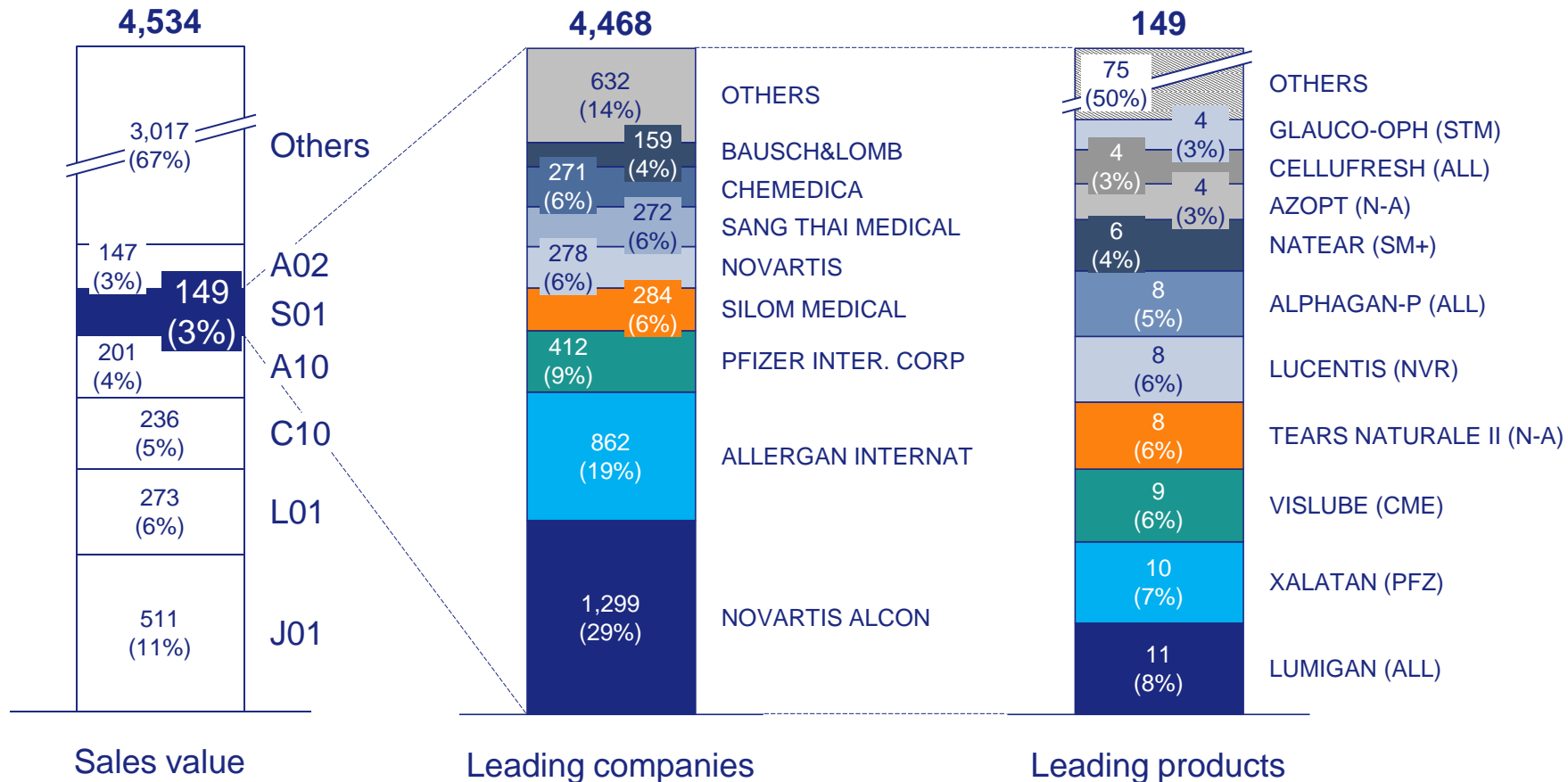
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Ophthalmological drugs are largely originators rather than generics, led by Novartis, Allergan, and Pfizer

Market situation by key category

S01 OPHTHALMOLOGICALS, 2014, Sales value (USD, mn)



Note: Assume constant exchange rate at THB 30/USD
Source: IMSPlus

A02: A-ACID A-FLAT A-ULCERANTS
S01: OPHTHALMOLOGICALS
A10: DRUGS USED IN DIABETES
C10: LIPID-REG/ANTI-ATHEROMA
L01: ANTINEOPLASTICS
J01: SYSTEMIC ANTIBACTERIALS

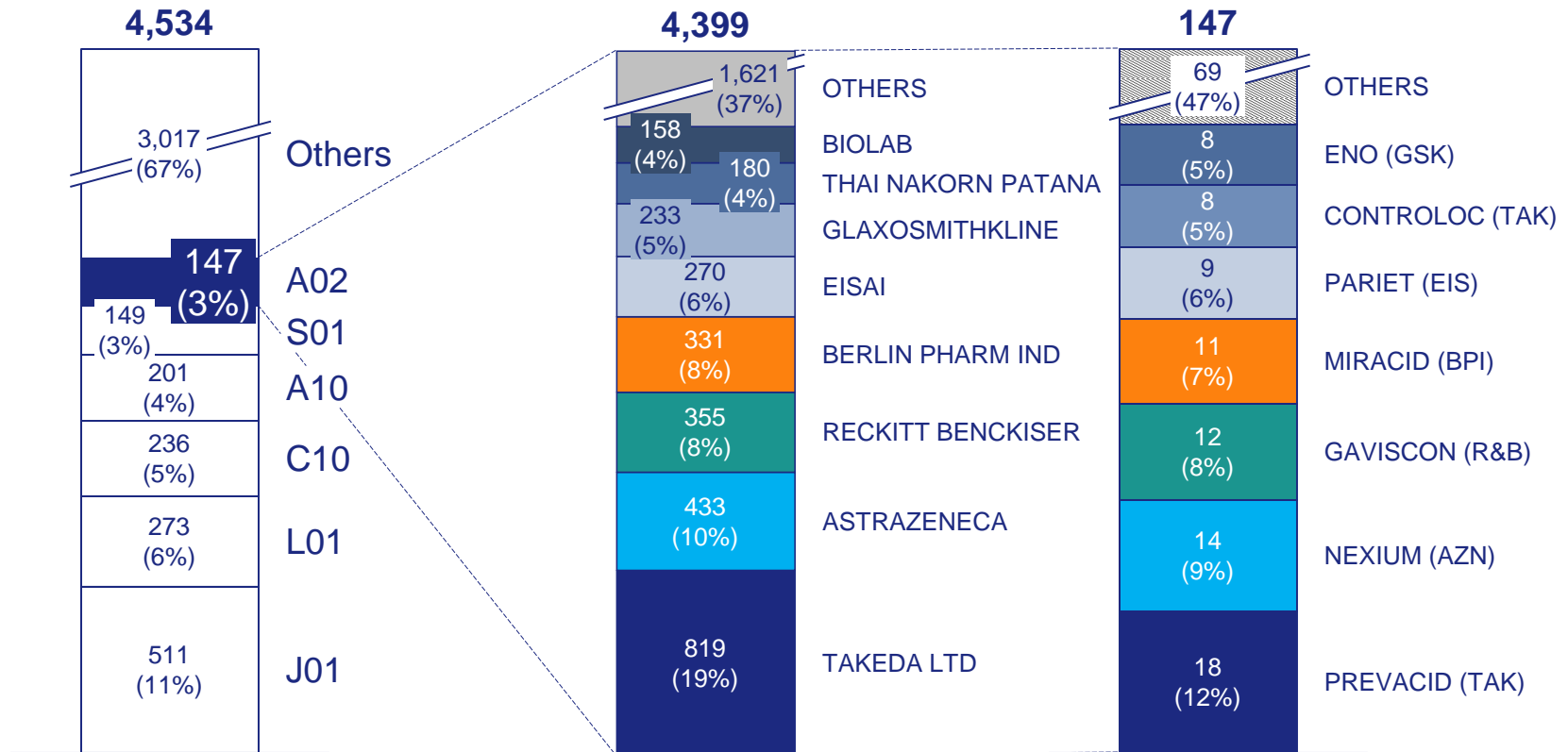
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Takeda is the market leader in Acid-related disorder drugs of 20% value share from its high-usage product 'Prevacid' and 'Controloc'

Market situation by key category

A02 A-ACID A-FLAT A-ULCERANTS, 2014, Sales value (USD, mn)



Sales value

Note: Assume constant exchange rate at THB 30/USD
Source: IMSPlus

Leading companies

A02: A-ACID A-FLAT A-ULCERANTS
S01: OPHTHALMOLOGICALS
A10: DRUGS USED IN DIABETES
C10: LIPID-REG/ANTI-ATHEROMA
L01: ANTINEOPLASTICS
J01: SYSTEMIC ANTIBACTERIALS

Leading products

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Category and Market highlight (1/4)

Category	Market Highlight
J01: SYSTEMIC ANTIBACTERIALS	<ul style="list-style-type: none"> • In overall, Systemic Antibacterials market has steadily grown at 5% CAGR (2010-2014) with the significant increase during 2012-2014 (8% annually), in which the market expansion is driven by generics prescription (14% growth 2013-2014) while the shrink of original drug prescription has presented with negative growth since 2012 and it is projected to continue decreasing • At the present, the market is dominated by Generics (~70% of total sales) and 90% of drug in this drug class is reimbursable (almost all Generics are typically reimbursable). This is not the attractive market for MNC players who are unable to compete with local generics in term of price • Siam Bhaesaj, M&H Manufacturing, Pfizer, Sandoz, and GSK are major players with combined 50% market share. In respect of popular products, Penem (MHM), Augmentin (GSK), Zefaxone (MHM)
L01: ANTI- NEOPLASTICS	<ul style="list-style-type: none"> • Majority of drugs are original due to the high investment in drug development compared with other drug classes; however the value sales proportion between listed vs. non-listed in NLEM are almost equal. • Up to 94% of this market value is generated from government hospitals in which present the high traffic of cancer treatment compared with private hospitals • Unfortunately, Generics accounted almost 50% of the market in 2014, with 23.1% CAGR during 2011-2014 which is considered as a big threat to MNCs • Antineoplastics drug market is fragmented among players in which a greater part is MNCs; Roche, Fresenius, ad Novartis, and Pfizer together account for 58% of total market. In respect of high-sales drug, Glivec (Novartis), Herceptin (Roche), Mabthera (Roche), and Intaxel (Fresenius) are outstanding but with minor market share, not greater than 10% each due to high market fragmentation

Category and Market highlight (2/4)

Category	Market Highlight
C10: LIPID- REG/ANTI- ATHEROMA	<ul style="list-style-type: none"> • This market has recovered from market from regression in 2011 and slow growth during 2012-2013 by showing 8% growth in 2014. This is driven by the higher prescription of Generics (20% increase) while original drug usage has consistently shrunken by -6.5% CAGR (2010-2014) • In line with the higher prescription of Generic drugs in which most of them in this drug classification are listed in NLEM, the market recovery and expansion are escalated by reimbursable drugs (NLEM) through the healthcare practice at government hospitals and medical schools rather than private hospital as it is chronic disease/symptom requiring long-term treatment • Pfizer, MSD, Berlin Pharma, AStraZeneca together contribute 64% of total market value with their leading products such as Lipitor (Pfizer), Crestor (AstraZeneca), Ezetrol (MSD), Xarator (Pfizer), and Bestatin (Berlin Pharma) accounting for 55% of C10 drug sales in 2014
A10: DRUGS USED IN DIABETES	<ul style="list-style-type: none"> • THB 47bn healthcare treatment expenditure is spent to DM patients in 2013 (both government and private expenditure) • Oral drug significantly dominates DM treatment market as the convenience of patients and budget constraint while insulin will be prescribed to patients with moderate-to-severe with not many generics in the market • Even many of DM drugs are Originators, many of them are listed in NLEM since government realizes on the need of medication to patient's quality of life, particularly insulin • Outperformers in Diabetes drugs are Novo Nordick, MSD, Berlin Pharma, Sanofi, and Takeda while the popular products include Mixtard HM Penfill (Novo Nordick), Utmos (Berlin Pharma), Januvia (MSD), Actos (Takeda), and Metformin (GPO)

Category and Market highlight (3/4)

Category	Market Highlight
S01: OPHTHALMOL OGICALS	<ul style="list-style-type: none"> • Among all 6 highest drug classes, Ophthalmological drugs demonstrate the largest proportion of original usage compared with generics usage since this drug indications require prominent innovation and investment budget with the patent constraint at the moment; this results in low competition from Generic manufacturers • The market has gradually grown at 11.7% CAGR (2010-2014), driven by the impressive sales growth from both Original and Generic drugs, 13% and 8% respectively. With respect to NLEM listing, listed and non-listed drugs share almost equal sales contribution (52% vs. 48% in 2014) • Top 3 companies (Novartis, Allergan, and Pfizer) dominate up to 58% of Ophthalmological drug market whereas the brand/product share are more fragmented. Eminent brands are Lumigan and Cellufresh (Allergan), Xalatan (Pfizer), Vislybe (Chemedica), and Tears Naturale II and Lucentis (Novartis)
A02: A-ACID A-FLAT A-ULCERANTS	<ul style="list-style-type: none"> • Antacids, Antiflatulents and Anti-Ulcerants market has slowly expanded at 2% CAGR (2010-2014), stimulated by Generic usage (7% sales growth in 2014) rather than original drug usage (-1% sales decrease in 2014). Even this market has presented a amount of sales value but it is less attractive to new players due to market maturity and strong dominant existence • The leading manufacturers include Takeda, AstraZeneca, Reckitt Benckiser, Berlin Pharma, Eisai, and GSK, together play 55% of total market • In term of popular products, Prevacid and Controlloc (Takeda), Nexium (AstraZeneca), Gaviscon (Reckitt), Meracid (Berlin), Pariet (Eisai), and Eno (GSK) account for 53% of A02 sales value

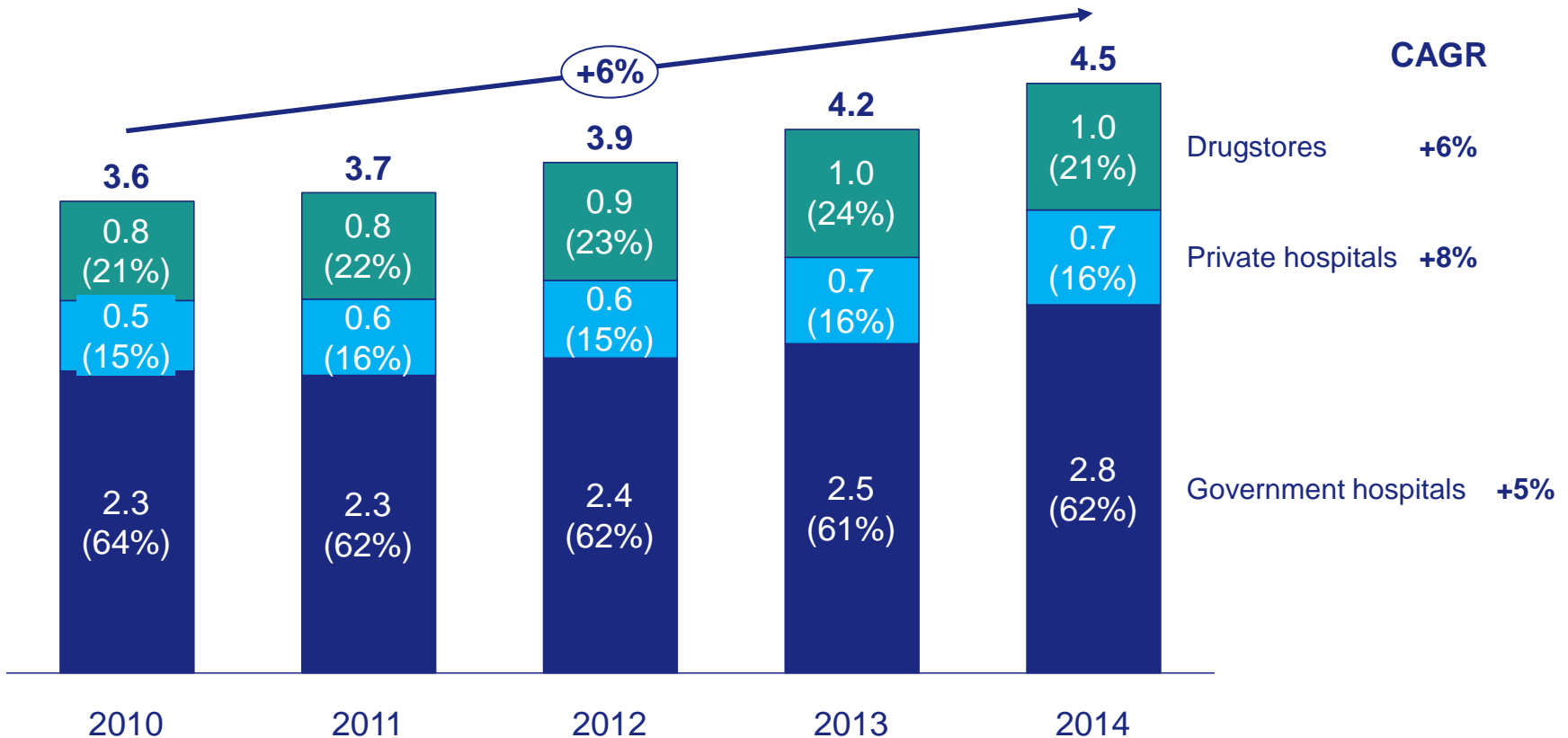
Category and Market highlight (4/4)

Category	Market Highlight
R03: ANTI-ASTHMA & COPD PROD	<ul style="list-style-type: none">• The overall market is driven by Inhalant products, prescribed for both Asthma and COPD• According to IMS prescription database, R03 products has been growing for Asthma prescription at 18% CAGR during 2011-2014, compared COPD 12% CAGR; GSK's price reduction (Seretide) in 2011 is one of the main factors driven this category growth (it is also listed in NLEM, as well as AZ's Symbicort)• Top 5 manufacturers dominate up to 75% of total market sales (GSK, B. Ingelheim, AstraZeneca, MSD, and Silom Medical. Regarding high sales product, Seretide and Ventolin (GSK), Symbicort (AstraZeneca), Singulair (MSD), and Berodual NDI and Spiriva (BI) show 61% of total R03 sales in 2014. Seretide and Symbicort are mostly prescribed for Asthma which is growing faster than COPD in Thai market

Government hospital is major drug dispersing channel; private hospital and pharmacy have constantly expanded due to surge in self-pay

Channel contribution

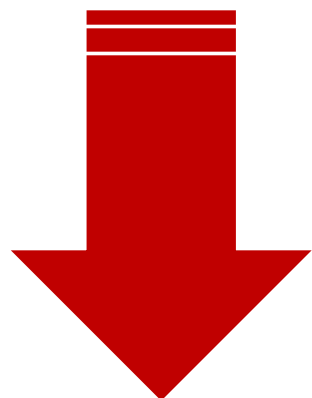
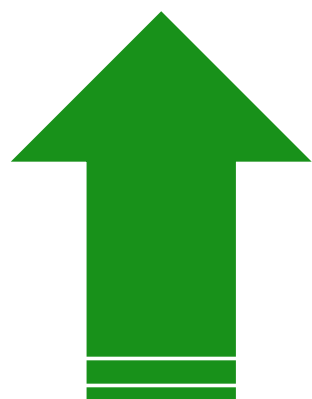
Total Thailand, Sales value (USD, bn)



Note: Assume constant exchange rate at THB 30/USD

Source: IMSPlus

Even with smaller sales, private hospitals seem to be more attractive to new MNCs as there is less government control on budget with impressive growth



Government hospital

- **Significant patient traffic** due to the higher healthcare scheme accessibility at government hospitals
- **Expertise recognition** at Government hospitals especially medical schools lead to higher patient number, shown by the **consistent capacity expansion** (facility and human resource) of many government hospitals

- According to **government budget control**, several impactful policies have been implemented to **encourage the prescription of generic** drug due to greatly cheaper price.
- Some of those policies are centralization on price negotiation, Purchase preference on Government Pharmaceutical Organization (GPO) at government hospitals, and cost effectiveness analysis for non-NLEM drugs reimbursed through CSMBS scheme

Private hospital

- **Middle-to-high incomers** are willing to visit private hospitals for **better services and convenience** as majority of them will have private insurance to cover some medication expenses
- This channel is attractive for MNC companies with original drugs due to less price constraints to patients compared with government hospitals

- **High competition among MNC drugs** to gain the share in private hospital channel as they are seeking for business expansion and avoid the strict control on price and prescription volume at government hospital channel
- Single price policy (list price is shown to patient for each drug item) will indirectly drive private hospital to purchase original drugs with more affordable price to obtain the high profit margin

Pharmacy

- **The great amount of outlets** in Thailand can present the great potential for OTC drugs or drugs with SMP approval (allowed to dispense at pharmacy with pharmacist)
- **Strong presence in health supplement products** such as medical nutrients, vitamins, hormone drug, together with drug for mild diseases that patients are unlikely to visit hospitals for this cause

- **Require sales force effort** to penetrate the pharmacy channel especially for new players
- New drugs approved by FDA **cannot be distributed** through this channel, it must be in **SMP stage for 1-2 years** (limited distribution channel to only hospital/clinic) before being allowed to access pharmacy distribution
- High price sensitivity of patients purchasing at pharmacy

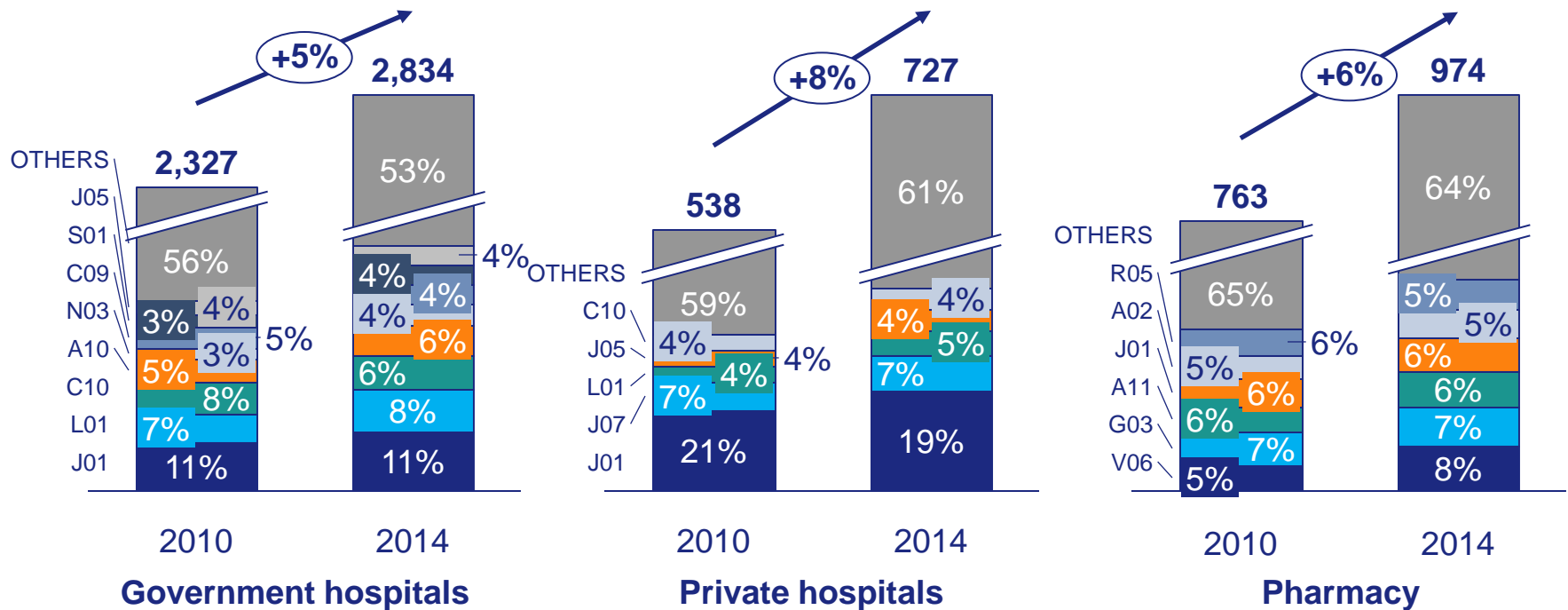
Government hospitals show the lowest growth among 3 channels, but it still dominates the largest market value share

Major categories in each channel

Total Thailand, Sales value (USD, mn)

J01: SYSTEMIC ANTIBACTERIALS
L01: ANTINEOPLASTICS
C10: LIPID-REG/ANTI-ATHEROMA
A10: DRUGS USED IN DIABETES
N03: ANTI-EPILEPTICS
C09: RENIN-ANGIOTEN SYST AGENT
S01: OPHTHALMOLOGICALS

J05: ANTIVIRALS SYSTEMIC USE
V06: GENERAL NUTRIENTS
G03: SEX HORMONES
A11: VITAMINS
A02: A-ACID A-FLAT A-ULCERANTS
R05: COUGH & COLD PREPARATIONS



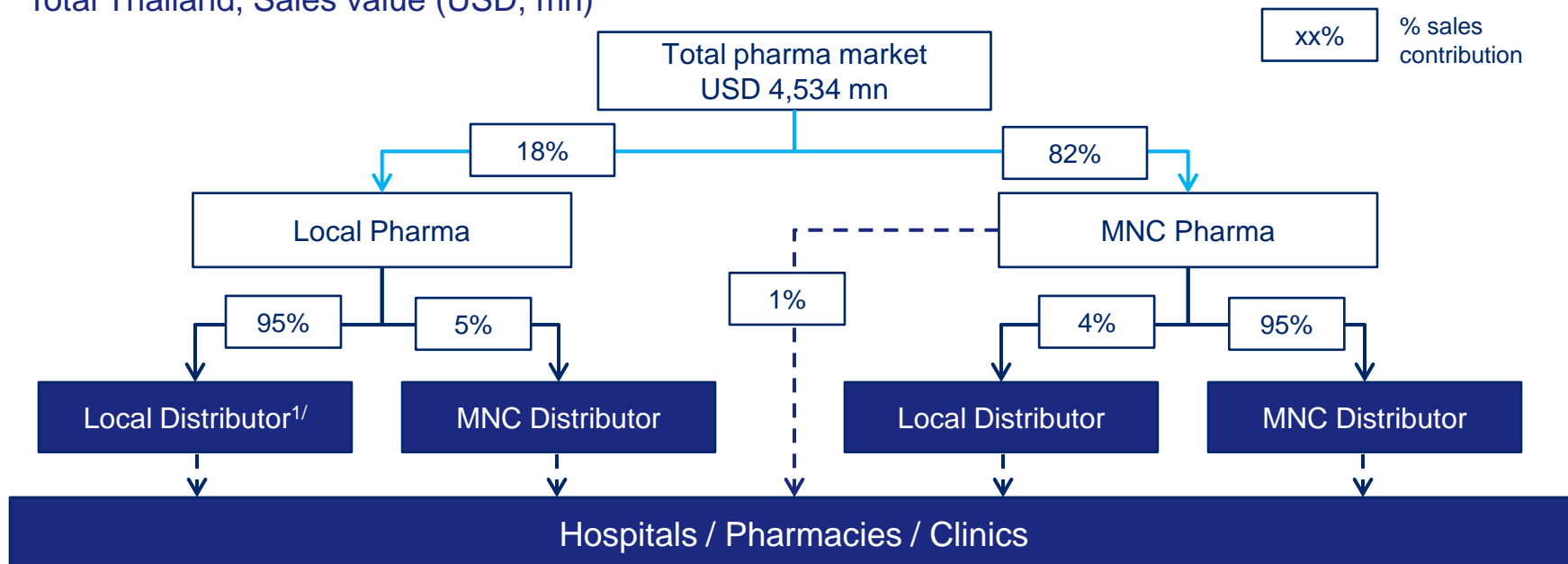
Note: Assume constant exchange rate at THB 30/USD

Source: IMSPlus

Sales contribution is dominated by MNCs with their strong MNC distributors (DKSH and Zuellig Pharma)

Distribution channel contribution, Local Vs. MNC

Total Thailand, Sales value (USD, mn)



- MNCs still dominate Thailand market even there is high competition among them and local pharmacoms (generics^{2/}); some MNCs have launched their generics as fighting brands and offered aggressive marketing strategy to compete with local drugs.
- MNC distributors i.e. DKSH and Zuellig are the leader in MNCs' distribution (up to 95%) while Local pharmacom normally supply their products via Local distributors in which majority of them are their own company or subsidiary under the group.

Note: ^{1/} Local pharmacom typically operates its own logistics business

^{2/} There is no originator produced by local pharmacoms at the moment

Source: IMS internal data; IMS analysis

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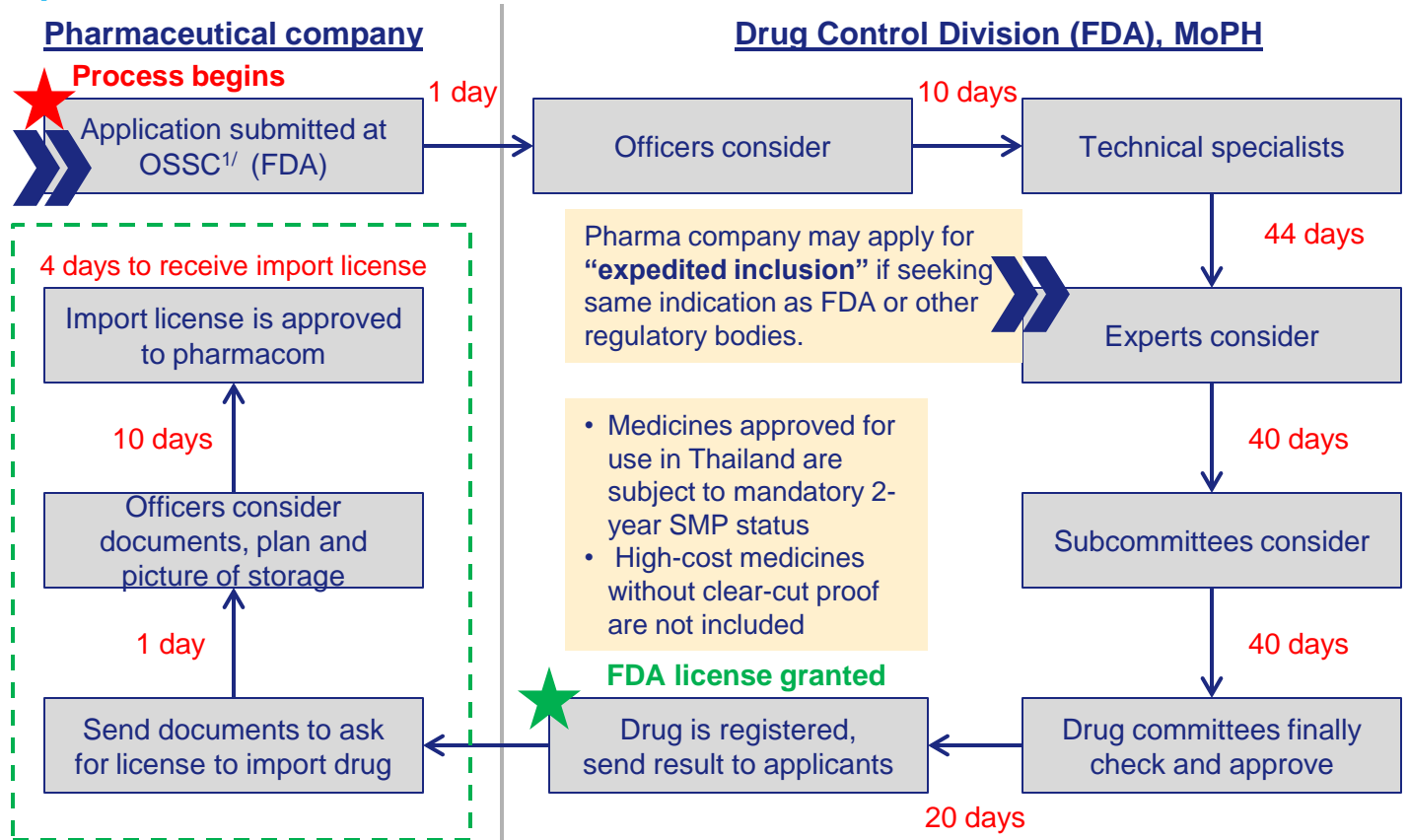
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First step of drug launch in Thailand is to acquire FDA license which practically takes up to 1-2 years to complete

Drug registration process in Thailand

- Dossier can be processed earlier if it is submitted earlier than cut-off date (end of every quarter)
- Total of **155 days** are required for drug license registration; however practically it takes around 1-2 years to complete due to insufficient or unqualified document esp. clinical studies and certification from trails at local Medical schools

After drug license is approved from FDA, pharmacom processes Import license application; **total 15 days** are officially planned for import license consideration



Note: ^{1/} OSSC = One Stop Service Center (dedicated FDA unit to manages license registration works for Ministry of Public Health (MoPH))
Source: Food and Drug Administration of Thailand (FDA), MoPH; Customs department, Ministry of Commerce


➤ Possible areas to accelerate process

All drugs must be registered at OSSC (FDA) to acquire license before official import, distributing or listed in NLEM

<p>Registration</p> 	<p>Prerequisites</p>	<ul style="list-style-type: none"> • All drugs are required to register under ASEAN Harmonization since January 2009 (to be prepared for AEC) • All drugs are subject to the same registration procedure, there is no separate procedure for OTC products • Both locally produced and imported drug can apply for drug registration in Thailand; however manufacturer of imported drug has to be previously recorded in Drug registration system with GMP license issued by FDA of Thailand and Certificate of Pharmaceutical Product • Registration is the responsibility of Bureau of Drug Control - Division of the Ministry of Public Health; One Stop Service Center (OSSC) is direct agency who mainly account for all administrative registration processes • The registration process is necessary to ensure quality, safety and efficacy of the drugs being marketed in the country. Only authorized licensees are qualified to apply for product registration. Manufacturing plants, in which drug products are manufactured, are subject to inspection for GMP compliance. • For Chemical New Drug (unlike well established drug1/), it must register under 'New Drug Registration – ASEAN Harmonization' issued by FDA Thailand, together with copy of orphan drug registration document
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Source: Manual for Drug Registration under ASEAN Harmonization and Drug Act B.E. 2510, Food and Drug Administration, Ministry of Public Health, Thailand (published Sept 2007)

Generics or New generics are likely to require shorter timeline, compared to New medicines which will have solid clinical trials at local medical schools first

<p>Registration</p> 	<p>Drug classifications</p>	<ul style="list-style-type: none"> • The process of drug registration will be carried out in 2 channels, which differ in degrees of control and dossier submission: Registration of General Medicines, and Registration of Thai Traditional Medicines. • Due to some differences in the requirements for dossiers to be submitted for product approvals, the general medicines will have to be further defined as: <ol style="list-style-type: none"> 1) Generics “<i>Pharmaceutical products with the same active ingredients and the same dosage forms as those of the original products, but manufactured by different manufacturers</i>”, whose registrations require only dossiers on product manufacturing and quality control along with product information. “ 2) New medicines “<i>Products of new chemicals, new indications, new combinations or new delivery systems and new dosage forms</i>” whose registrations require a complete set of product dossiers 3) New generics “<i>Medicines with the same active ingredients, doses and dosage forms as those of the new compounds registered after 1992</i>”, whose registrations require dossiers of bioequivalence studies in addition to the required dossiers for generics submission
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Source: Manual for Drug Registration under ASEAN Harmonization and Drug Act B.E. 2510, Food and Drug Administration, Ministry of Public Health, Thailand (published Sept 2007)

Official 155 days are necessitated for process completion; however it takes up to 1-2 years in practice

<p>Registration</p> 	<p>Official timeline</p>	<ul style="list-style-type: none"> • Drug registration processes consist of 6 stages (excluding clinical and non-clinical tests for certifying product's quality, safety and efficacy); the processes require total 155 days for 6-stage completion and application must be only submitted at 'One Stop Service Center – OSSC' under FDA operation. <ul style="list-style-type: none"> - Stage 1 Administrative staff receives application, checks for document completion, and issues the temporary approval number (1 day) - Stage 2 Academician examines the application and accuracy of information, and issues the official approval number (10 days) - Stage 3 Academician verifies the application to determine whether to grant the license (44 days) - Stage 4 Specialist examines the application package and verification from academician (40 days) - Stage 5 Committee deliberates the approval result (40 days) - Stage 6 Academician verifies the result for reconfirmation and issues the license (20 days) • Product licenses must be renewed every five years. • In case of orphan drugs, it can be registered under New Drug – ASEAN Harmonization through “Fast Track” to speed up the process. It will be considered before other drug submitted for FDA drug registration as government would like to encourage the drug accessibility in Thailand.
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Source: Manual for Drug Registration under ASEAN Harmonization and Drug Act B.E. 2510, Food and Drug Administration, Ministry of Public Health, Thailand (published Sept 2007)

Clinical trial is mandatory to have approval from FDA on license registration

<p>Registration</p> 	<p>Trail Requirement</p>	<ul style="list-style-type: none">• Drug performance certificate - quality, safety and efficacy, issued by Department of Medical Sciences, is mandatory for registration, approval of drug's trial has to be granted for local manufacturer while approval of importing drug sample is a must for drug produced overseas• Besides certificate of quality, safety and efficacy, stability test is obligatory . Accelerated stability data takes at least 6 months and long-term stability data takes 12 months• If drug is solely produced for export, stability test can be fast track in which 12-month stability data is not required• 2-3 drug batches are required to pass the tests above
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Source: Manual for Drug Registration under ASEAN Harmonization and Drug Act B.E. 2510, Food and Drug Administration, Ministry of Public Health, Thailand (published Sept 2007)

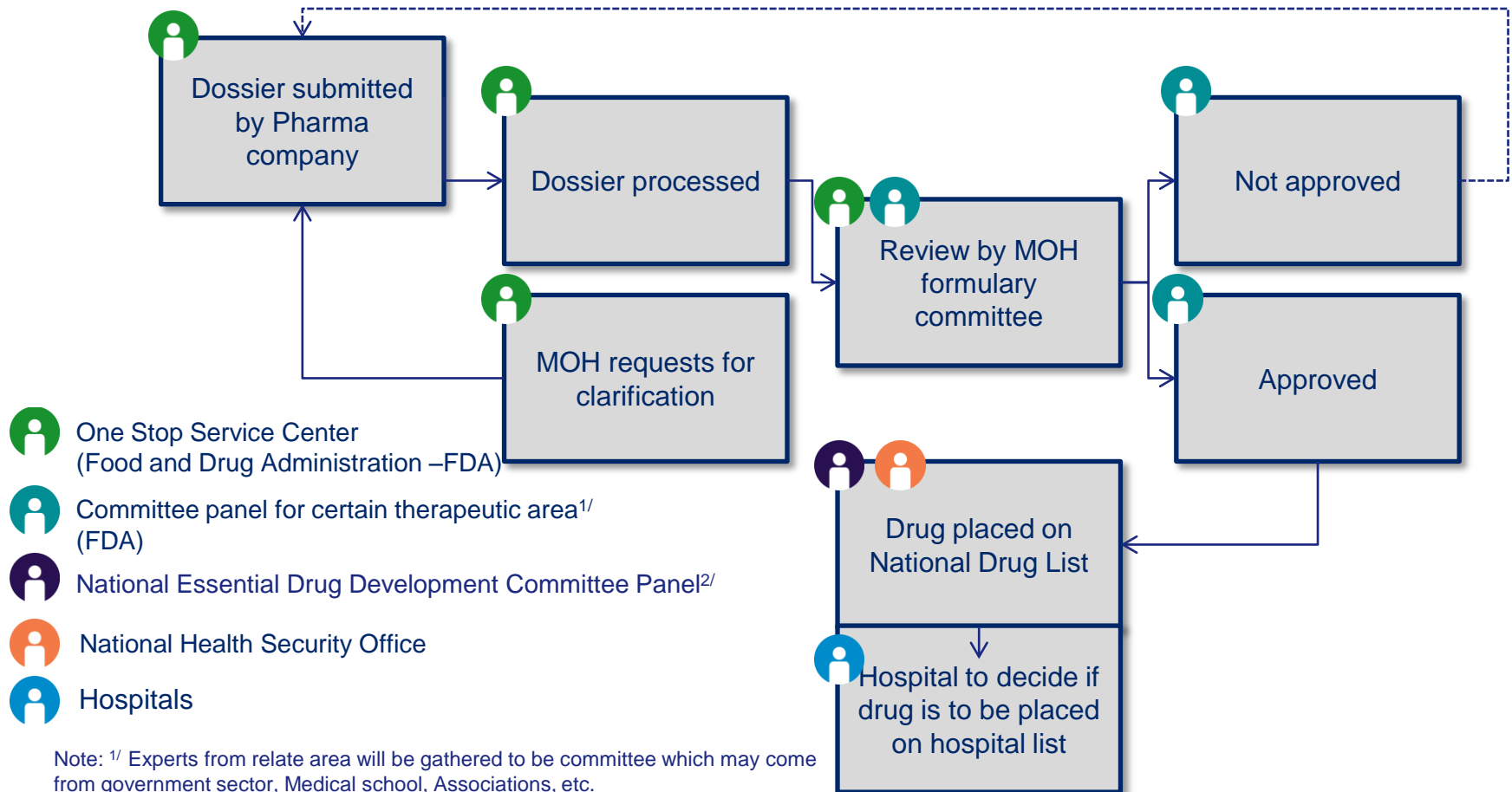
Drug is prohibited from media advertisement as well as doctors cannot communicate product brands/names to any media channels

Labeling 	Label regulations	<ul style="list-style-type: none"> • Drug labels are classified into 3 types: Unit Carton, Inner Label, and Blister/Strips • Imported food requires 'Original language label' along with Thai label and English label
	Restricted words	<ul style="list-style-type: none"> • Words that exaggerate the drug properties to be more effective than are proved clinically • Samples of misleading words are superior, the safest, completely recover, no side effect, non-allergenic, absolutely, promptly, cease/eliminate the diseases, always number one, miracle, magic, etc.
Product Claims 	MoPH Guidance	<ul style="list-style-type: none"> • If there is health claim in advertisement, the scientific test result in human and published paper must be submitted accordingly

Source: Manual for Drug Advertising under Drug Act B.E. 2510, Food and Drug Administration, Ministry of Public Health, Thailand

After drug license approval, being listed in NLEM will escalate products sales through large usage volume from healthcare coverage schemes

National List of Essential Medicines

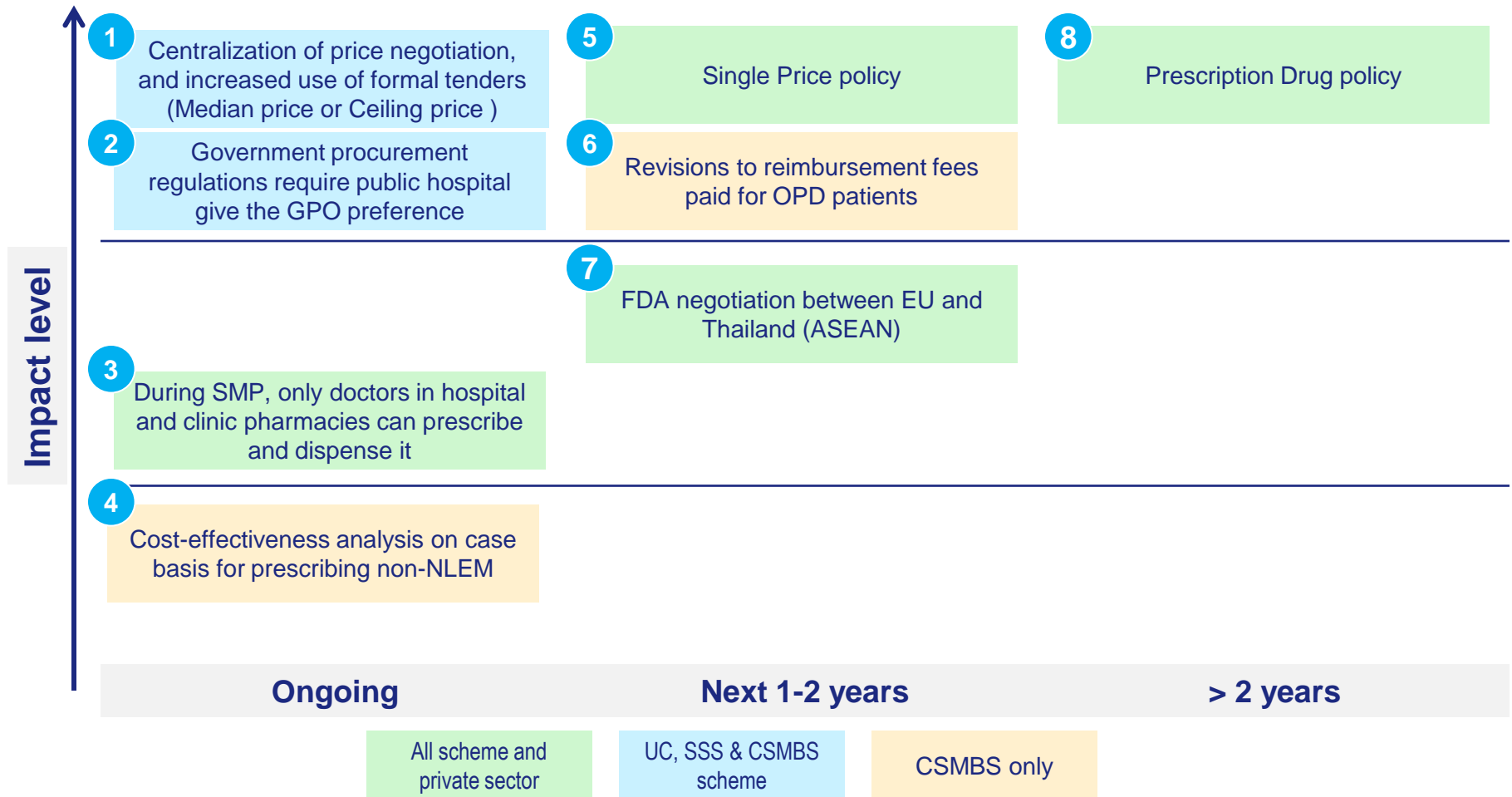


Note: ^{1/} Experts from relate area will be gathered to be committee which may come from government sector, Medical school, Associations, etc.

^{2/} HITAP (Health Intervention and Technology Assessment Program) assists in term of cost benefit analysis of listing certain drug in NLEM

Source: National List of Essential Medicine Committee, Ministry of Public Health

Key government laws & regulations impacted to Thai pharmaceutical industry



Source: American Chamber of Commerce in Thailand 'Thailand pharmaceutical market update 2014'; Food and Drug Administration, Ministry of Public Health; Thai Customs Department, Ministry of Commerce; Stakeholders' interview; IMS analysis

Centralization procurement leads to Originator-by-Generics replacement due to cost containment on median price

1

Centralization of price negotiation, and increased use of formal tenders, are playing an important role

Attribute	Description/Rationale
Description	<ul style="list-style-type: none"> Policy enforces Government hospitals and Medical schools to procure pharmaceutical products under the 'Median price' (AKA Ceiling price) set by The Controller General's Department' (CGD). This indirectly controls Originators used in Pubic hospitals due to low chance of awarded centralized procurement; however some Government hospitals still have Originators in their stock but they potentially cannot be reimbursed through Universal Coverage (UC), Social Security Scheme (SSS), and Civil Servant Medical Benefit Scheme (CSMBS) More rigorous enforcement of "one brand one generic" policy to be implemented in Government hospitals
Area of influence	<ul style="list-style-type: none"> Drugs under UC, SSS, CSMBS schemes
Potential impact	<ul style="list-style-type: none"> Aggressive price competition to be in reimbursable drug lists MNCs will have disadvantages in the public hospital market
Timing of impact	<ul style="list-style-type: none"> Ongoing
Scenarios & probability	<ul style="list-style-type: none"> To control the government's healthcare expenditure To encourage more effective financial planning and policy implemented at execution level

Source: The Controller General's Department' (CGD); Price of Goods and Services Act 1992; Stakeholders' interview; IMS analysis
 Thai Pharmaceutical Market Analysis
 September 2015

Not only competition between Originators and Generics, Generic manufacturers must compete with GPO to survive in the market

2

Government procurement regulation requires public hospital give the Government Pharmaceutical Organization (GPO) the preference

Attribute	Description/Rationale
Description	<ul style="list-style-type: none">GPO (Government Pharmaceutical Organization – stated owned company under Ministry of Public Health) is prioritized as the preferable drug brands over the others at procurement of Government hospitalsOther Generics can be purchased only if GPO does not manufacture such a molecular, or there is necessary matter related to effectiveness of treatment or budgeting
Area of influence	<ul style="list-style-type: none">Generics (there is no Originators produced by GPO as of now)
Potential impact	<ul style="list-style-type: none">High rivalry among Generics producers particularly price competition
Timing of impact	<ul style="list-style-type: none">Ongoing and will be more aggressive enforcement by Ministry of Public Health and The Controller General's Department
Scenarios & probability	<ul style="list-style-type: none">Promote local generic competitionMedicines will be developed as a result of innovation by researchers and drug companies

Source: The Controller General's Department' (CGD); Price of Goods and Services Act 1992; Stakeholders' interview; IMS analysis

Policy of limitation on dispensed channels is implemented to ensure the product efficacy and safety before allowing sales through Pharmacy

3

During Safety Monitoring Program (SMP) , only doctors in hospitals and clinic pharmacies can prescribe and dispense it

Attribute	Description/Rationale
Description	<ul style="list-style-type: none">• A mandatory Safety Monitoring Period required for all newly drugs which are approved for the license less than 2 years or have completed 2 years but they are still wait for final approval from FDA on withdrawn SMP status• Those drugs can be prescribed at hospitals or clinics by doctors only• During SMP period, drugs cannot file for NLEM application
Area of influence	<ul style="list-style-type: none">• All new drugs which are less than 2 years FDA license granted (called pre-market approval, after SMP status is removed from the drug, it will be called post-market approval)
Potential impact	<ul style="list-style-type: none">• Limitation of sales through other channels besides hospitals and clinics• New originators find the hard time to distribute their products widely and take longer time to establish the brand in OTC market (if needed)
Timing of impact	<ul style="list-style-type: none">• Ongoing (effective since 1991)
Scenarios & probability	<ul style="list-style-type: none">• N/A

Source: Drug safety monitoring program (SMP), Minister of Public health; Stakeholders' interview; IMS analysis

Over requested budget of CSMBS sparks off the initiative of cost containment on Non-NLEM from fully reimbursement

4

Cost-effectiveness analysis on case basis for prescribing non-NLEM

Attribute	Description/Rationale
Description	<ul style="list-style-type: none"> As patients under CSMBS can reimburse drugs either listed in NLEM or Non-NLEM and most Non-NLEM drugs are greatly more expensive than NLEM drugs. The reimbursement approval is only required doctor's consent form with rationales of patient's needs, this leads to over reimbursement budget. CGD has established dedicated committee to deliberate the cost-effectiveness and solid rationales for Non-NLEM drug request to control the budget of CSMBS reimbursement. The case is considered from cost-benefit analysis of healthcare expenditure on such a patient
Area of influence	<ul style="list-style-type: none"> Non-NLEM drugs
Potential impact	<ul style="list-style-type: none"> Doctors are encouraged by hospitals to prescribe NLEM drugs if available in order to ensure the reimbursement approval from CGD In case that Non-NLEM expense is raised and CGD denies the request, hospital must absorb those cost
Timing of impact	<ul style="list-style-type: none"> Ongoing but will be stricter especially for rare diseases (orphan drugs)
Scenarios & probability	<ul style="list-style-type: none"> Originators are replaced by Generics at the point of prescription Patients are limited to access Originators which may be more efficacy to their treatment

Source: The Controller General's Department' (CGD; Minister of Public health; Stakeholders' interview; IMS analysis

Thai Pharmaceutical Market Analysis
September 2015

To demonstrate the apparent on medication costs at private hospitals, Single Price policy is raised for government's deliberation

5 Single Price Policy: Enforcement on hospitals either public or private to demonstrate price of drug

Attribute	Description/Rationale
Description	<ul style="list-style-type: none"> Due to the debate of high medication costs at private hospitals which limits healthcare accessibility to majority of Thai nationals (low-to-middle income), there is potential new regulation to enforce the price label of drugs shown to patients (or either itemized in the bill) so that patients can decide which drugs they would like to purchase. For example, patients may be interested in Generics over Originators, or they prefer purchasing at Pharmacy rather than at hospital The objective is to control the over mark-up at hospitals and escalate healthcare accessibility to patients
Area of influence	<ul style="list-style-type: none"> All drugs but mainly impacts on Originators due to its nature of higher price
Potential impact	<ul style="list-style-type: none"> Hospitals are willing to list more Generics brand in their hospital formulary list as they can gain higher mark-up from Generics compared with Originators (even the price to patient of Generics will be lower due to lower cost of inventory)
Timing of impact	<ul style="list-style-type: none"> Likely to be officially implemented in 1-2 years
Scenarios & probability	<ul style="list-style-type: none"> There is strong offense from private hospitals as they claim of not high mark-up on drug costs as incriminated If this regulation is actually implemented, private hospitals possibly charge more on other costs such as hospitalization, consulting fee, etc.

Source: Minister of Public health; Stakeholders' interview; IMS analysis

To encourage Generics usage in Government hospitals in order to control CGD budge; potential policy of restricted markup is in discussion

6

Revision to reimbursement fees paid when out-patient medicines are dispensed

Attribute	Description/Rationale
Description	<ul style="list-style-type: none"> In order to control healthcare expenditure of government, the implementation plan by CGD is to specify mark-up on drug costs that hospitals can charge to them <ul style="list-style-type: none"> ✓ For Originator, they can charge back to CGD only 103% (100% of drug cost + 3% of operational cost) ✓ For Generics, they can charge the full amount of real billable payment (resulting in much higher operational costs can be paid due to CGD determines the cost of Generics is significantly lower than Originators – substitution)
Area of influence	<ul style="list-style-type: none"> Originators prescribed in Government hospitals and reimbursed under CSMBS (financed by CGD)
Potential impact	<ul style="list-style-type: none"> Prescription will be inclined to Generics as hospitals require to have a amount of reimbursement budget to cover their operational expense
Timing of impact	<ul style="list-style-type: none"> Likely to be officially implemented in 1-2 years
Scenarios & probability	<ul style="list-style-type: none"> Originators will be replaced by Generics if there is same molecular available Originator producers will be toward to self-pay or private hospitals market as there is no such of this constraint

Source: The Controller General's Department' (CGD; Minister of Public health; Stakeholders' interview; IMS analysis

FTA between EU and Thailand will benefit European Pharmacom to advantageously penetrate in ASEAN markets

7 FDA negotiation between EU and Thailand (ASEAN)

Attribute	Description/Rationale
Description	<ul style="list-style-type: none">• At the present, imported pharmaceutical products excluding Vaccine, therapies for HIV, malaria, Thalassaemia, and Plasma Protein are levied at 25-30%• This lowers competitive advantages to MNCs and protect local Phamacom
Area of influence	<ul style="list-style-type: none">• Imported drugs; mostly are original drugs which are initially expensive
Potential impact	<ul style="list-style-type: none">• Originators' price remains high due to imposed fees
Timing of impact	<ul style="list-style-type: none">• Being used up until now and able to change without prior notice• However, this Free Trade Agreement (FDA) is unlikely to be happened from stakeholders' perspective
Scenarios & probability	<ul style="list-style-type: none">• MNCs may consider setting up plants in Thailand to eliminate this financial burden and gain benefits from BOI. As well, some MNCs have decided to manufacture fighting brand (their Generics brand to compete with local pharmacom) thus this might be sustainable strategy for them

Source: Ministry of Public Health; Stakeholders' interview; IMS analysis

Prescription drug policy will advantage patients on more affordable drugs; however there is strong offense from hospitals

8

Prescription Drug policy

Attribute	Description/Rationale
Description	<ul style="list-style-type: none">• After the policy of Pharmacy regulation - in which Pharmacy is required to have full-time pharmacist for their license renewal as well as enforced for all registered Pharmacy, government would like to accelerate healthcare/pharmaceutical products at more affordable price to patient (with professional standard) by discussing on Prescription Drug policy• Prescription Drug Policy is policy that any patients can ask for prescription from doctors at hospital and purchase those prescribed drugs at Pharmacy instead. This policy is widely used in USA and other developed countries
Area of influence	<ul style="list-style-type: none">• All drugs
Potential impact	<ul style="list-style-type: none">• Hospitals can gain much lower from drug sales as patients may prefer purchasing at Pharmacy instead• Hospital channel will be less important to Pharmacom
Timing of impact	<ul style="list-style-type: none">• Recently discussed; should not be finalized within 2 years
Scenarios & probability	<ul style="list-style-type: none">• Hospitals especially private hospitals disagree with this policy as they claim of risks patients will confront if they purchase drugs outside hospitals. Some patients might purchase over dosage due to their connection with Pharmacists which will greatly affect their health

Source: Ministry of Public Health; Stakeholders' interview; IMS analysis

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Key Stakeholders/Association (1/2)

Role & Responsibility of Key Stakeholders / Associations



**Food & Drug
Administration (FDA),
Ministry of Public Health**

Role: License registration

- Drug, Food, Cosmetics, Medical devices, relevant healthcare products must be applied for FDA license approval
- Monitoring product quality after approval

NLEM

**National Essential List of
Medicine
(NLEM's Committee)**

Role: Drugs listed in NLEM

- To determine whether drugs should be listed in NLEM in which they can be reimbursed through 3 healthcare schemes (UC, SSS, and CSMBS)
- To work closely with NHSO, CGD, HITAP, and other government agencies to ensure on cost effectiveness analysis and accessibility to healthcare service of Thai nationals



**National Health of
Social Office (NHSO)**

Role: Encourage the healthcare accessibility to Thai nationals and improve healthcare standard

- Be financer/payer for Universal Coverage (UC) which covers majority of Thai nationals
- Be involved and high influencer in NLEM listing consideration

Key Stakeholders/Association (2/2)

Role & Responsibility of Key Stakeholders / Associations



**The Comptroller
General's Department
(CGD)**

Role: Financial management of all government expense occurred at public agencies

- To approve, control, and examine all government expenditure including healthcare expenses
- To set up the median price applied for all procurement at public agencies



**The Medical Council of
Thailand and professional
associations**

Role: Center of Healthcare professionals to exchange knowledge and to develop new practice in Thailand

- To encourage education, clinical studies, and medical professionals in develop their knowledge in the area
- To be involved in establish and improve diagnosis and treatment guideline in Thailand



Medical School

Role: Offer full range of Medical services and have high influencing power in treatment practice

- Most of them are specialized medical centers for critical/chronic diseases
- To conduct clinical trials for new drugs requesting FDA license and be key influencer in NLEM listing, treatment guideline

List of companies specializing in pharmaceutical industry (1/2)

List of key distributors / wholesalers in Thailand

Company Name	City	Key partners	Annual Sales (USD)
DKSH (Thailand)	Sukhumvit Rd. Band Chak, Bangkok	<ul style="list-style-type: none"> • Partner with 380 companies to serve 160,000 clients nationwide; its healthcare portfolio consists of Medical device, OTC and consumer health products, and Pharmaceutical products • Some of its key partners are Roche, Omron, BASF, AstraZeneca, Bristol-Myers Squibb, MSD, Meiji Pharmacuetical (Thailand), B. Braun, Bayer, Eisai, Eli Lilly, Fresenius Kabi, etc. 	3,786mn (2013)
Zuellig Pharma	Ploenchit center, Sukhumvit Rd. bangkok	<ul style="list-style-type: none"> • Partners Some of its key partners are AstraZeneca, Pfizer, Bayer, Abbott, Boehringer Ingelheim, Danone, A. Menarini, Thai Otsuka, Sanofi, Sandoz, Novo Nordisk, Mega Lifesciences, MSD, Novartis, Otsuka, etc. 	1,349mn (2013)
Boots Retail (Thailand)	Pakin Bldg., Ratchadapisek Rd., Bangkok	<ul style="list-style-type: none"> • Operates its own chain Pharmacy with ~200 locations nationwide; the company offers 'Boots' & 'Botanics' consumer health product line, and professional Pharmacy with full-time pharmacists. • The company has partnered with DKSH to support their full logistics. 	183mn (2014)
LF Asia	Maneeya center, Ploenchit Rd., Bangkok	<ul style="list-style-type: none"> • Some of its key partners are Gilead, Mundipharma, Rowa, Lab Rubio, Okasa Pharma, etc. 	90mn (2013)

Source: IMS in-house database; Department of Business Development, Ministry of Commerce; IMS analysis

List of companies specializing in pharmaceutical industry (2/2)

List of key distributors / wholesalers in Thailand

Company Name	City	Key area and Partner	Annual Sales (USD)
Business Alignment	Silom, Bangrak, Bangkok	<ul style="list-style-type: none"> Be strong partner with medical school and hospitals on supplying healthcare products used in oncology area 	29mn (2014)
Thai gauze	Karnchanapisek Rd., Prawet, Bangkok	<ul style="list-style-type: none"> Focus on consumable healthcare products with the long operation history of 32 years 	17mn (2014)
Tsuruha (Thailand)	Sathorn Rd, Sahn, Bangkok	<ul style="list-style-type: none"> Operate its own super chain Pharmacy named 'Tsuruha' with 28 branches by end of 2015 and mainly sell Japanese products Be Joint Venture between Sahapathanapibul (One of the largest FMCG distributor in Thailand with their own products) and Tsuruha Holdings Inc. (Japan) 	8.6mn (2014)
Inter Pharma Plus	ITF Tower, Silom Rd., Bangkok	<ul style="list-style-type: none"> Expertise in Probiotic and Prebiotic products 	6.7mn (2014)
Pacific Healthcare (Thailand)	Supalai Grand Tower, Rama 3, Yannawa, Bangkok	<ul style="list-style-type: none"> Partner with many pharmacoms and healthcare product suppliers, covering Drugs & Biotech, Medical supplies, Medical technology, and consumer health in their product portfolio The company also offers fully vertical sales services (product registration, sales force, until cash collection for client) 	54.7mn (2013)

Source: IMS in-house database; Department of Business Development, Ministry of Commerce; IMS analysis

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Generics present potential markets in Thailand, while segmentation and targeting, and network development are critical activities

Opportunity	Description	Key success factors
Low degree of Generics in some therapeutic areas	<ul style="list-style-type: none"> There are rooms for Italian pharmacom to play especially in some therapeutic areas with low Generics competitor such as Oncology drugs (but require significant R&D efforts) and Ophthalmological drugs 	<ul style="list-style-type: none"> Qualified in NLEM listing and recommended by healthcare professionals in medical schools Strong distribution network for delivering products outside Bangkok. Establishing a connection with MNC distributors (e.g. DKSH and Zuellig who have strong presence) is required for nationwide penetration
Rapid growth in Private hospitals and Pharmacy	<ul style="list-style-type: none"> Even low competitive advantages of MNCs with Originators in government hospitals, those drugs are more welcome at private hospitals and pharmacies which demonstrates the impressive growth 	<ul style="list-style-type: none"> Partner with private hospitals through Patient Assistance Program (PAP) and loyalty program on drug sales will motivate long-term relationship Optimized segmentation and targeting for private hospitals and pharmacies for prioritizing sales efforts Right product portfolio for OTC channel
Professional relationship with Medical schools/associations	<ul style="list-style-type: none"> All new drugs must pass clinical trials conducted by Medical schools, and those healthcare professionals there have high influencing power on NLEM listing, CGD budget planning, treatment guidelines. Thus, good relationship is required for successful entrants 	<ul style="list-style-type: none"> Satisfactory support for academic through seminars' invitation at either local or global level, as well as sponsorship on clinical studies especially in rare or chronic diseases by encouraging trails of Italian pharmacom's products Competitive drug prices for medical school hospitals to encourage the usages for successfully product introduction

Source: Stakeholders' interview; IMS analysis

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