



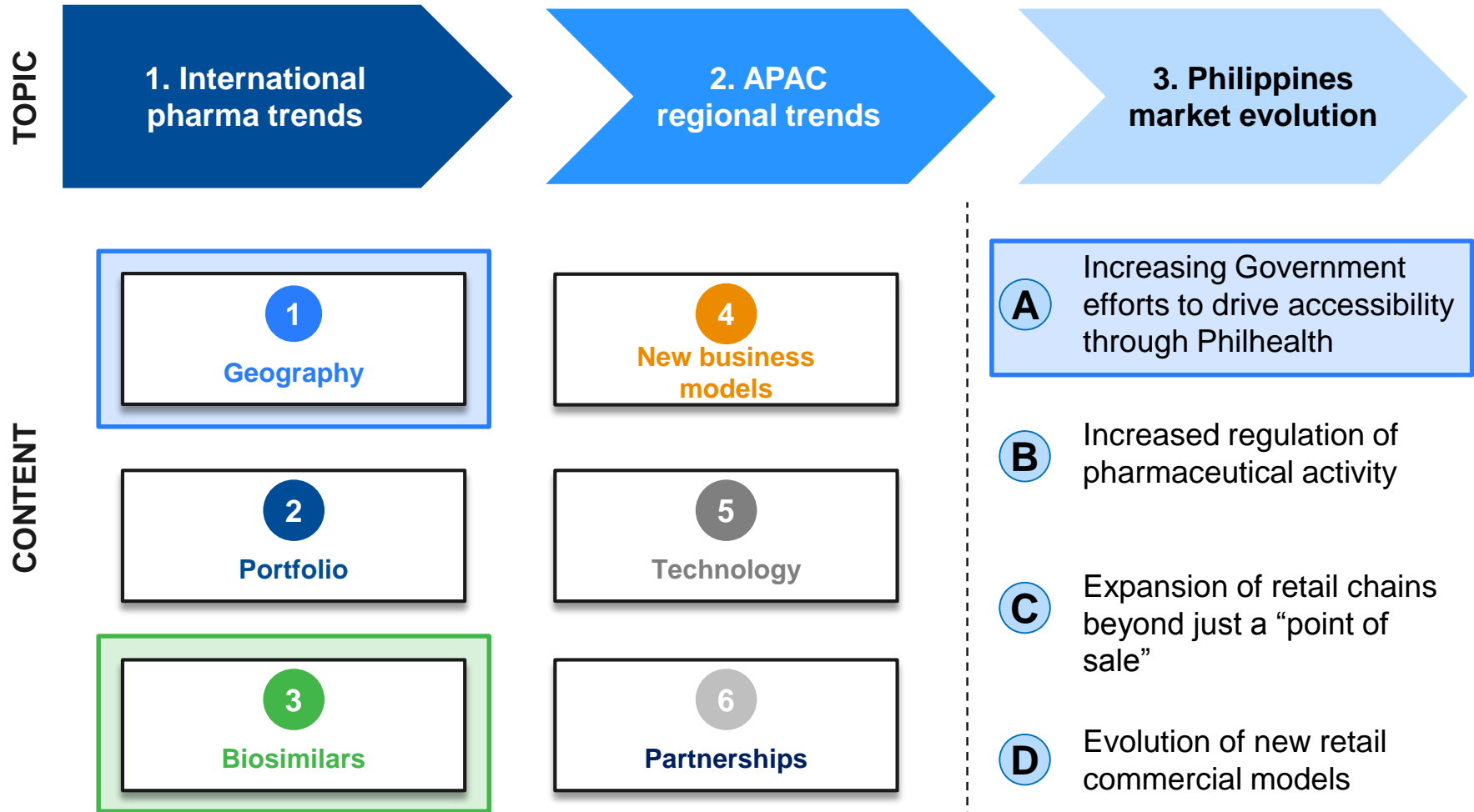
QuintilesIMS™

Regional Pharma Trends Update and Impact on the Philippines

Angela Yik
GM, South East Asia and Pakistan
QuintilesIMS

July 2017

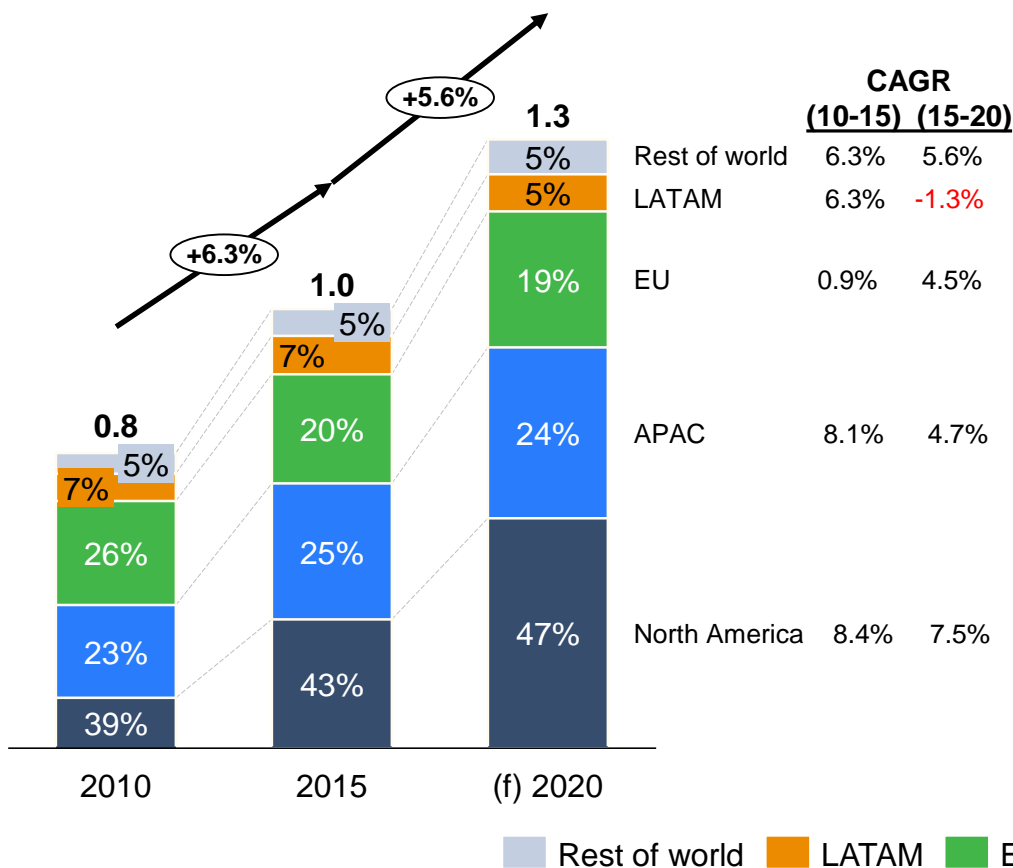
Today we will focus on additional trends shaping SEA and PH including follow-on biologics



While declining from 31% to 21%, Asia's contribution to growth will remain one of the largest globally

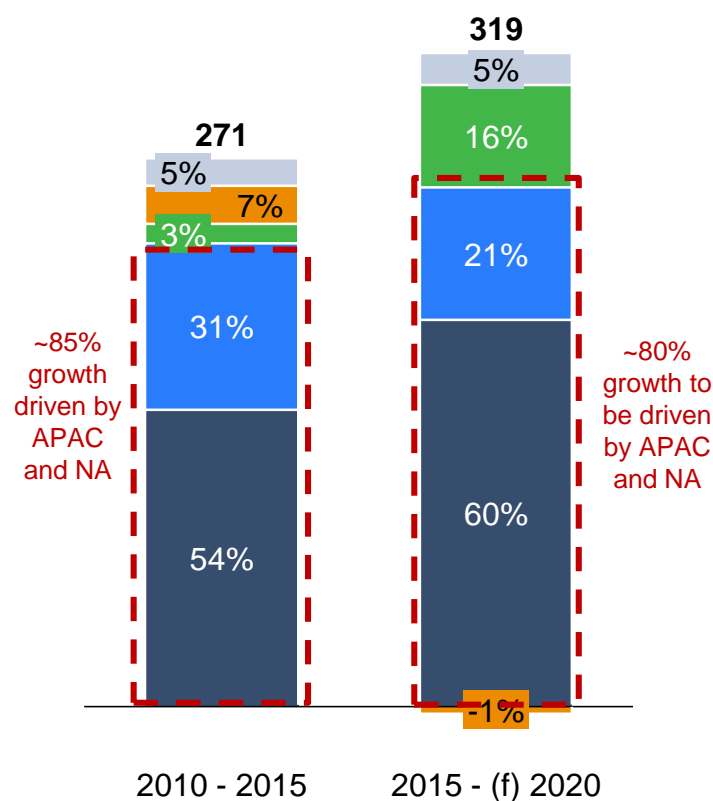
Global pharmaceutical market size by region

(2010-2020, US\$ Trn)

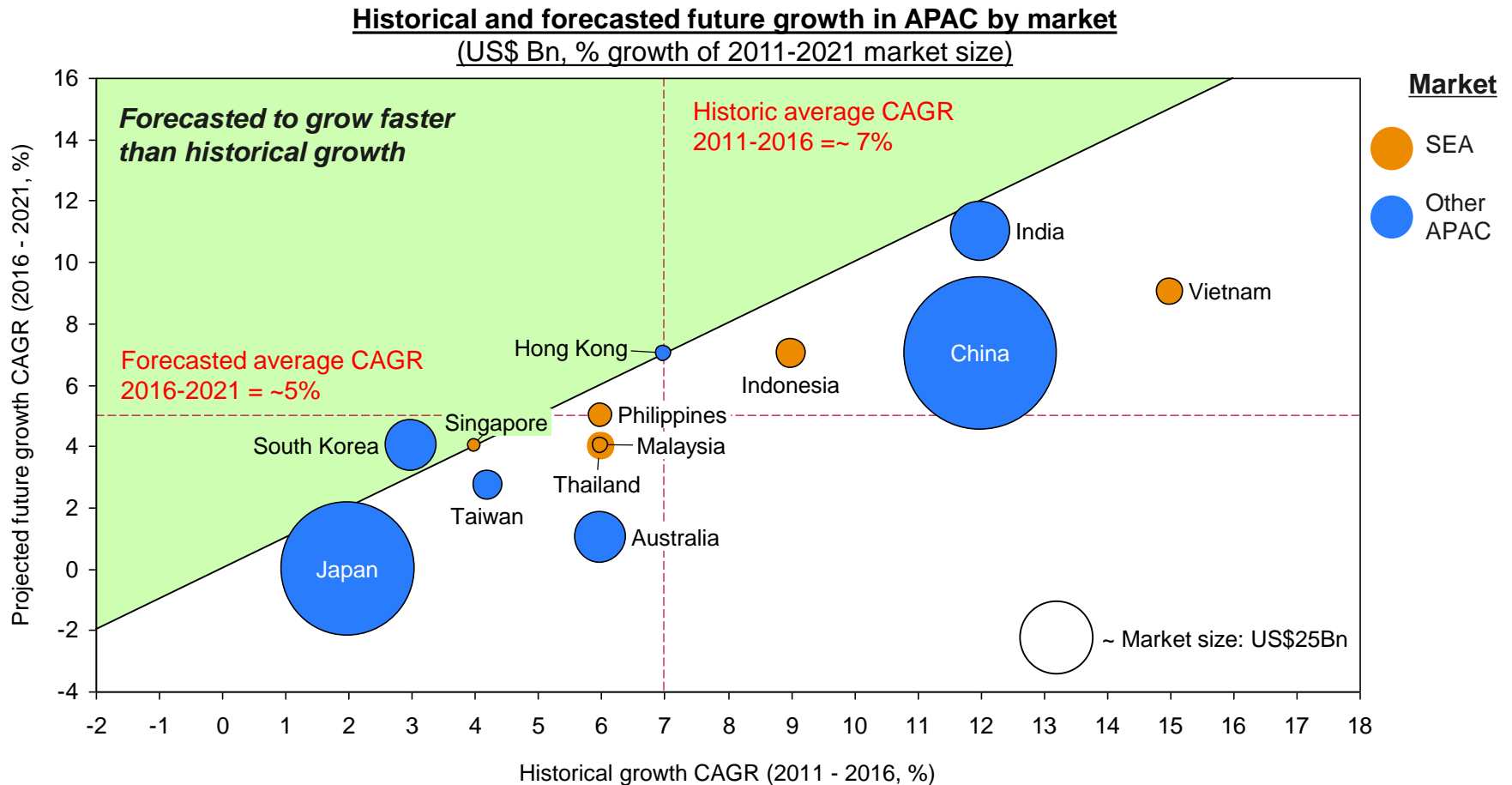


Contribution to global sales growth












(2010-2020, US\$ Bn)



SEA markets will continue to grow strongly, attracting investment from APAC and globally



Philippines has different competitors than SEA, Unilab faces producers from India, Thailand and Pakistan

Country of Corporation	Total Non-originator Export Sales ¹ to SE Asia ² , US\$ Mn (2016)	2012-16 CAGR	PH Sales, US\$ Mn (2016)
 India	90% // 10% 293	10.6%	\$95.5
 Korea	74% // 26% 114	1.8%	\$8.3
 Philippines	99% 1% 64	3.9%	n.a.
 Thailand	100% 54	19.1%	\$23.7
 Pakistan	92% 8% 46	4.9%	\$39.4
 Taiwan	100% 0% 35	-3.8%	\$1.3
 Bangladesh	100% 21	28.7%	\$2.3
 Australia	73% 27% 20	-6.0%	\$11.9
 Indonesia	76% 24% 9	6.1%	\$0.2
 Malaysia	100% 0% 9	-17.1%	\$5.2
 China	67% 33% 8	5.1%	\$1.4

Top 2 countries comprise ~60% of total APAC exports to SEA

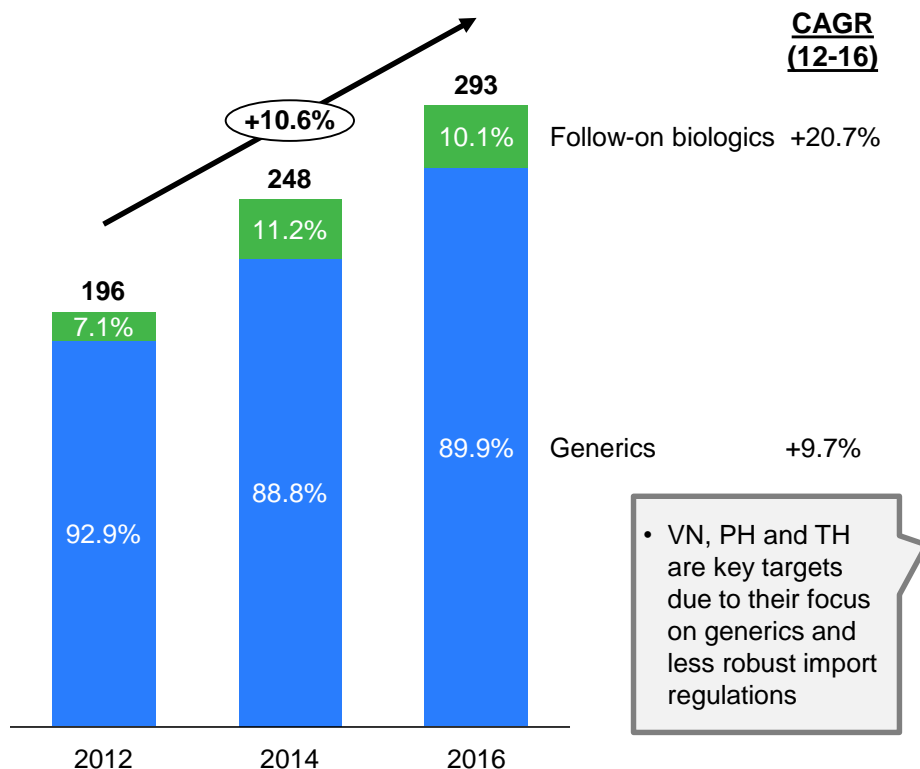
Generics³ Follow-on Biologic⁴

Imports to PH

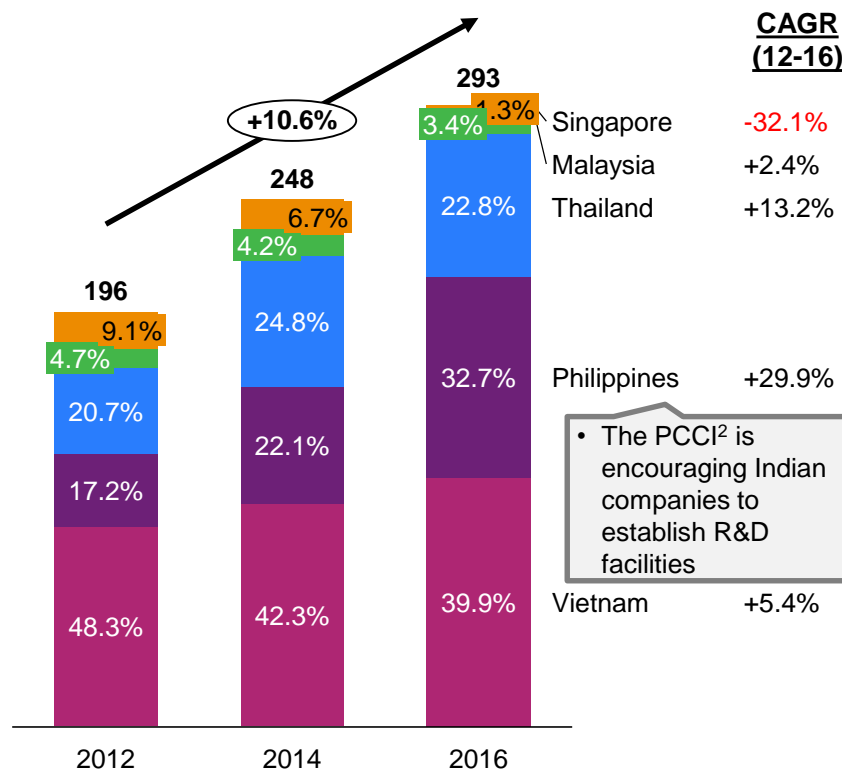


Most exports from India are generics, Philippines is the second largest target and growing very fast

Non-originator export to SE Asia by product type
(\$USD Mn, 2012-2016)



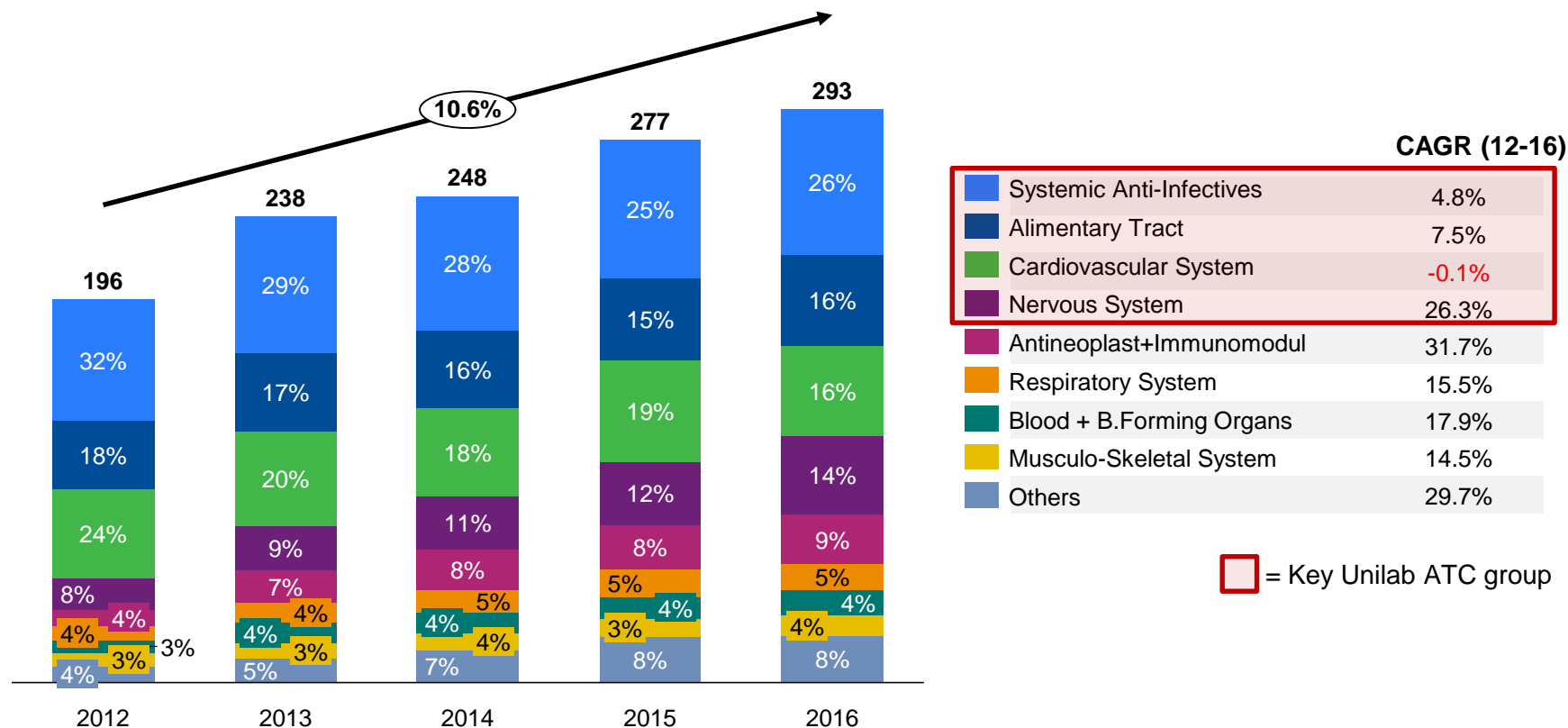
Non-originator export to SE Asia by country¹
(\$USD Mn, 2012-2016)





Key growth areas for Indian exports are CNS and oncology, with other areas growing roughly with market

Breakdown of non-originator export to SE Asia by therapy area
(\$USD Mn, 2012-2016)





Lupin and Torrent are competitors to watch for Unilab, with both exhibiting greater than market growth

Manufac.	Total Sales in SE Asia US\$ Mn (2016)	2012-16 CAGR (SEA)	PH total sales US\$ Mn (2016)	2012-16 CAGR (PH)
Lupin Laboratories	95% 5% 34	28.3%	30.4	31.4%
Torrent	100% 33	19.0%	27.4	22.1%
Sun Pharma	64% 36% 28	-3.7%	0.1	39.6%
Zydus Cadila	100% 26	37.1%	13.0	123.7%
Glenmark Pharm	100% 17	20.2%	10.1	28.6%
Cadila	100% 10	13.4%	0.0	-29.4%
Micro Labs	100% 8	4.7%	0.0	49.2%
Venus Remedies	100% 8	27.3%	n.a.	n.a
Cipla	100% 6	4.9%	0.8	18.4%
Dr Reddys Lab	83% 17% 6	8.1%	0.1	4.1%

Legend: Follow-on biologics (Green), Generics (Blue)

Lupin and Torrent are key competitors due to high exports to SE Asia, especially PH, and high growth

~60% of India's export to SE Asia

Lupin specifically, has most of its SEA exports to Philippines and is shifting towards biosimilars



APAC entry strategy

- **Philippines is a key market in SEA** where Lupin entered through the **acquisition of MultiCare in 2009**
- **Establishing new plants and upgrading existing facilities in APAC**



SEA / PH business mix

- **~90% of exports to SEA are to Philippines**, growing at a **CAGR of 31%** between 2012-16
- Key **Therapeutic Areas** in Philippines include **anti-infectives (33%)** and **alimentary tract (metabolism) (28%)**



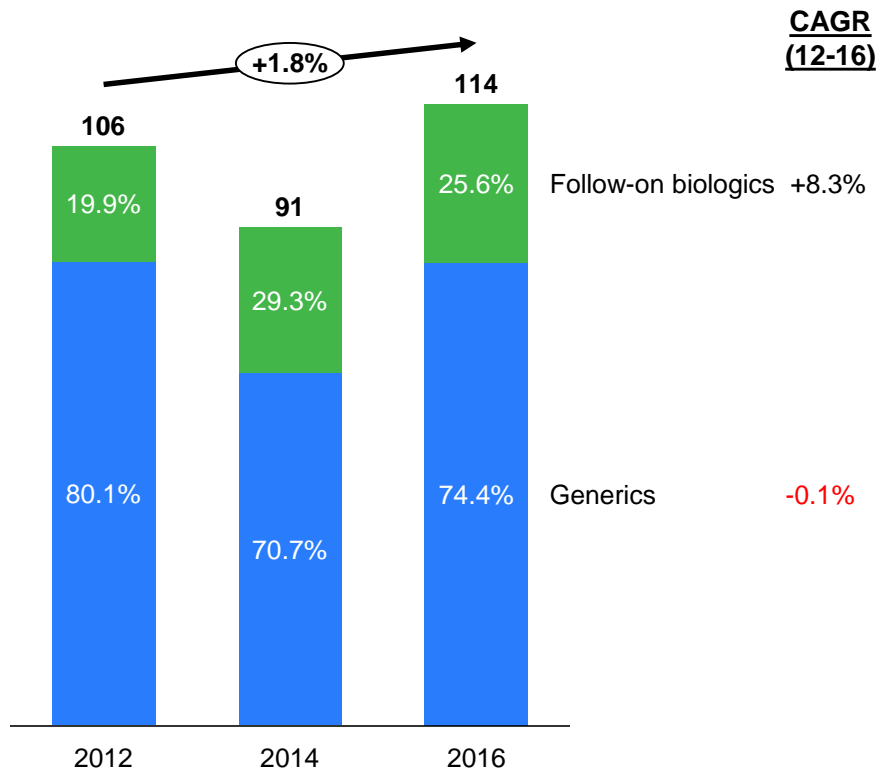
Future strategy

- Lupin looking to **move towards a more complex business mix**:
 - Complex generics → follow-on biologics / biosimilars → specialty business
- **Strong follow-on biologic pipeline** with R&D at 9% of 2017 spend
 - Pipeline includes follow-on biologics for **Enbrel, Lucentis, Perjeta** etc.

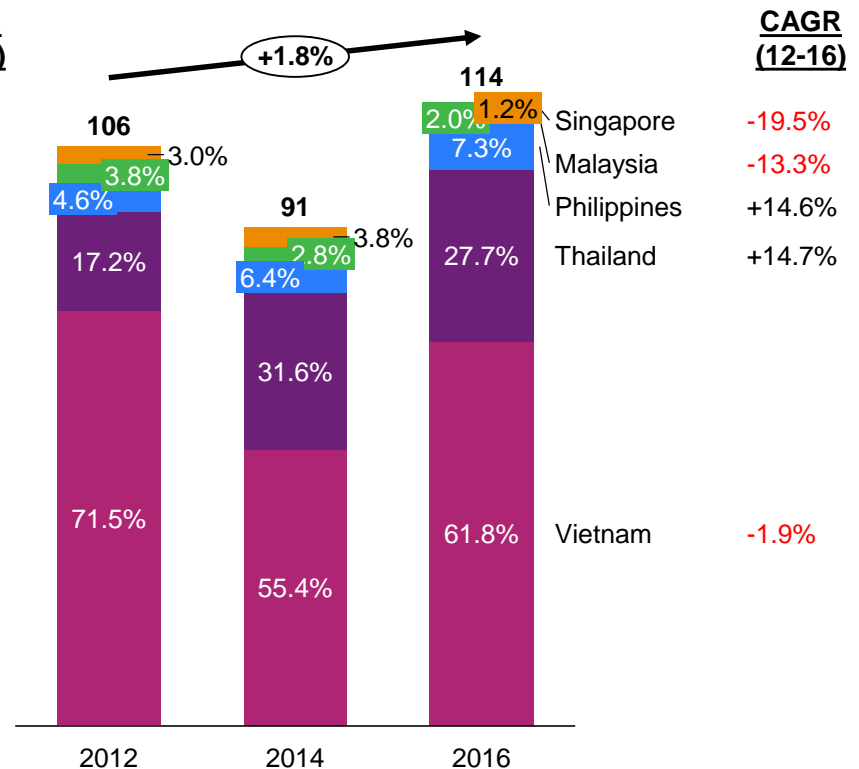


For Korean manufacturers, Vietnam and Thailand appear to be the main priorities

Non-originator export to SE Asia by product type
(USD Mn, 2012-2016)



Non-originator export to SE Asia by country¹
(USD Mn, 2012-2016)



Koreans will likely continue to expand their follow-on biologics footprint through partnerships in SEA

PanGen Biotech entry to Malaysia



- PanGen Biotech Inc, a biologics company in Korea, has formed joint venture with a Malaysia pharma CCM Duopharma biotech Bhd (CCMD), as part of the strategy to expand its footprint in the biologics market in SEA
- Leveraging on CCMD's local network, PanGen's gains access to distribute and market its follow-on biologics in Malaysia, Singapore and Brunei, with combined market value estimated to be RM50mil annually

Genexine and Samyang Biopharmaceutical entry to Indonesia













2015

2014

- Genexine (Korea), a specialized biologics company, forms an alliance with Kalbe Farma (Indonesia) in building a factory for follow-on biologics in Jakarta. Via Kalbe's nationwide distribution network and production facilities, Genexine accelerates its expansion into SEA market.
- Samyang Biopharmaceutical (Korea) collaborates with Kalbe in setting a factory for generic oncology drugs in Jakarta, allowing the Samyang to tap into the rising Indonesia domestic need for cancer medication.

As strong sellers' patents expire, follow-on biologics represent a significant area of growth in SEA

Molecule (Originator)	Originator SE Asia sales (US\$ Mn, 2016)	US expiry date	EU expiry date	Follow-on biologics availability in SE Asia (2016) ¹
Adalimumab (Humira)	6	2016 ⁴	2018	
Insulin Glargine (Lantus)	48	Expired	Expired	<ul style="list-style-type: none">  Basalin (Gan & Lee Pharma)  Basalog (CCM Pharma)²   Glaritus (Lupin Lab)
Etanercept (Enbrel)	8	2028 (extended)	Expired	
Infliximab (Remicade)	8	2018	Expired	<ul style="list-style-type: none">  Remsima (Celltrion)^{2,3}
Rituximab (Mabthera)	48	2018	Expired	<ul style="list-style-type: none">  Acellbia (Biocad)²
Bevacizumab (Avastin)	45	2022	2019	<ul style="list-style-type: none">  Bevacizumab (Biocad)²
Trastuzumab (Herceptin)	94	2019	Expired	<ul style="list-style-type: none">  Hertraz (Biocon)²
Insulin Aspart (Novorapid)	71	Expired	Expired	
Glatiramer Acetate (Copaxone)		Expired	2017	
Pegfilgrastim (Neulasta)	4	Expired	2017	<ul style="list-style-type: none">  Neupeg (Intas)  Peggrafeel (Dr Reddy's Lab)

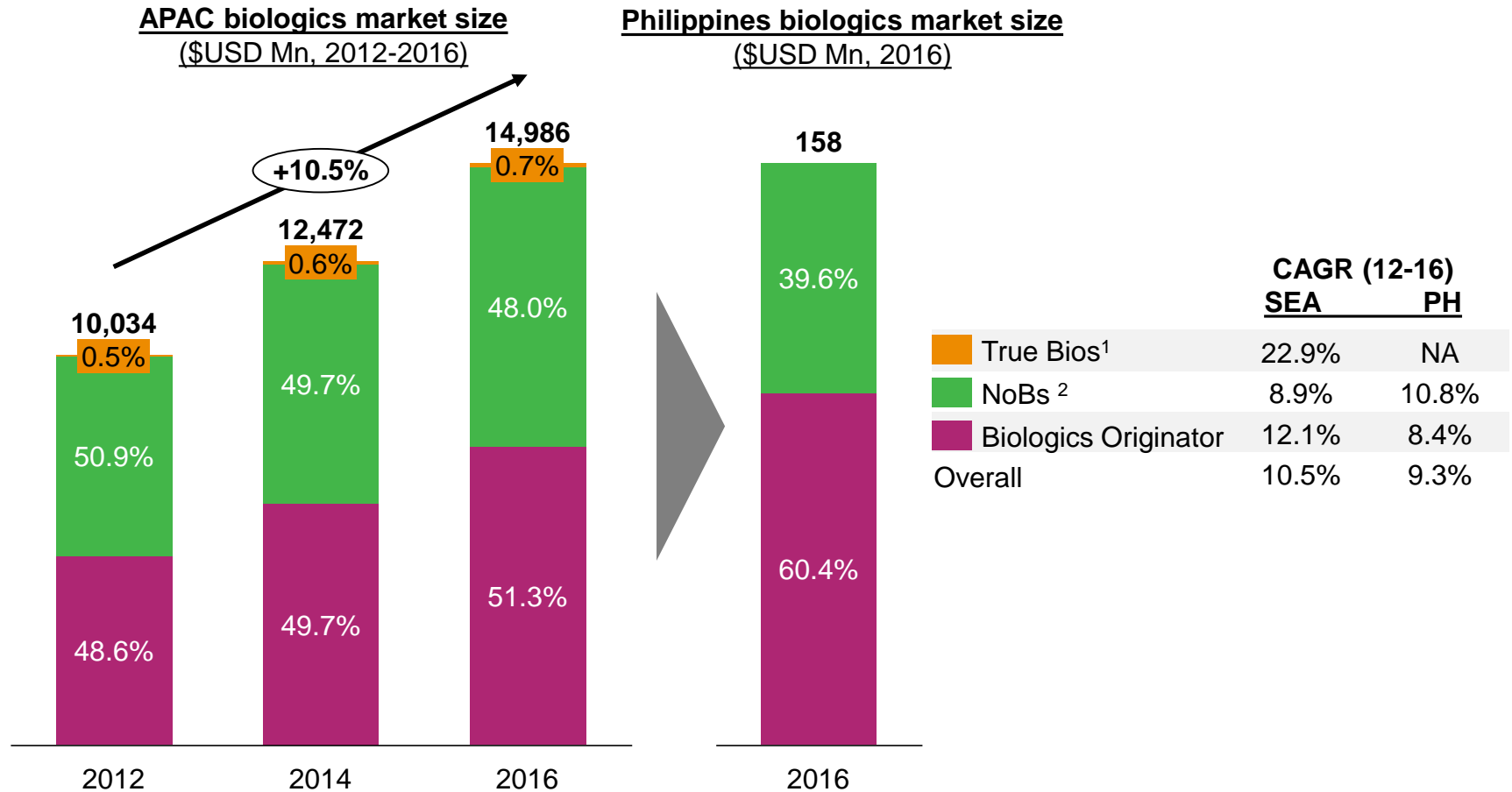
Defining generic biologics will allow us to better analyze market dynamics and define the opportunity

Terminology	Originator biologics	Follow-on Biologics	
		Non-original biologics (NoB)	True Biosimilars ¹
Explanation	<ul style="list-style-type: none"> • “Original” version of the biologic which usually have few years of patent protection • Originator biologics undergo trials like those needed for the launch of a new drug 	<ul style="list-style-type: none"> • Copy products of originator biologics • Products that undergo less stringent trials on comparability • Products produced & marketed in countries with less formal regulatory protocols with the aim of gaining quick access 	<ul style="list-style-type: none"> • Molecules which undergo trials on clinical equivalence & comparability to originator • Molecules which followed EMA / FDA / WHO approval guidelines for a biosimilar agent

Examples



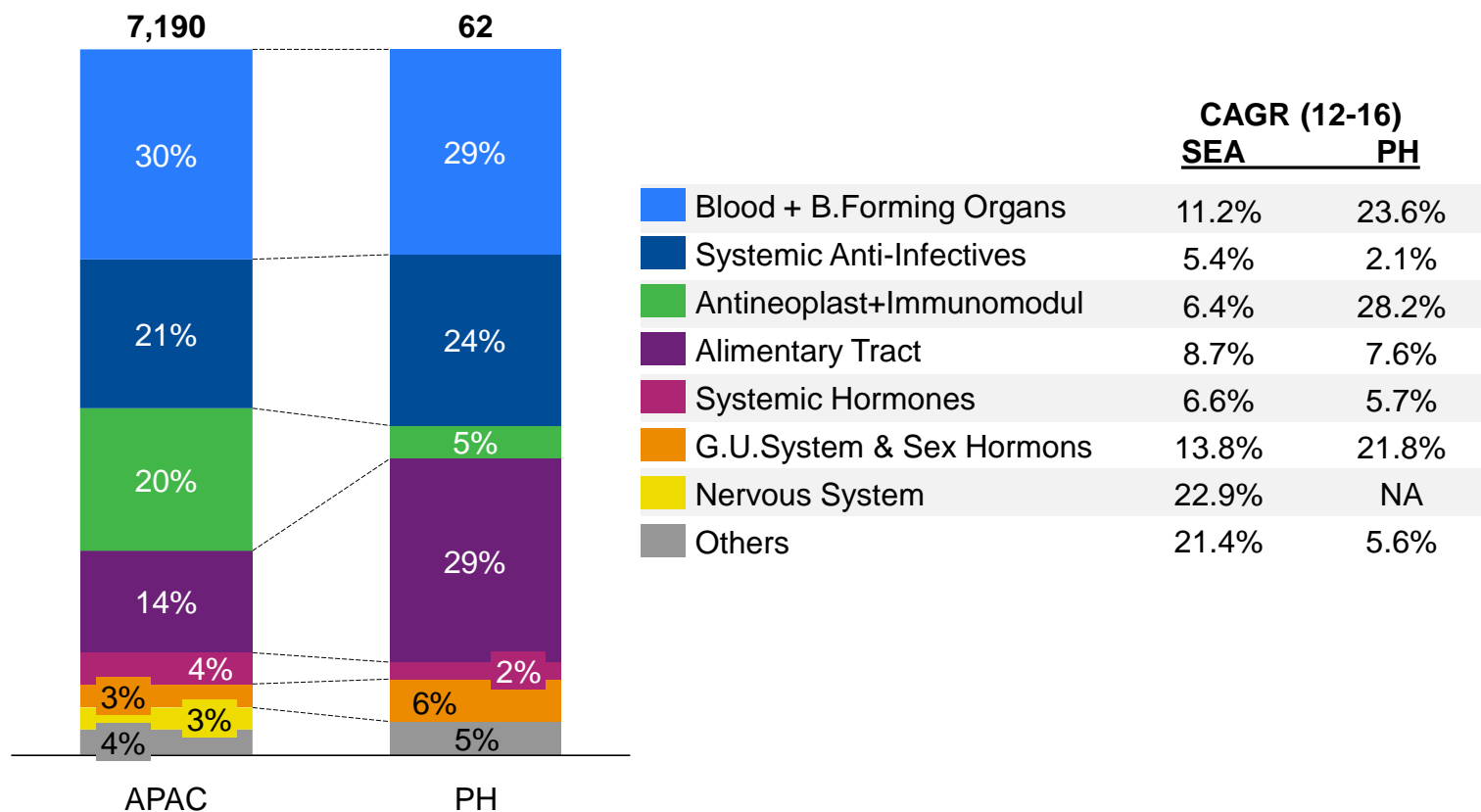
Follow-on biologics market in Philippines is under-penetrated compared to APAC but shows higher growth



PH target diseases for follow-on biologics aligns with APAC, although oncology is underpenetrated

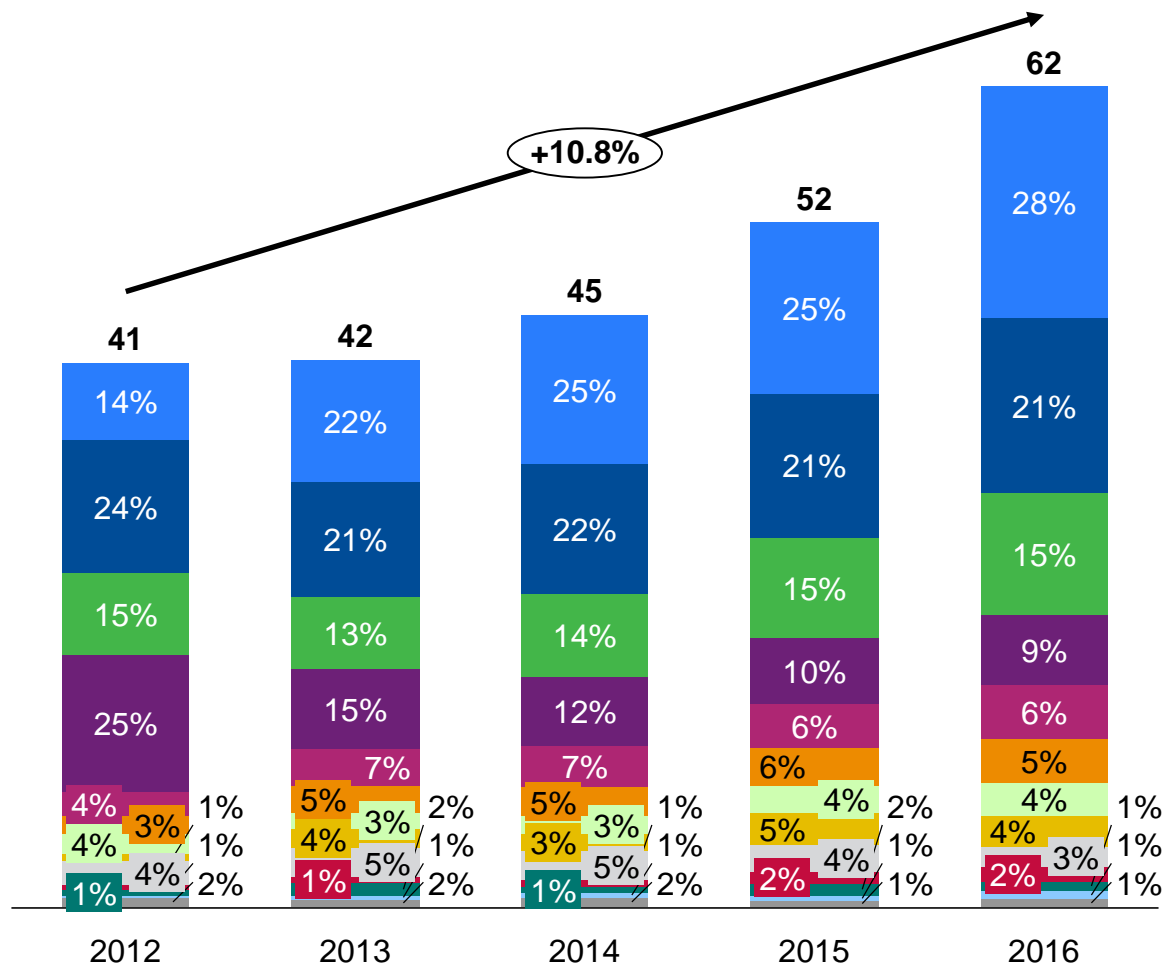
Breakdown of APAC and PH follow-on biologics market by therapy area

(Sales percentage, \$USD Mn, 2016)



PH imported follow-on biologics largely originate from USA and Denmark, with India seeing the highest growth

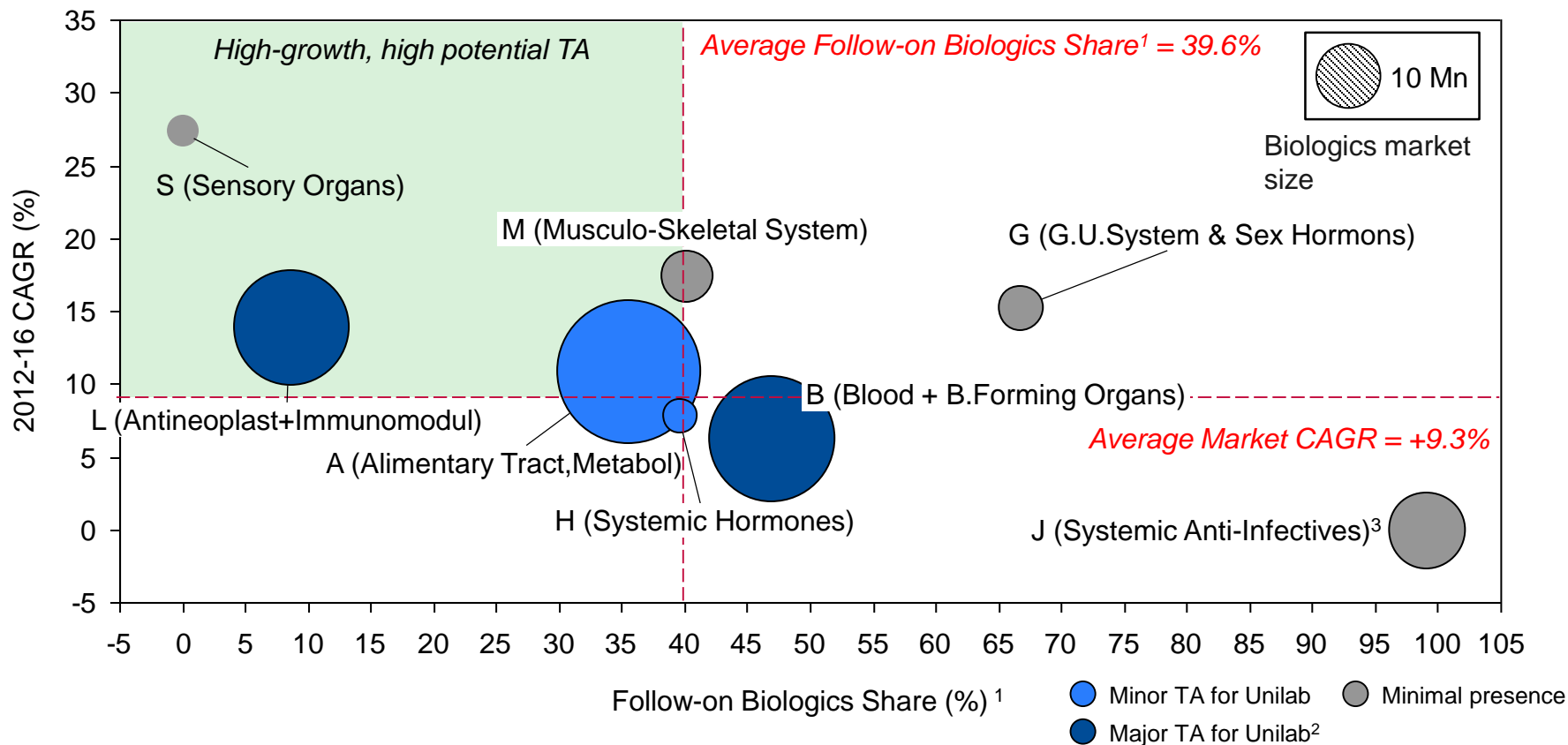
Breakdown of PH follow-on biologics¹ by countries
(2016; \$USD Mn, Value Share %)







CAGR (12-16)	
Philippines (domestic)	31.3%
USA	7.1%
Denmark	10.6%
France	-15.4%
Switzerland	22.2%
Pakistan	26.5%
Italy	12.1%
India	44.0%
Poland	-2.5%
China	32.3%
Japan	9.8%
Korea	39.8%
Others	-2.9%

The oncology ATC appears to show the greatest opportunity for follow-on biologics in PH

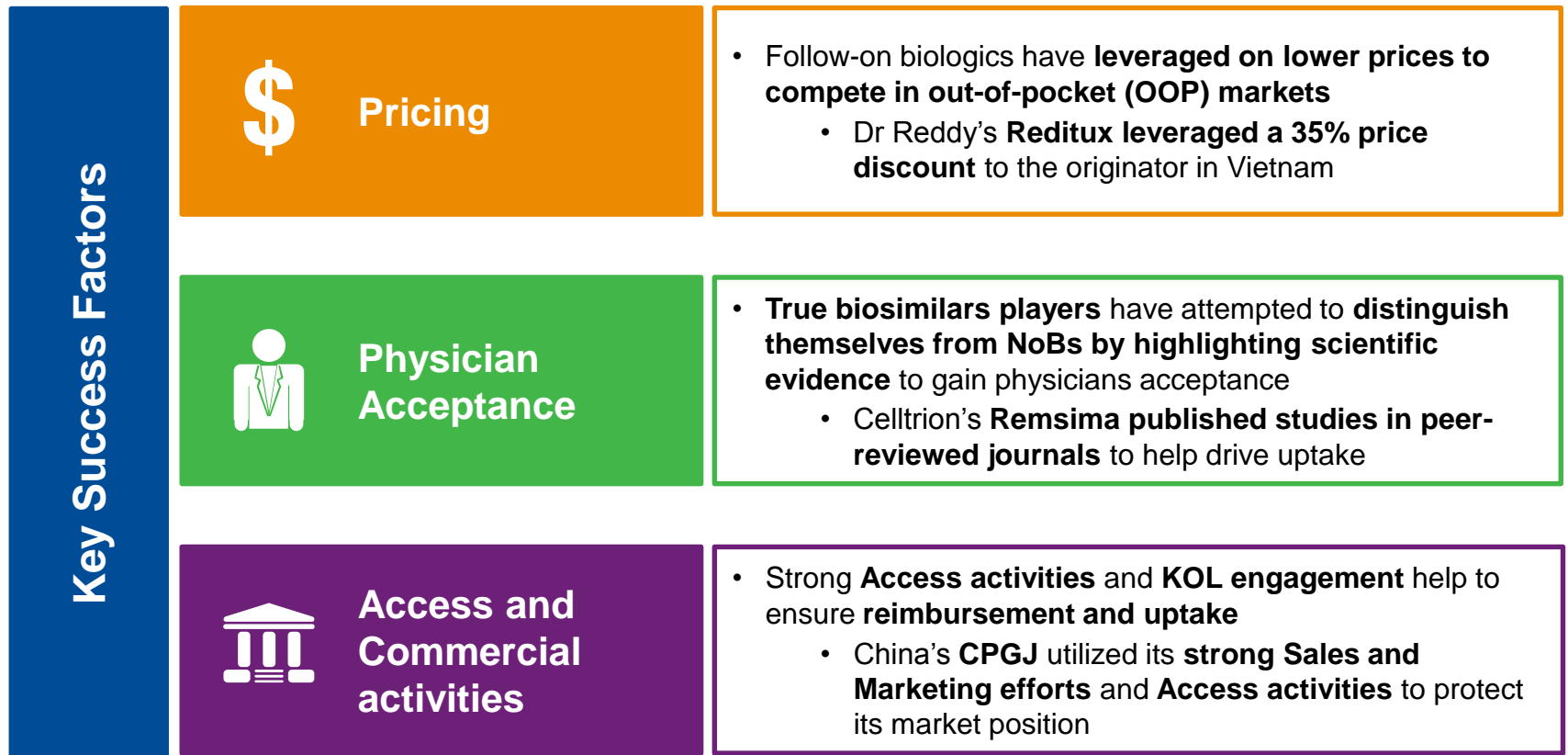
Philippines follow-on biologics share vs 4-Yr CAGR by key ATC class
(2012-16; \$USD Mn)



There may be an opportunity to partner to bring rituximab follow-on biologic products to Philippines

ATC	Molecule	Total follow-on biologics sales in SE Asia of products not in PH US\$ Mn (2016)	2012-16 CAGR (SEA)	Key products	Pipeline products ¹
Oncology (L)	Rituximab	 3.96	317.7%	Reditux, Dr. Reddy's, India	
	Thymalfasin	 0.54	n/a	Thyfacin, Pharbaco, Vietnam	
	Triptorelin	 0.07	n/a	Diphereline, Menarini, Italy	

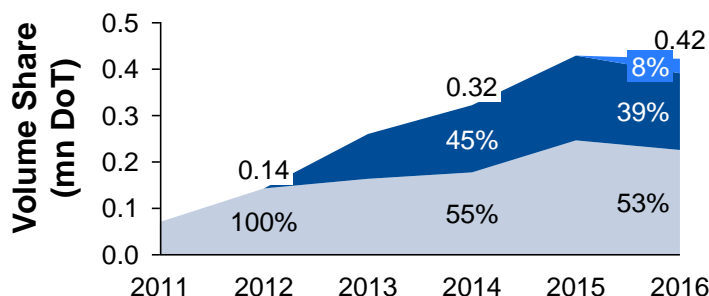
Follow-on biologic manufacturers have leveraged various KSFs when launching their products in APAC



Leveraging on KSFs along with lower manufacturing costs can result in strong uptake and ROI

Reditux, a NoB for rituximab, has employed a significantly lower price than originators in Vietnam

Volume Share: Rituximab in Vietnam
(2011-2016; Mn days of therapy)



Value Share (%)	2011	2012	2013	2014	2015	2016
MabThera	100%	100%	72%	65%	67%	64%
Reditux	-	-	28%	35%	33%	31%
Acellbia	-	-	-	-	-	5%



Reditux (Dr. Reddy's) ~67% of MabThera price
Acellbia (Biocad) ~50% of MabThera price

Rituximab biosimilar, Reditux was launched in Vietnam with ~35% price discount to Ox

Dr.Reddy's

Reditux™
Rituximab

- Reditux was **world's first non-originator mAb**
- Vietnam launch took place in 2012
- At launch, it is **~35% cheaper** than MabThera for a 500mg/10ml dose
- Reditux captured a peak share of **~43% within 3 years since launching despite MabThera being on the Reimbursed Drug List offering discounts to patients**
- **Acellbia** was launched by Biocad in 2016 at **50% of the MabThera price** cutting into Reditux's share



True biosimilars such as Remsima have leveraged scientific evidence as basis for physician acceptance



Celltrion focused on sharing scientific evidence to ensure biosimilar uptake

Initiative

Impact

1

Published data and studies on biosimilar infliximab in **peer-reviewed medical journals**



Gained physician trust as medical journals are their most trusted source of information

2

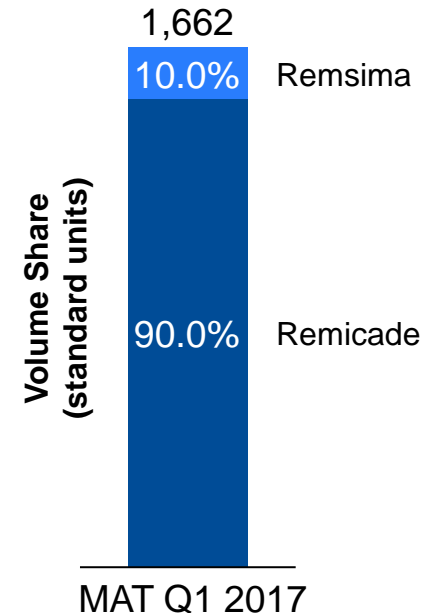
Conducted additional validations to the data packages based on **journal editor's request**



Secured publications in **Rheumatology journal, Annals of the Rheumatic Diseases (ARD)**

Remsima (Celltrion) is able to erode into originator share immediately after launching in Q3 2016

Volume Share: Infliximab in Malaysia
(MAT Q1 2017; standard units, volume share %)

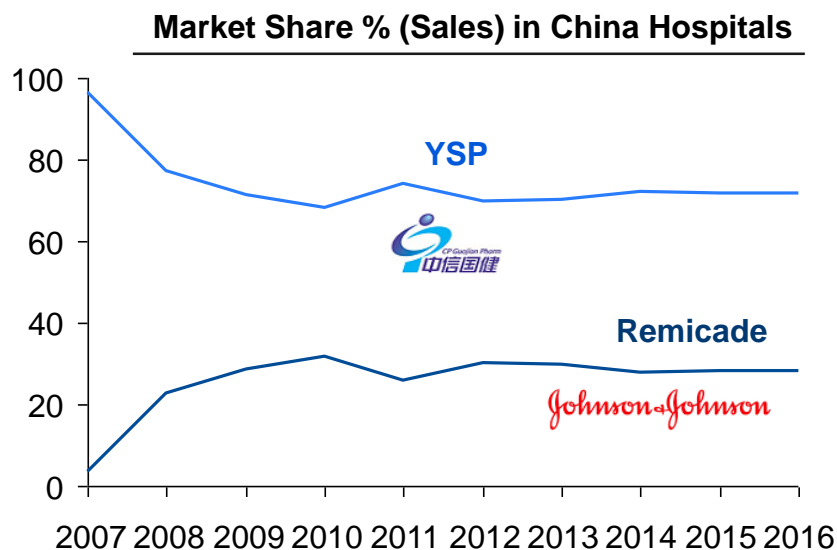


Beside pricing at a discount to the originator biologics Remicade, Remsima has leveraged on the availability of strong scientific evidence as basis to support marketing activities

CPGJ leveraged on strong Access and Commercial activities to protect its market leading position vs. MNCs



CPGJ is the number one local player in biologics market...



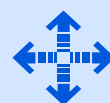
Product	Company	CAGR ('12-'16)	CAGR ('14-'16)
YSP	CPGJ	+12%	+6%
Remicade	J&J	+5%	+6%

YSP is a NoB to Enbrel that has faced strong competition from MNCs such as J&J in RA

....due to a number of Key Success Factors

Key Success Factors

Strategic marketing



- Positions product strategically to target large population
- Engages with KOL consistently
- Invests in patient education

Investment in medical



- Invests in proving efficacy and superiority of product continuously
- Works closely with leading KOLs to develop data

Comprehensive sales model



- Covers remote markets
- Frequent detailing to maintain high penetration and physician loyalty

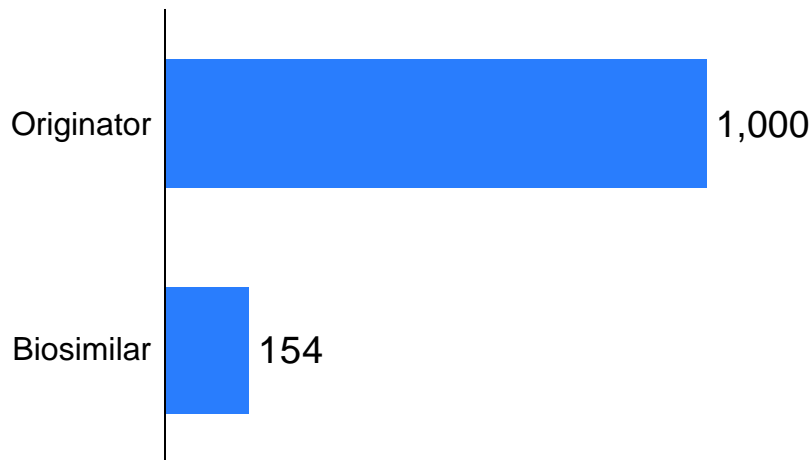
Strong Gov't Affairs



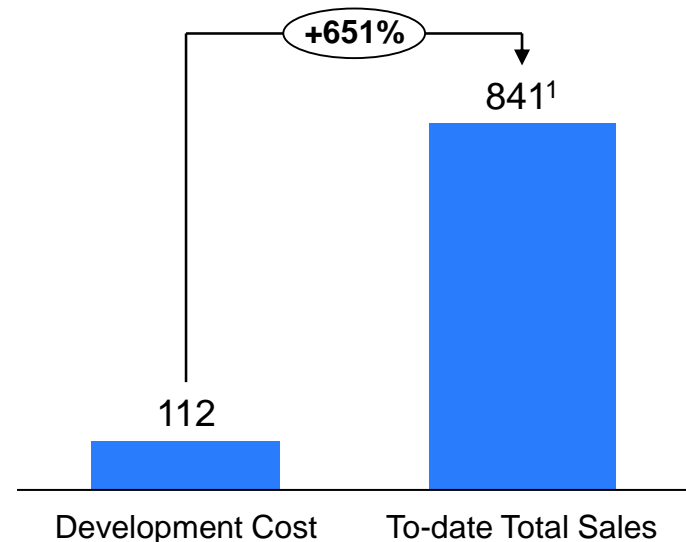
- Achieved listing in 7 PRDLs (incl. SH, Guangdong, Hunan etc.)
- Received strong support from the government

Lower development costs help to drive strong returns, particularly where commercial activities are maximized

Development Cost of Originator Biologics vs Biosimilars
(USD\$ Mn)



Remsima's Development & Global Market Performance
(USD\$ Mn)



- **Cost advantage:** Biosimilars are cheaper to develop as compared to originators with the most cost incurred in the pre-clinical (~60% total costs) and phase III trial stage (~35% total costs)
- **Shorter development time:** On average, a biosimilar development takes about 8-10 years as compared to 12 years for originators
- In 2008, **Celltrion entered the biosimilar market** based on its **contract manufacturing organization** experience
 - Since first approval from Korea FDA in 2012, **Remsima, together with Inflectra (through marketing partnership with Pfizer)** has captured **~8.1% sales share**

Moving on the Philippine's specific trends, There are a number of key drivers and risks to market growth

Drivers of growth



- ✓ Universal Healthcare expansion
- ✓ Infrastructure investments
- ✓ Growth of key chronic and acute treatments due to generics and oncology
- ✓ Growing support for local manufacturing

Risks to growth

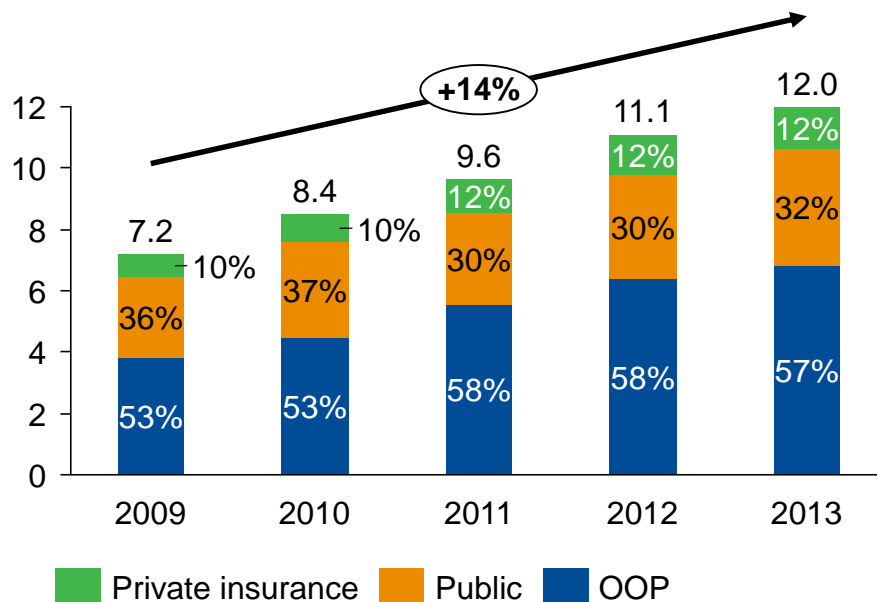


- Possible re-implementation of price controls



Healthcare spend in PH remains largely OOP but gov't. aggressively pushes the Universal Healthcare agenda

Healthcare expenditure breakdown



% of healthcare spending on drugs	25%
-----------------------------------	-----

Overview of healthcare expenditure

- PhilHealth currently covers ~87% of population
- President Duterte administration is most vocal about prioritizing health needs of the poor
- Only ~10% of the population have private health insurance, and is not expected to increase significantly over the next 5 years due to planned expansion in national health insurance
- **Gov't will look at enhancing operational capabilities to improve healthcare access**
 - Develop capacity for medicines needs forecasting
 - Supply chain management
 - Benchmarks for more accurate health reimbursement/case rates funding



Both private and public institutions active in efforts to improve healthcare infrastructure and services



...eyes more health care ventures



Expanding bed capacity: 2k to 5k



Telehealth care facility with an Australian firm



Offering mall-based diagnostic services

US\$ 61 M budget for hospital acquisitions



De Los Santos Medical Center
A METRO PACIFIC HOSPITAL

Develops/expands facilities to earn US\$ 20 M in 2019



Marikina Valley Medical Center



Dr. Jesus C. Delgado Memorial Hospital



Ayala ...expands healthcare portfolio

By 2020: To build 10 hospitals nationwide



Investment in 6 hospitals
Mall-based clinics in key cities

Leads in development of community-based primary care network

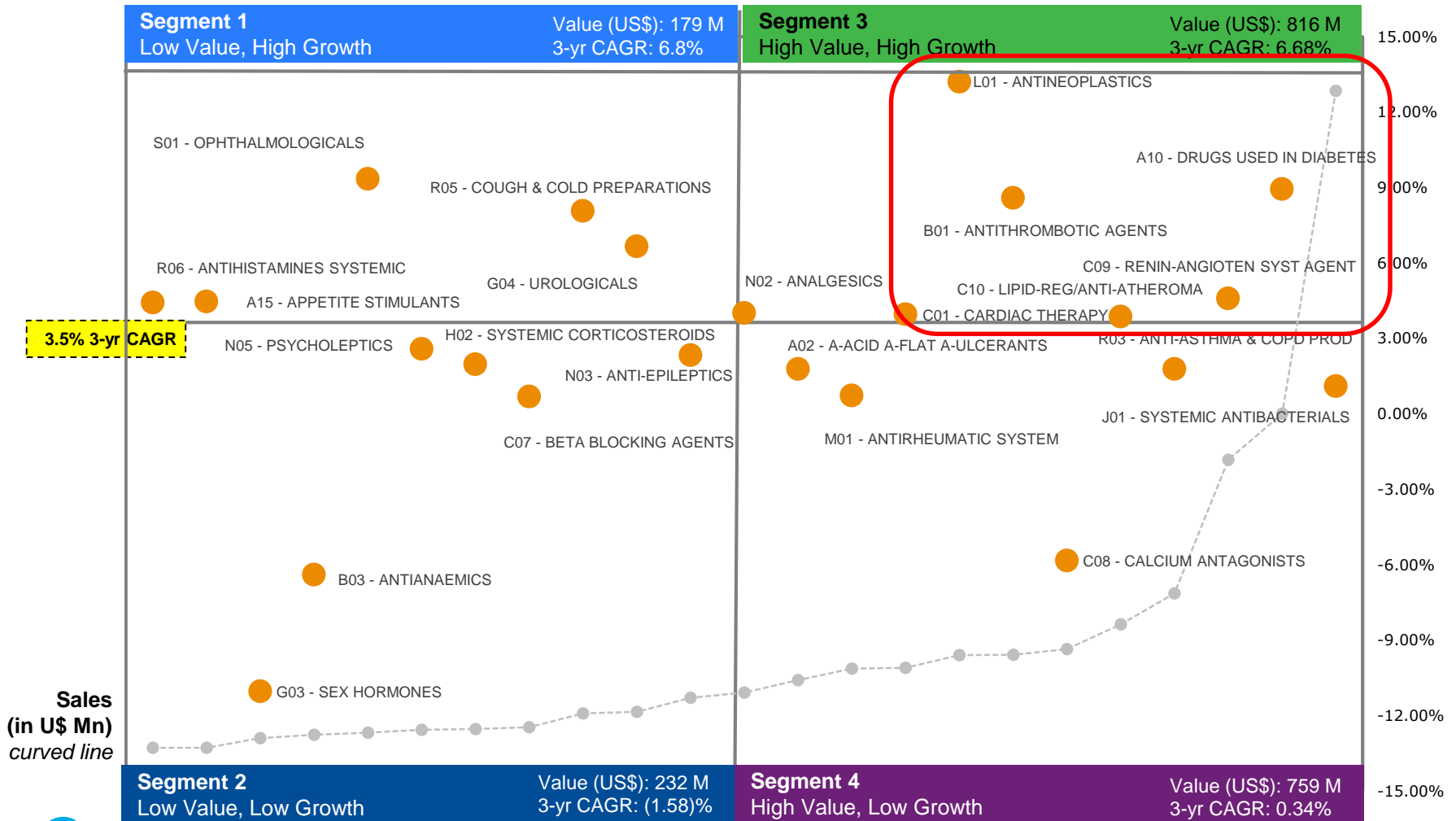


- On-going initiative to regularly measure service level quality in government-run hospitals
- Re-location/refurbishing of biggest maternity hospital in 2018

Oncology and Cardiovascular categories are significant drivers of Ethical market growth



Philippines ethical market sales and growth by ATC
(MAT April 2014-17; USD\$ Mn)





Public sector is exploring the feasibility of building a local pharma manufacturing hub

Oncology and follow-on biologics identified as core in the potential list of products to be prioritized in local manufacturing

- Follow-on biologics
- Vaccines
- Oncology
- Diabetes (Generics)
- Herbal Medicines
- Veterinary Drugs and Products

To be driven as an inter-agency initiative between DOH and DTI-BOI



Looming cost containment measures and international price referencing may slow down the Ethical market



Qualifiers for government cost controls



Products focus to be mainly Ethical



Off-patent Innovator products with few generic competitors



Products in the Philippines with comparatively higher prices versus other 3rd countries in APAC/SEA (e.g., India, Thailand, Vietnam, India)

There are a number of planning response Unilab could consider in response to market trends

Key market trends

Continued **competition from Indian generics and follow-on biologics importers**

Follow-on biologics will continue to grow in SEA and PH

Significant investment in PH healthcare market by public and private organizations

Government cost containment measures

Opportunities

Threats

Potential planning responses

Consider **partnership opportunities** with companies entering SEA and PH

Investigate **follow-on biologic import / licensing opportunities in PH**, particularly for oncology mAbs

Continue to focus on **SEA expansion** to mitigate PH market risks

Potential feasibility for



?



QuintilesIMS™

quintilesims.com