Stuck In The Middle ?

The Way Forward For Malaysian Pharmaceutical Industry

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Excerpts of data and statements were taken from:

- Pemandu
- IMS
- BMI
- GBI
- Reuters
- MOPI

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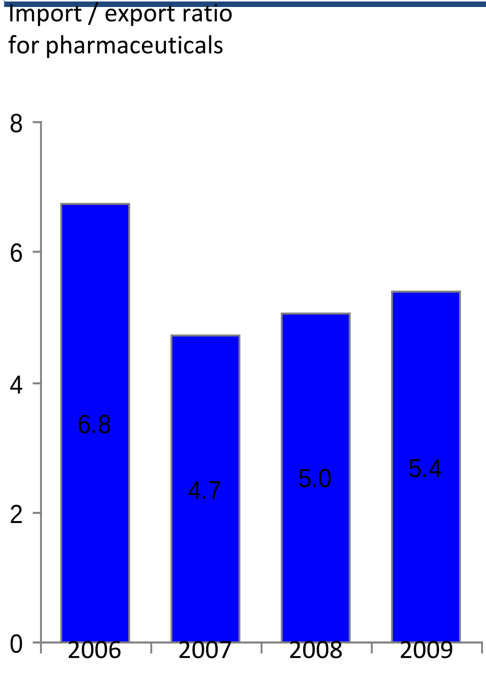
Case for change:

Current Malaysia Pharmaceutical Snap Shot

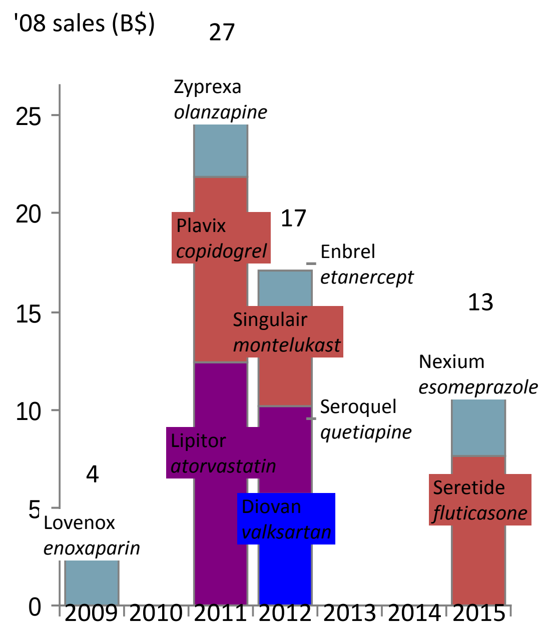
Import reliance, global dynamics creating opportunity to react

5:1 ratio of imports to exports in Malaysia



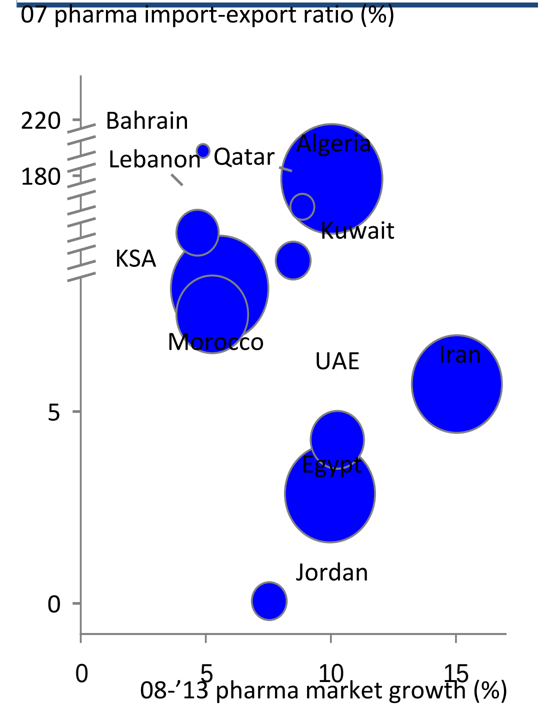
Prioritize local manufacturers for domestic market

10 of the top 15 blockbusters face upcoming patent expiry



Tap large market for generic version of drugs with newly-expired patents

Attractive OIC markets, where Malaysia has advantage

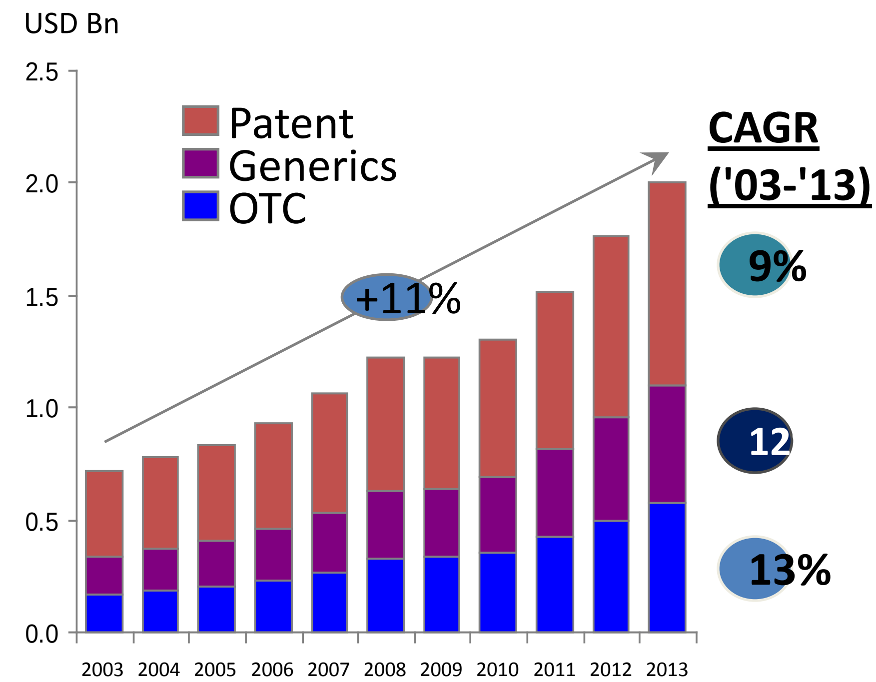


Leverage European mfg. standard and good reputation among OIC countries to gain market access

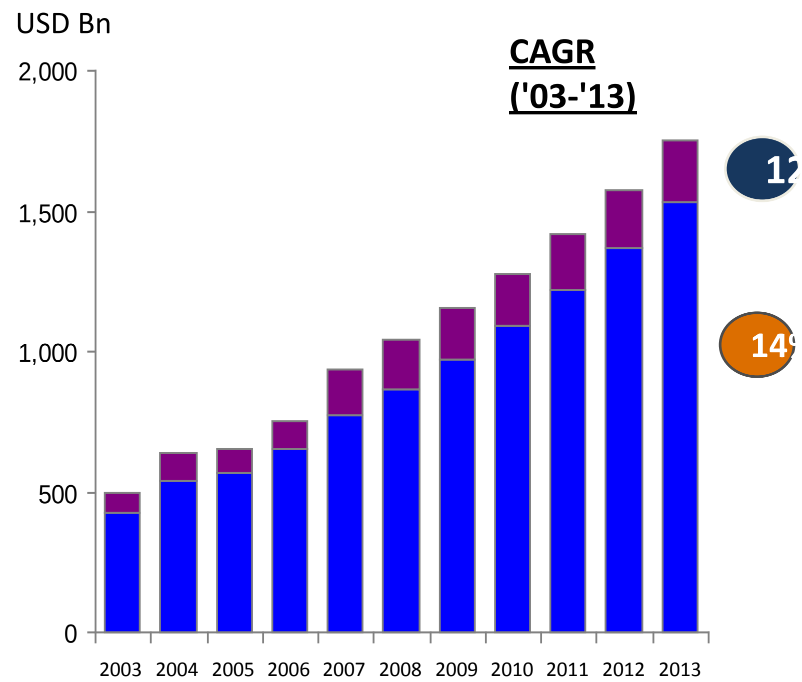
Source: IMS; BMI; ESPICOM; USAID; Press search; BCG analysis

Pharmaceutical market growing in Malaysia, however is mostly from generics and imports

Malaysia Generic market growing at a rate of 12% vs 9% for patented



Imported drugs in Malaysia growing at a rate of 14% vs 12% for local



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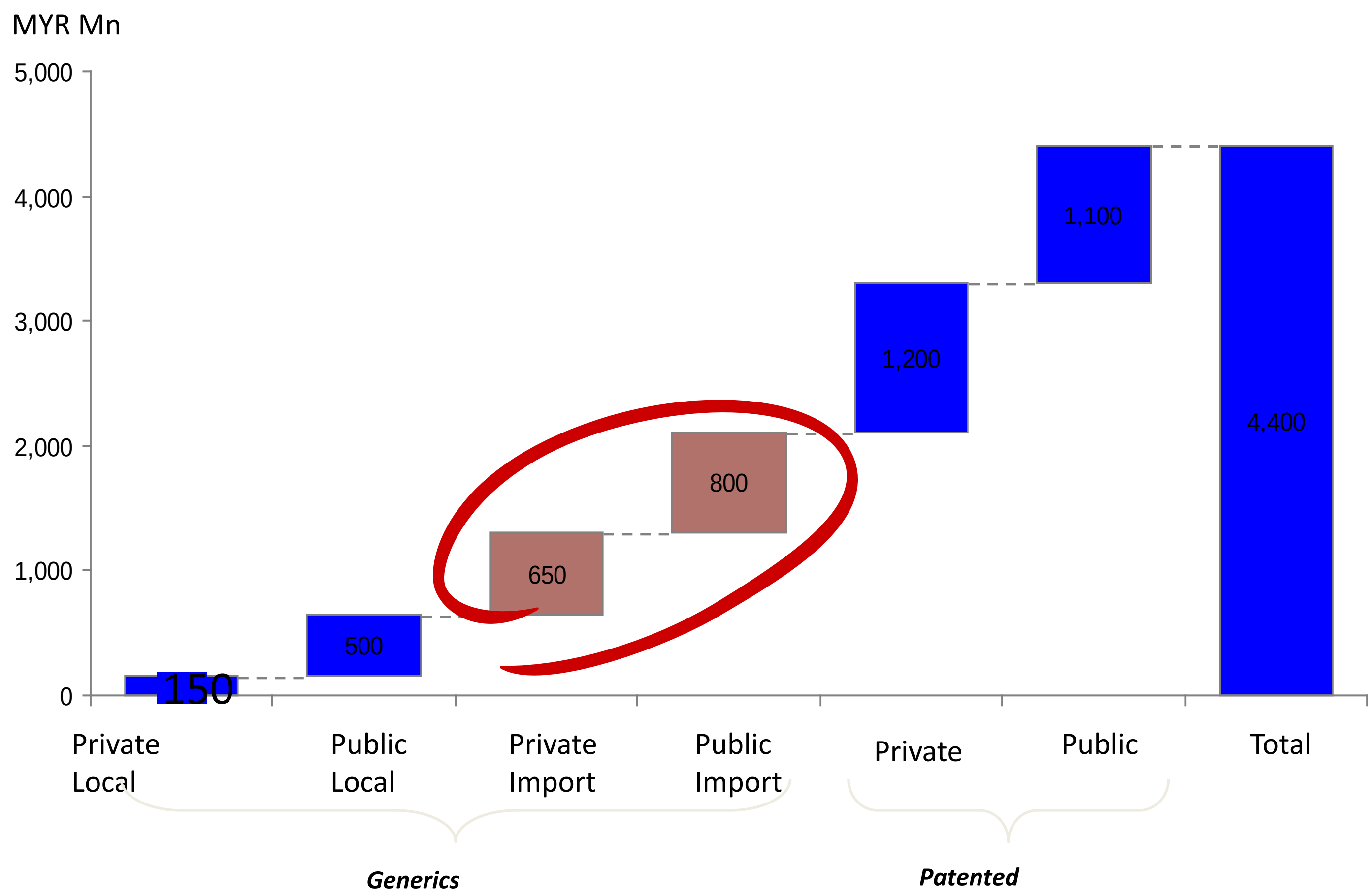
MYR 1.45Bn spent in 2009 for imported generics



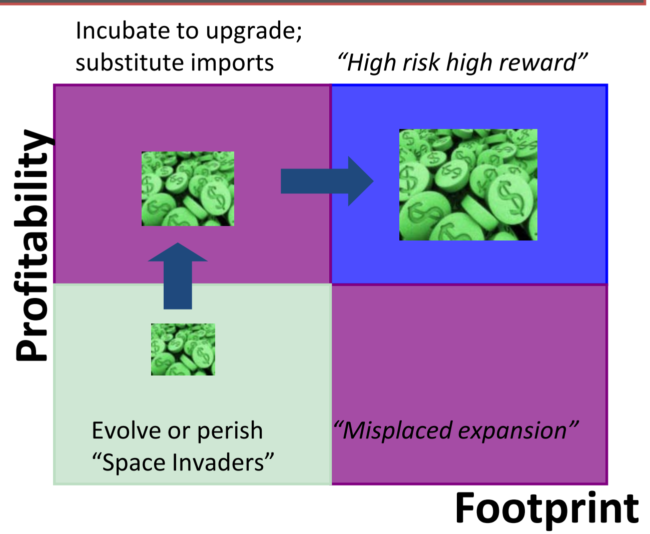
Malaysia global generics strategy

Contribution to GNI | **US$4.3Bn**

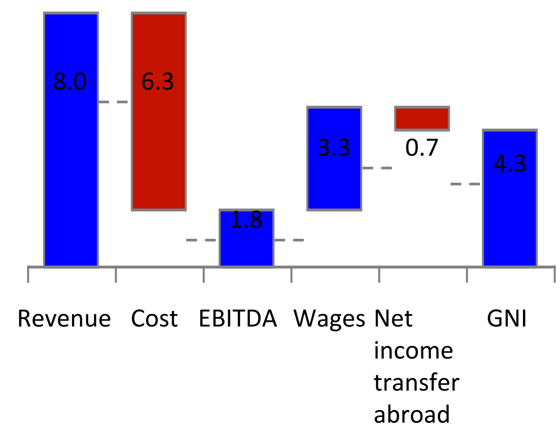
Context

- **Incoming challenge from regional players due to ASEAN harmonization**
- **High reliance on imports**
  - RM$4B of imports, vs RM$ 0.8B of exports in 2009
- **High cost base**
  - Portfolio overlap across 32 local players
  - Low utilization (30%+) – small batches
  - High raw material cost - small vol. purchase
- **Archaic facilities (20+ years), resulting in high operating costs to bring up to GMP standards**
- **Replicated facilities**

Proposal



Financial impact (US$ Bn)



Assumptions

- Revenue sources include export, import substitution, and higher-value products from existing manufacturers
- Cost and wages based on local and international benchmark of generic companies
- Net income transfer assuming 40% foreign investment in new manufacturing clusters

Job creation

12k jobs

- Estimate based on calculation of FTEs needed for 60 new manufacturing facilities by 2020

Inputs & support required

MOH

- If drug passes BE test, immediately place on national formulary
- Mutual recognition of standards for drug registration in target markets, allowing direct sale
- Provide access to all data for local players
- More innovative procurement and treatment system

MITI MATRADE

- Review FTAs

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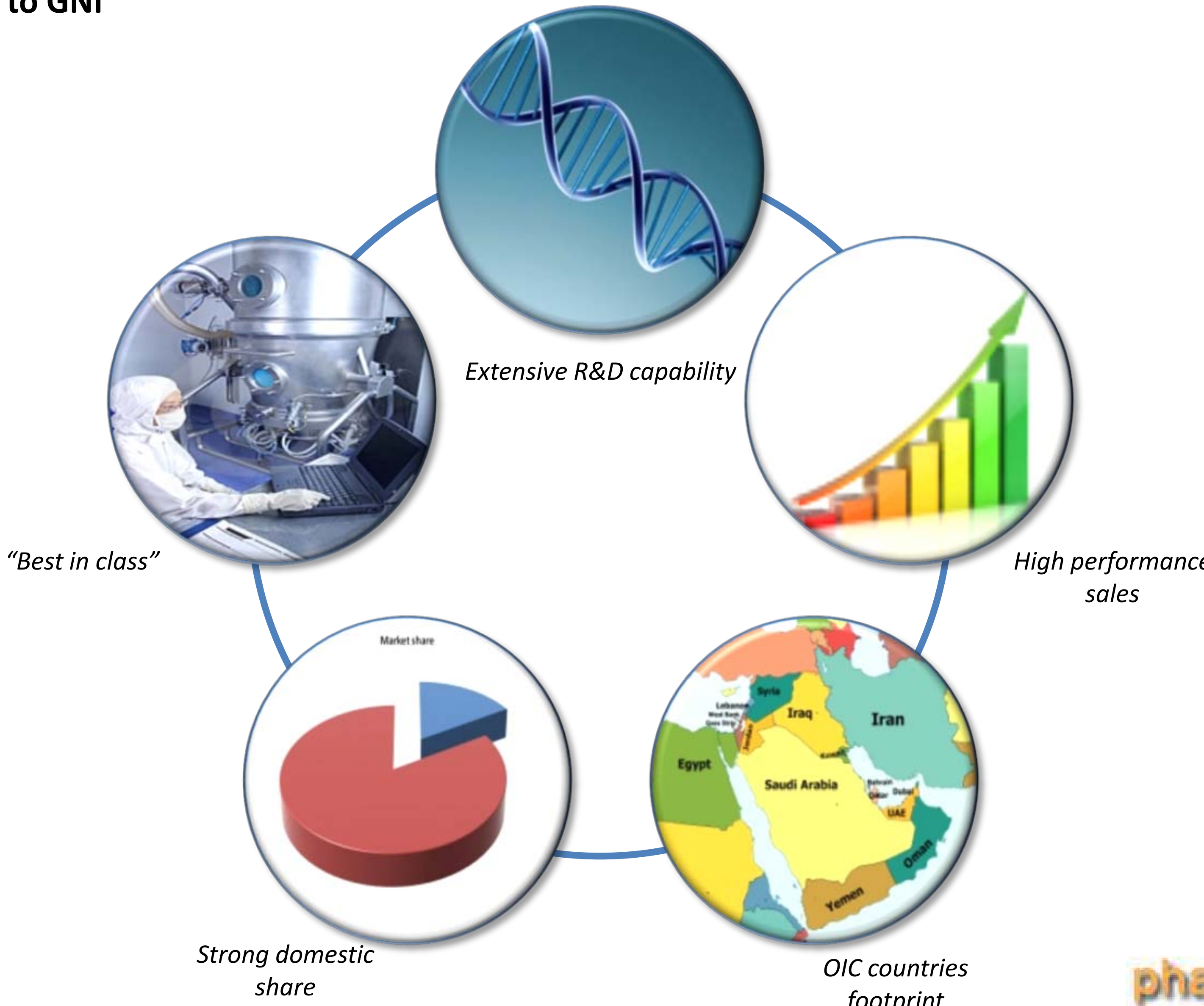
Where we want to be

Capable and profitable pharmaceutical and biopharma industry with a large contributes to GNI



Malaysian generics strategy

Increase efficiency to :
enable exports,
substitute imports, and
move into higher value products

Current ***Future***

'Super' generics

Enhanced generics, e.g. combination, new formulation, etc.
(e.g. Panadol ActiFast [2x+ price of Panadol]:

Negligible local participation

Established Malaysian players move up value chain to produce higher value products, e.g. enhanced generics, bio-similars

Generics

"Me-too" version of prescription drugs that have lost patent exclusivity
(e.g. Panadol; amlodipine)

Malaysian players largely producing for domestic market

Network of facilities to coordinate and optimize production of generics

New export-focused manufacturing cluster to complement existing resources

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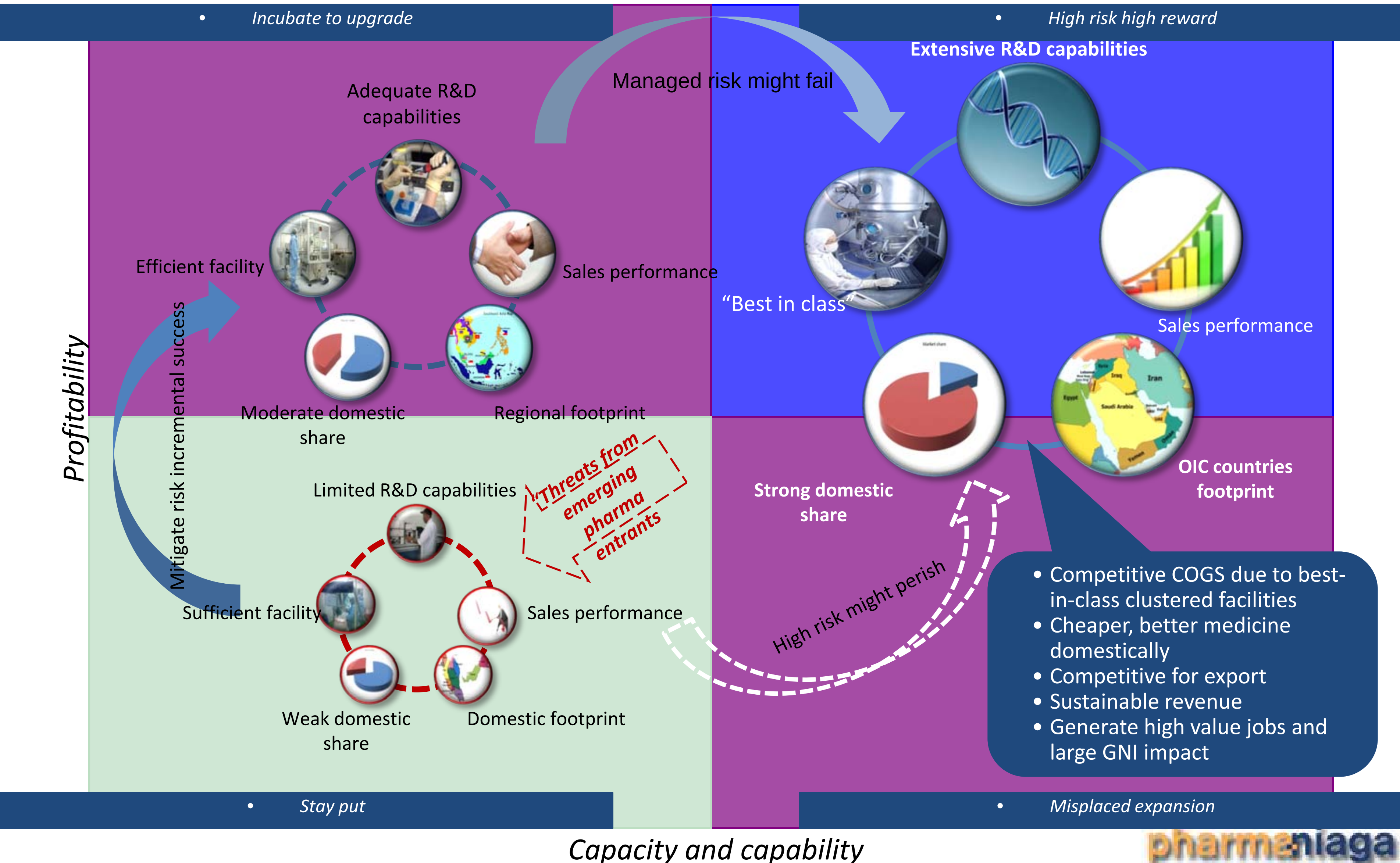
How do we get there?



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Plan to build a differentiated global business model

	TEVA	KRKA	STADA Arzneimittel	RANBAXY	Malaysia generics players
Geographic expansion	• Aggressive expansion via acquisition of local players • Worldwide coverage	• Mostly organic growth • Expansion in Germany via acquisition • Focused on Europe and Central Asia	• Mix of organic growth and acquisitions	• Globally active, supported by acquisitions (eg, Basics in Germany) • Strong Indian base	• Initially focused on selected OIC countries due to cost competitiveness and MY's reputational advantages
Portfolio/ Segments	• Largest operations API and Gx • Some patented drugs • Animal health division	• Gx drugs largest BU • Cosmetics and animal health division • Health resorts	• Pure Gx player • 2-label strategy (Aliud) • Acquisitions to strengthen branded Gx segments	• Gx drugs • Development of new patent protected drugs	• Initially focused on blockbusters with recent patent expiries
Products/ Pipeline	• Large portfolio/pipeline • Intense patent challenging • Biologicals/Injectables	• Traditional Gx portfolio • Plan to strengthen regulatory and development know-how	• Focus: patent-free APIs • Biosimilars activities via 15% share on Bioceuticals	• Attractive Gx pipeline • Limited biologics activities via partnerships	• More focused portfolio (concentrated in highest value therapeutic areas) to gain efficiency
Value chain	• Full coverage incl. R&D for patented/biol. drugs • Plan for set-up of direct distribution	• So far focus on manufacturing • Investments in M&S and distribution	• Shift from contact manufacturing to vertically integrated player along value chain	• In-house manufacturing, R&D • Intense out-licensing of IP to big pharma	• Focused on manufacturing, with upstream and downstream partnerships
	Diversified, fast-acting global player	**Regional play with traditional portfolio**	**Multiple activities and geographies (second tier)**	**Partnership model**	**Lean, focused model**

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Establishment of Centre of Excellence for Pharma R&D can drive innovations

Funding options
- Mandatory ploughback of sales by local players
- Access on pharma sales
- Ploughback from public tenders
- Self-funding in the mid-term, from fee-for-service and R&D commercialisation

Objectives
- Pooling resources (financial and talent) to overcome coordination failure and high barriers of entry for R&D
- Mechanism to drive higher R&D spend to create more innovative pharma industry
- Natural industry consolidation mechanism by raising the bar for business
- Bridge between researchers' focus and industry needs

National Center of Excellence for Pharma R&D

Governance and staffing
- National Center of Excellence
- Advisory Board comprising of MOH, MOHE, universities, MOPI, WHO and international key opinion leaders / scientists
- Staffed by key professors and scientists with relevant knowledge and experience

Services
- Development of overall R&D strategy for Malaysia pharma industry
- Fomulation and developmental work on enhanced generics (e.g. combination products, new delivery systems)
- Administrative, financial and legal advice (e.g. patent law advisory, interactions with venture capital
- Rental of high-cost equipment (e.g. xx)
- Help researchers outside their core competency areas (e.g. grant application)
- Potentially a commercialization platform for innovation

Requires high-level support from both MOH and MOHE, as well as policy changes (e.g. allowing academics to hold equity stakes in companies)

Transformation roadmap for generics industry

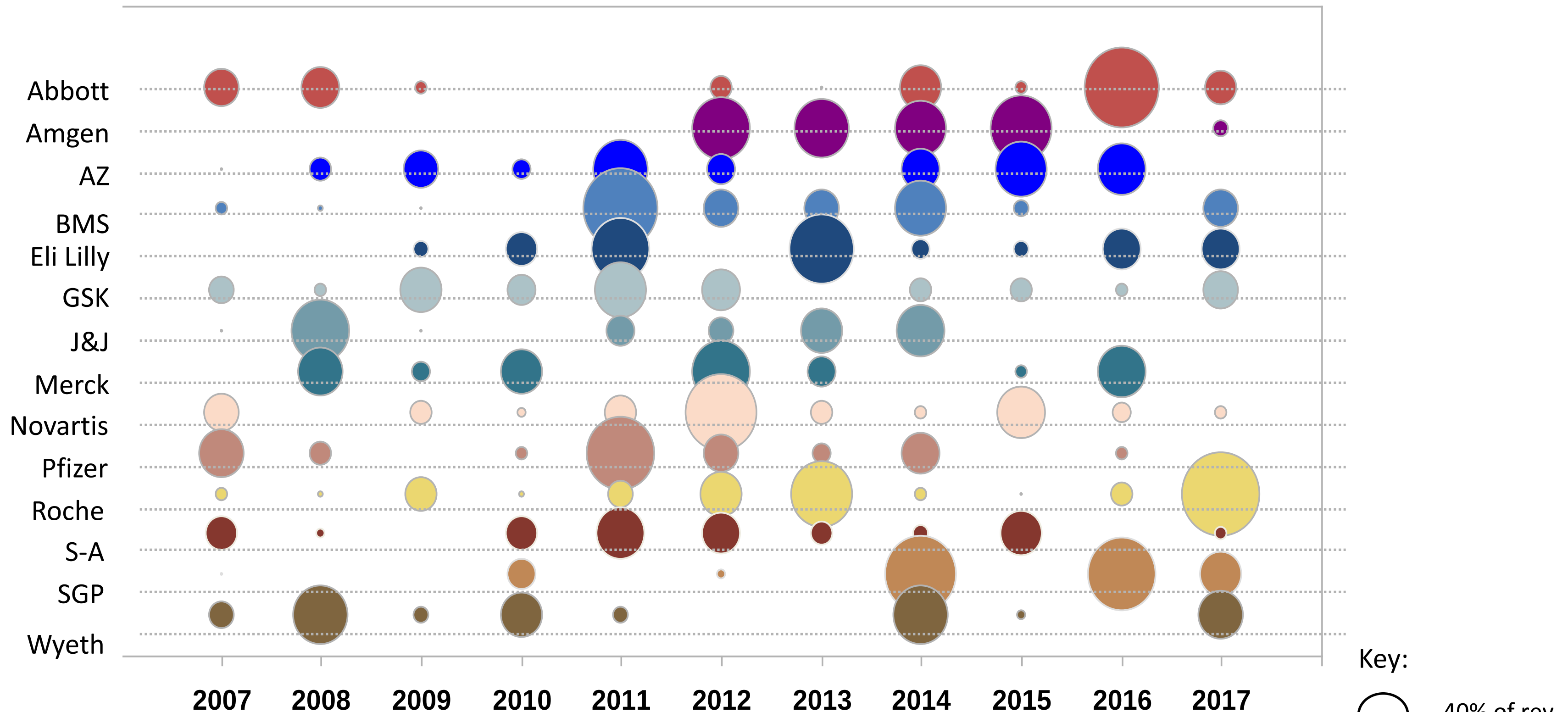
Incubate local players and create new facilities for globally competitiveness

Starting point *"plateau"*	2011-2014 *"incubation"*	2014-2020 *"globally competitive"*
5:1 import-export ratio		
32 domestic manufacturers with significant portfolio overlap	1 Create a new cluster of export-oriented manufacturing facilities to complement existing resources	Export generic version of recently expired blockbuster products, focusing on OIC markets as a starting point
Outdated facilities below GMP[1] standards		
Limited export due to lack of cost competitiveness	2 Use localisation to incubate upgrade of existing players' capabilities and facilities	Move into higher value-added products, e.g. enhanced generics and bio-similars
Large purchase of imported drugs by gov't (~60% of total MOH purchases)		
Low capacity utilization		

1. Good Manufacturing Practice for pharmaceutical products

Upcoming patent expiries create white space for new generics player

Biopharma revenue at risk due to patent expiration[1] (as % of 2006 revenue)



Industry average (%)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
	4.6	6.9	3.6	5.1	14.8	12.9	9.8	13.5	7.2	10.9	9.6

US$132 billion[2] worth of product by the top 10 pharma companies will face patent expiry by 2014

1. As percentage of 2006 revenues 2. Calculated form 2008 revenues
Source: BCG case experience; Business Insights; BCG analysis

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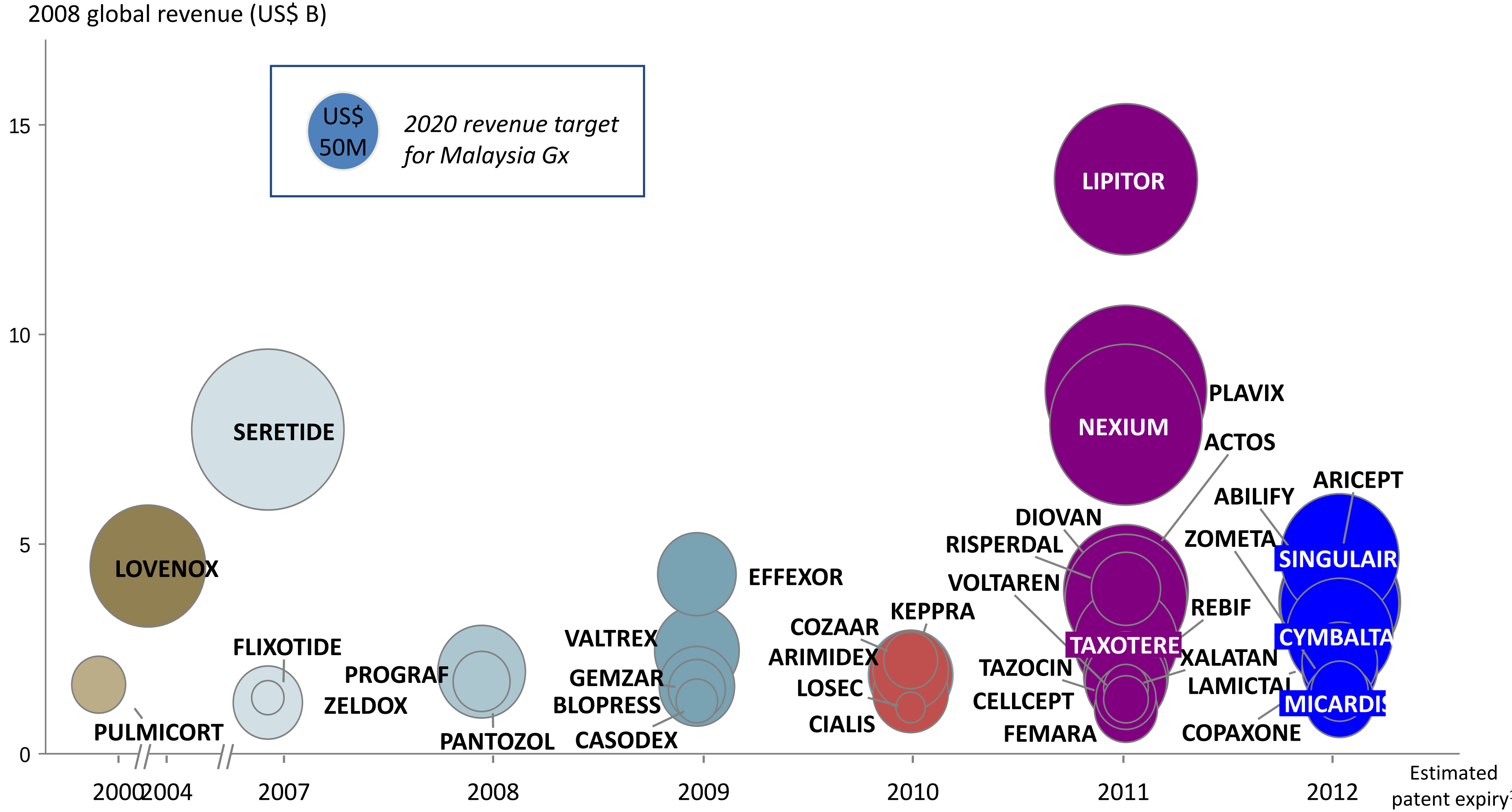
Malaysian generics: US$3.0 B revenue target for blockbusters expiring before 2013

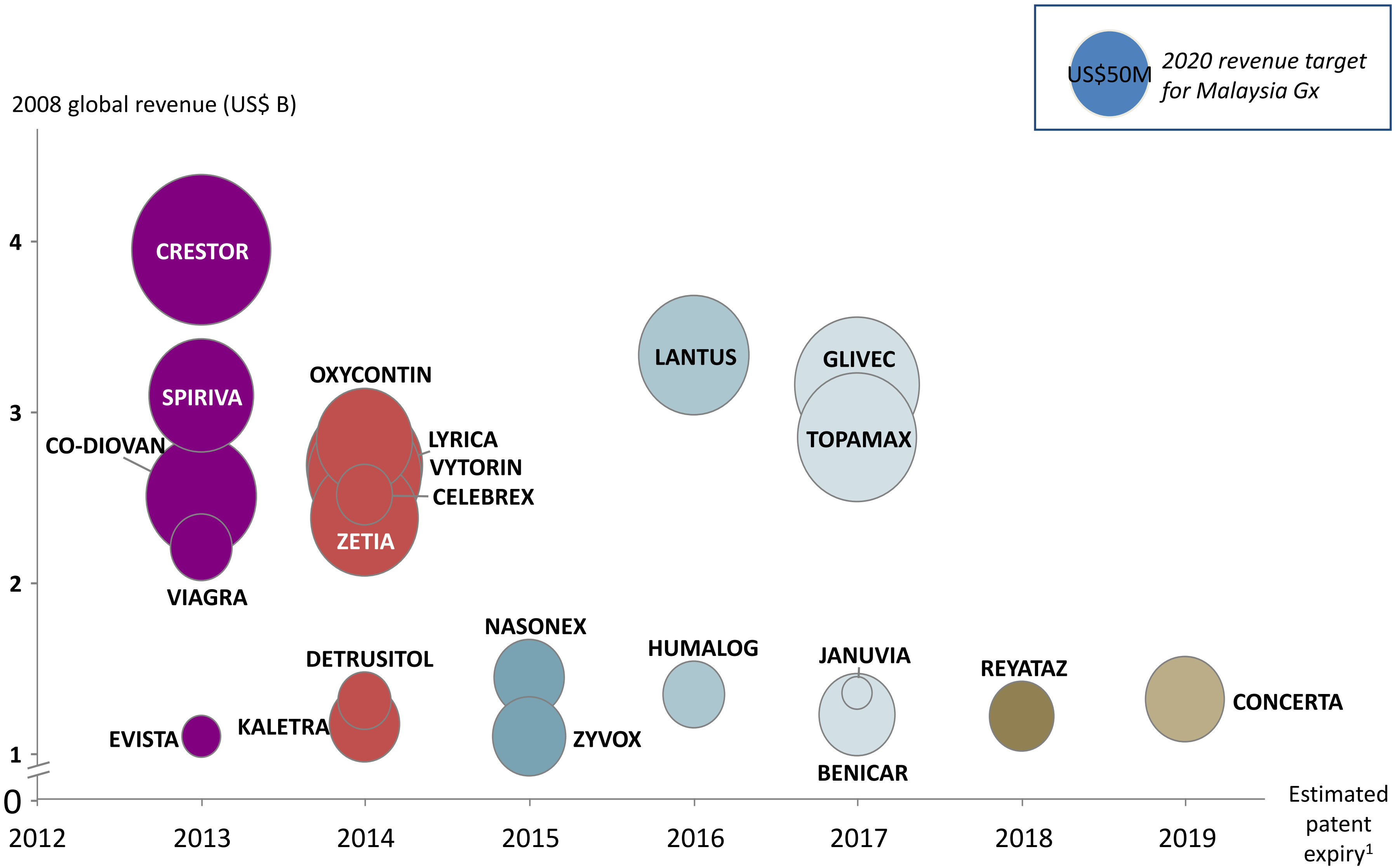


Note: Target revenue calculated by forecasting generics market size in 2020 (accounting for baseline growth, as well as price erosion and volume increase as a result of patent expiration) and applying a 1% aspirational global market share

1. Actual patent expiration to be confirmed by patent law specialists, as multiple patents are filed on a single product and relevant date is dependent on the generic product, e.g. its physical properties, indication, formulation, etc. patent expiration estimated by adding 12 months to the expiration of the first pediatric patent of a drug

Source: FDA Orange book; IMS; BCG analysis

Malaysian generics: US$2.9 B revenue target for blockbusters expiring 2013-2020



Note: Target revenue calculated by forecasting generics market size in 2020 (accounting for baseline growth, as well as price erosion and volume increase as a result of patent expiration) 3% aspirational global market share. Aspirational share of 3% (versus 1% for expiries before 2013) used because new Malaysian facilities would be ready and early market entry more likely to gain significant share

1. Actual patent expiration to be confirmed by patent law specialists, as multiple patents are filed on a single product and relevant date is dependent on the generic product, e.g. its physical properties, indication, formulation, etc. patent expiration estimated by adding 12 months to the expiration of the first pediatric patent of a drug

Source: FDA Orange book; IMS; BCG analysis

Malaysia's competitive advantages in the OIC countries

1 – Malaysia is the only OIC country that adheres to **PIC/S guidelines** (adopting cGMP)

2 – Industry is well regulated by NPCB to ensure **compliance to cGMP**

3 – Strong existing **manufacturing capabilities** (i.e. talent, infrastructure)

- Existing manufacturing base for generic products
- Potential increase efficiency in manufacturing that can lead to cost leadership

4 – Established leader where **"Halal"** is concerned

- Malaysia is taking very strong initiatives in producing "Halal" certified medicine
- Malaysia has a well structured Islamic banking and financial infrastructure in place—track record of innovation and leadership

5 – **Bilateral arrangements** between Malaysia and other OIC countries

- Malaysia currently negotiating FTA agreements with the GCC countries

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Halal platform a key differentiator for Malaysia

Unmet need in halal medicine

Halal pharmaceuticals could be worth up to US$500 B, accounting for 22% of global halal products market[1]

If a halal version of a medicine exists it would be preferred by Muslims, even though medicine is considered lifesaving and hence exempt from halal and haram considerations

Halal medicine in very early stages of development due to difficulty of establishing traceability to the source

1. 5th World Halal Forum, KL, June 2010

Competitors on the move, MY must regain the initiative

Brunei launched *The Brunei Darussalam Guidelines for Manufacturing and Handling of Halal Medicinal Products, Traditional Medicine & Health Supplements* in June 2010

Ambition to attract foreign investment to establish halal pharma manufacturing for export to Muslim world

- Attracted Canadian OTC company to establish facilities

Pulau Muara Besar port area to be developed into a Halal Pharmaceutical Hub

Nascent development in MY, need concerted development

Increasing interest and efforts from Malaysian companies

- 9bio, Jakim and OIC SecGen in discussions with GSK to produce porcine-free meningitis vaccines for the haj pilgrimage; aiming to build R&D and manufacturing facility in Bandar Ensted by 2011
- Bioven partnered with Cuba to develop halal vaccines

High potential to develop into a key competitive advantage and differentiator for Malaysian pharma export

Needs co-ordinated development + establishment of Halal drug standard

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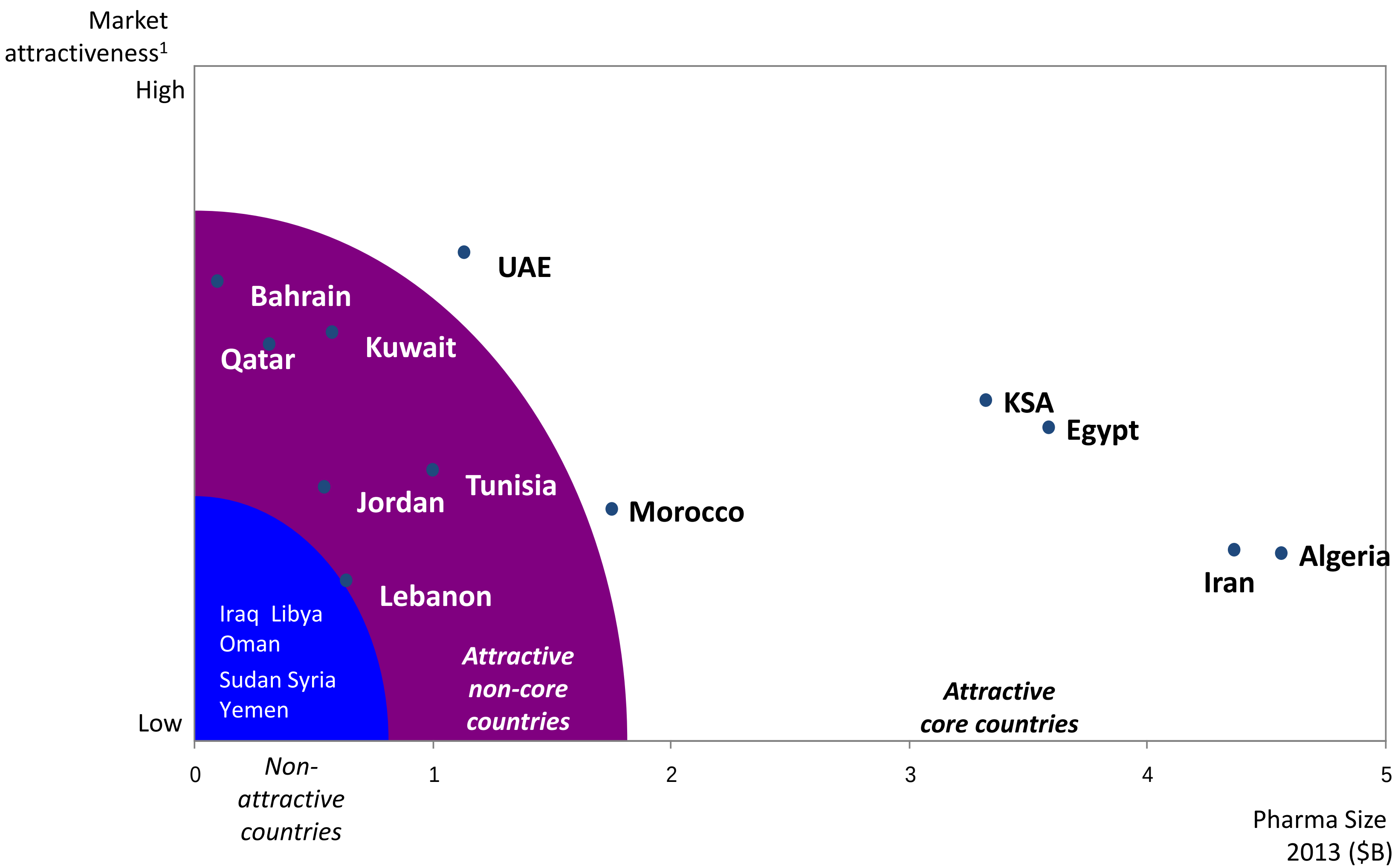
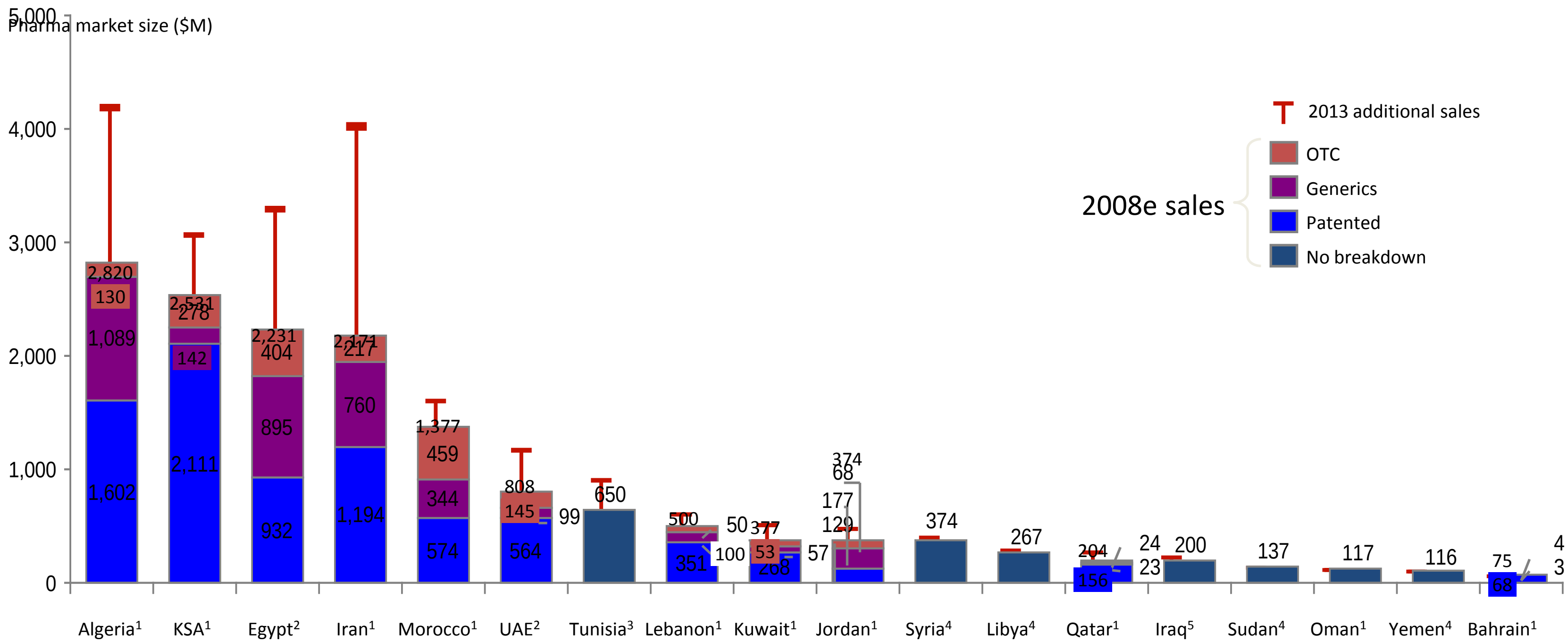
12 attractive countries in the Middle East and North Africa



1. Based on Pharma market attractiveness (60%), Macroeconomic attractiveness (25%), and Ease of doing business (15%) – see backup slides
Source: IMS; EIU; Espicom; BMI; PWC; Expert interviews; BCG analysis

Fast growing pharma market in 18 MENA countries...

Total Pharma market size 2008E ($M)



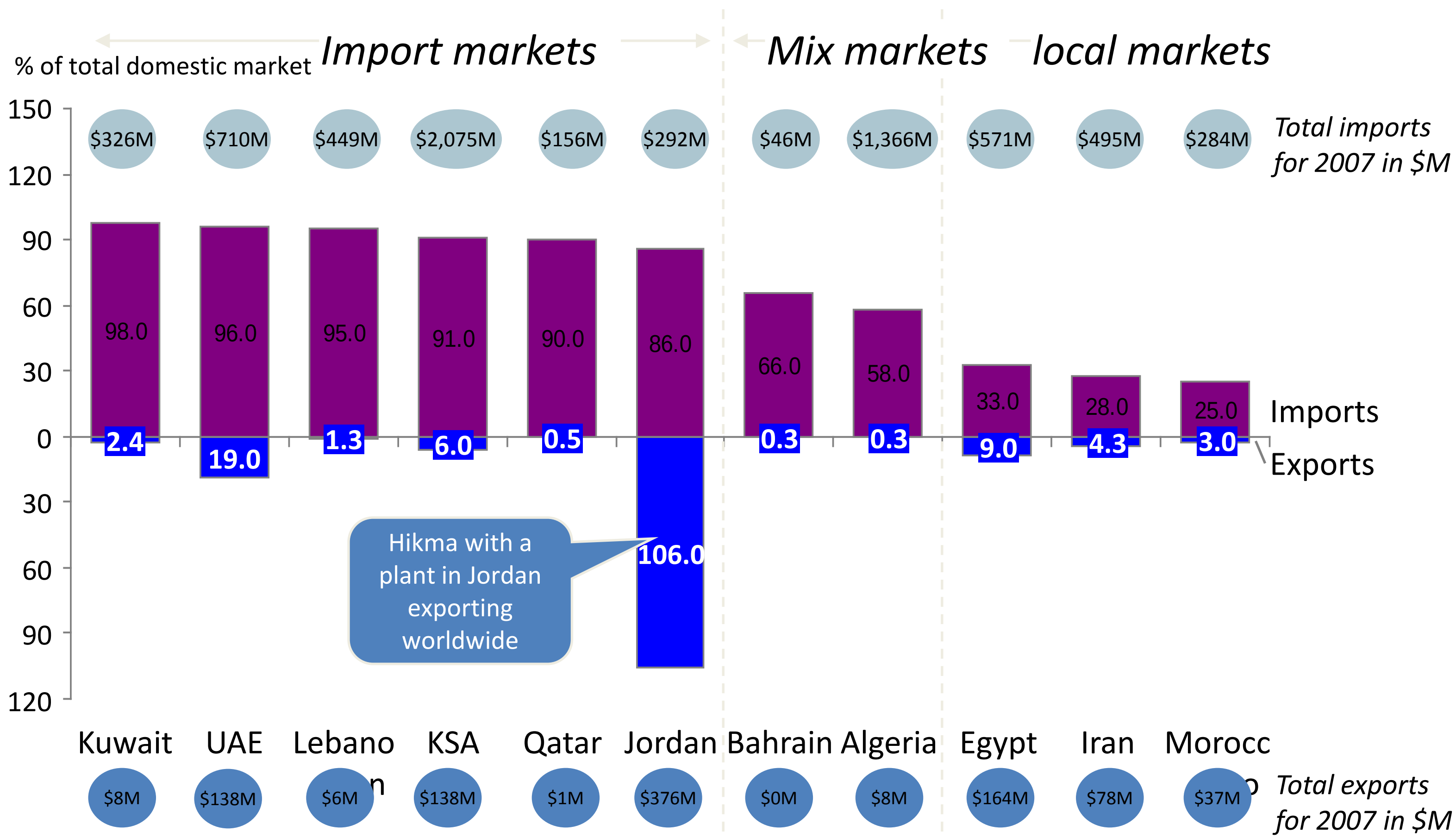
CAGR 08-13	10.1%	5.6%	10.0%	15.1%	5.3%	10.3%	9.0%	4.7%	8.5%	7.6%	2.6%	4.2%	8.9%	8.0%	4.3%	6.8%	3.9%	4.9%

1. BMI estimates/forecasts for 2008 market sizes 2. Based on IMS data 3. 2007 IMS ex-manufacturers' values projected to 2008 with 9% (CAGR '04-'07), multiplied by 1,3 to convert to retail prices, and assuming 10% hospital sales on top of retail 4. IMS 2005 forecast values for 2008 (ex-manufacturers' prices, including hospitals) multiplied by 1,3 in order to convert to retail prices 5. US Agency for International Development report

Source: IMS; BMI, ESPICOM, USAID, Press search; BCG analysis

...highly-dependent on pharma imports

Imports and exports as a % of domestic market - 2007



Source: BMI reports for 2008; Press search; BCG analysis

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Market protectionism in 6 core countries call for G-to-G negotiations to gain preferential entry

		Elements of pharma market protectionism
Lower protectionism	KSA	• Plant may be built by foreigner but the technical director has to be a registered national pharmacist[1] • Trade entity (medical store) can only be owned by a Saudi national[1] • Registration easier for drugs manufactured in MENA (excluding Iran), US, Europe and Japan • Import market: no import/ export taxes and all profits can be repatriated
	UAE	• Manufacturing: Pre-requisite for at least 51% local ownership for manufacturing and Managing Director or majority of board directors to be UAE nationals[2] • Trade entity (medical store): the licensee should be a UAE national[3] • Import market: no import/export taxes and all profits can be repatriated
High protectionism	Egypt	• Local producers favoured by authorities i.e. speed of registration (fast track) and price level approved • Theoretical import tax ranging from 4% for raw material to 28% for finished products (range not enforced)
	Morocco	• Up to 35% tax on imported drugs; 10% for Free Trade Agreement partners i.e. EU, US, Jordan, Egypt, Tunisia, Algeria – to be gradually abolished by 2012 • Cannot import if same molecule locally produced • Local partner legally required, receiving a legal "Rep Fee" of 20%
	Algeria	• Importer should develop manufacturing presence within 2 years of entry • Up to 30% tax on imported finished good products • Can not import if local production meets demand • Local import/distributor must pledge 45% of all imports to be generics
	Iran	• Up to 90% tax for imported drugs if similar drug produced locally • Key to have contacts at MoH for registration and MoC for importation • Drug can be imported once a local doctor prescribes it; more difficult for generics

1. Saudi counsel of ministers resulution NO78 2. UAE Pharmacy federal law No 4, 1983 - article 58 5 3. UAE Federal Law No1 1979
Note: Pharma market attractiveness score based on analysis on three axes: IP laws, Govt policy/reimbursement, and Approval process. See details in next slide
Source: BMI Q4 2008 report; BCG Analysis

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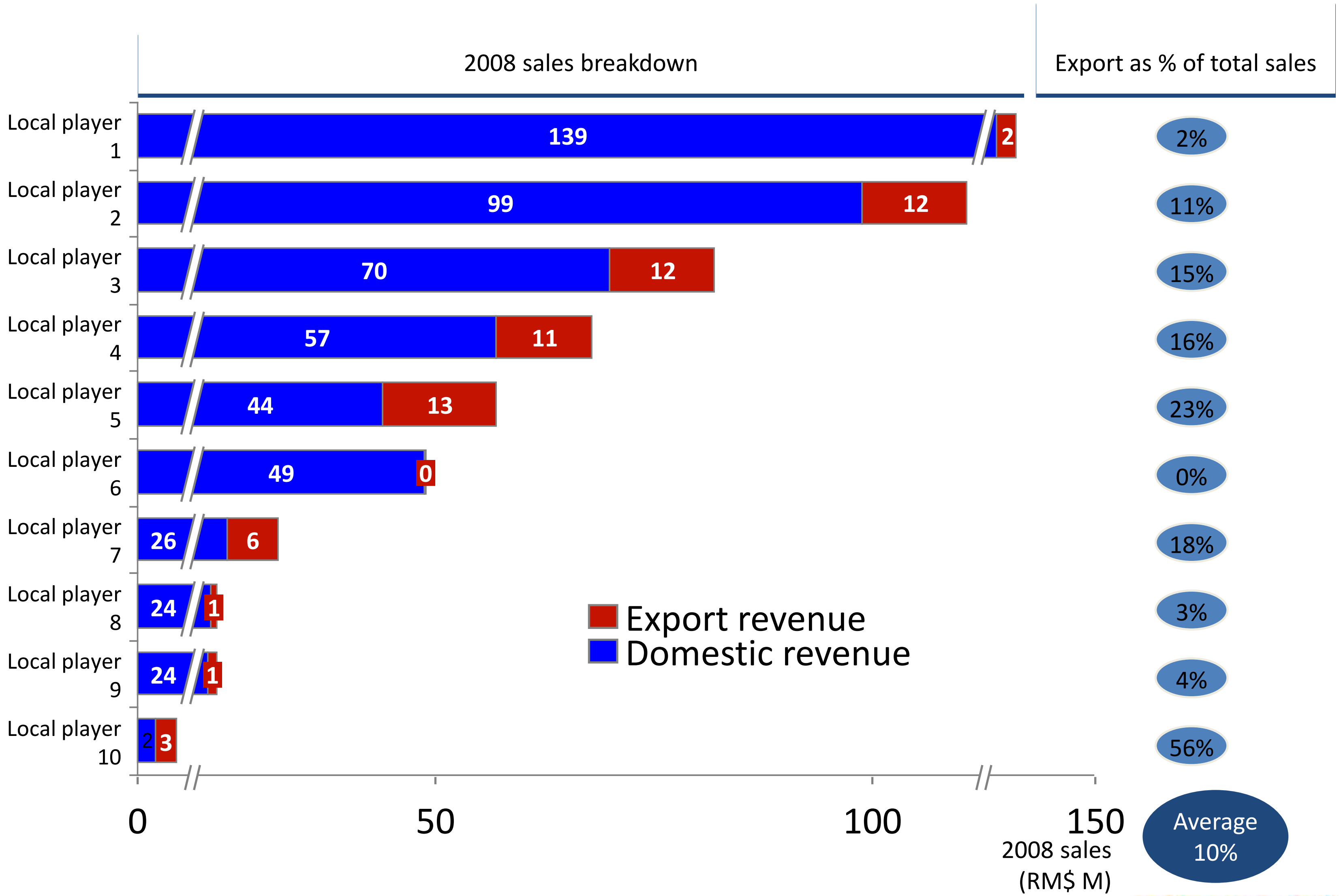
Local players predominantly focused on domestic market...
Exports are only 10% of pharmaceutical sales for manufacturers benchmarked



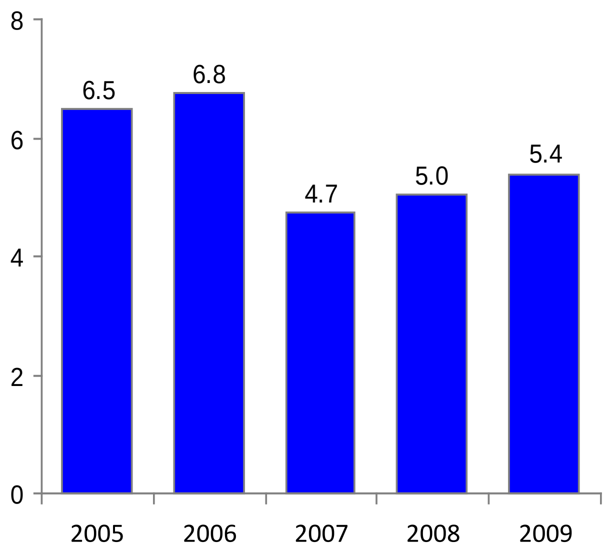
Note: Manufacturer's name masked due to data confidentiality; prescription drug sales only
Source: MOPI; BCG analysis

...but domestic market remains dominated by imports

Current status

Import growth has outpaced export growth in recent years

Imports / Exports ratio



In contrast with peers, top 10 players in Malaysia are all MNCs

#	Malaysia	Indonesia	Thailand
1	Merck	Kalbe	Pfizer
2	Pfizer	Dexa	Siam
3	Sanofi-Aventis	Sanbe	GSK
4	GSK	Tempo	GPO
5	Astra Zeneca	Pfizer	Sanofi-Aventis
6	Roche	Soho	Novartis
7	Merck Serono	Kimia Farma	Biolab
8	Abbott	Pharos Group	AstraZeneca
9	Bayer	Bayer	Roche
10	Novartis	Sanofi-Aventis	Berlin Pharma

MNC
Local

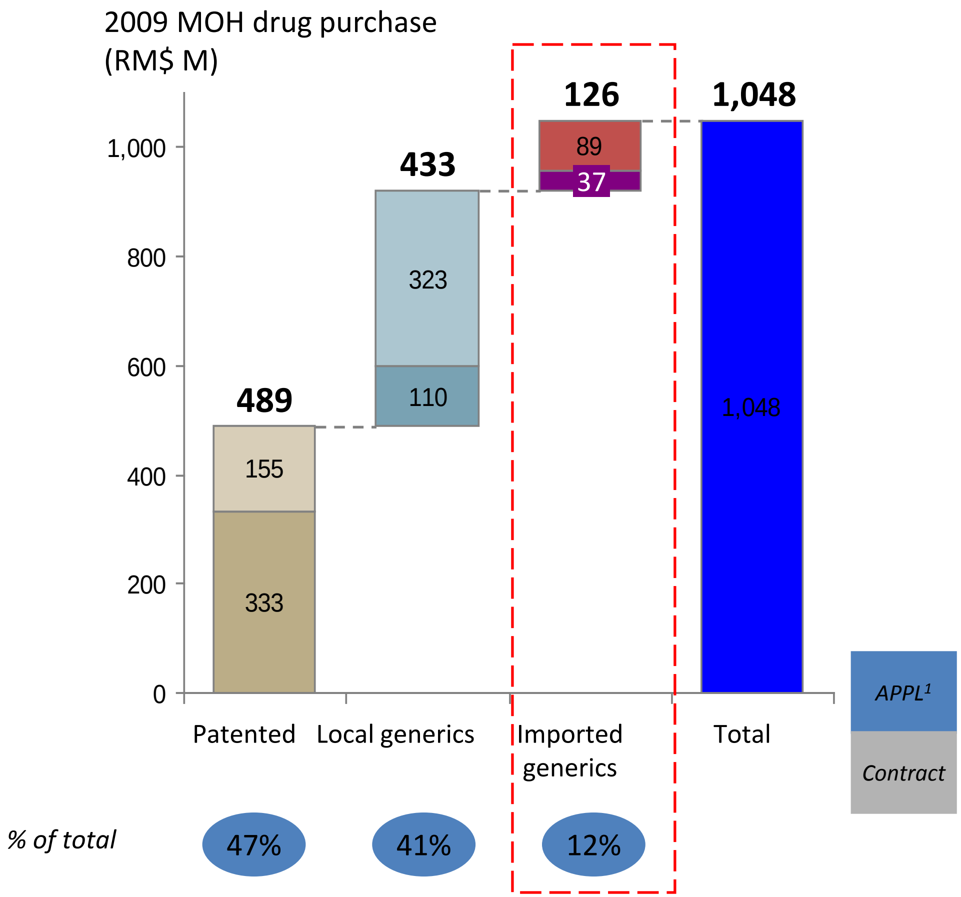
Game plan

- Import-substitute where possible
- Seek market access to ASEAN countries
- Require imports to match Malaysian player's PIC/S manufacturing standards

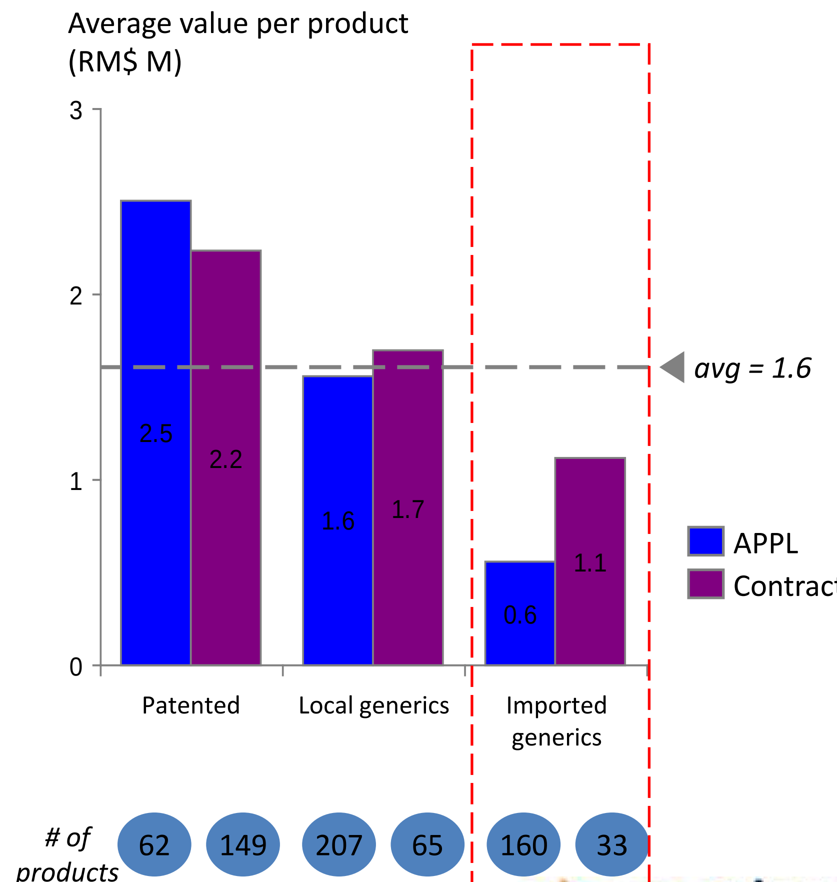
- Implement National Medicines Policy—encourage MNCs to outsource production to local players

Some room to import substitute, but potential limited by product fragmentation

12% of MOH's drug purchase substitutable by local generics...

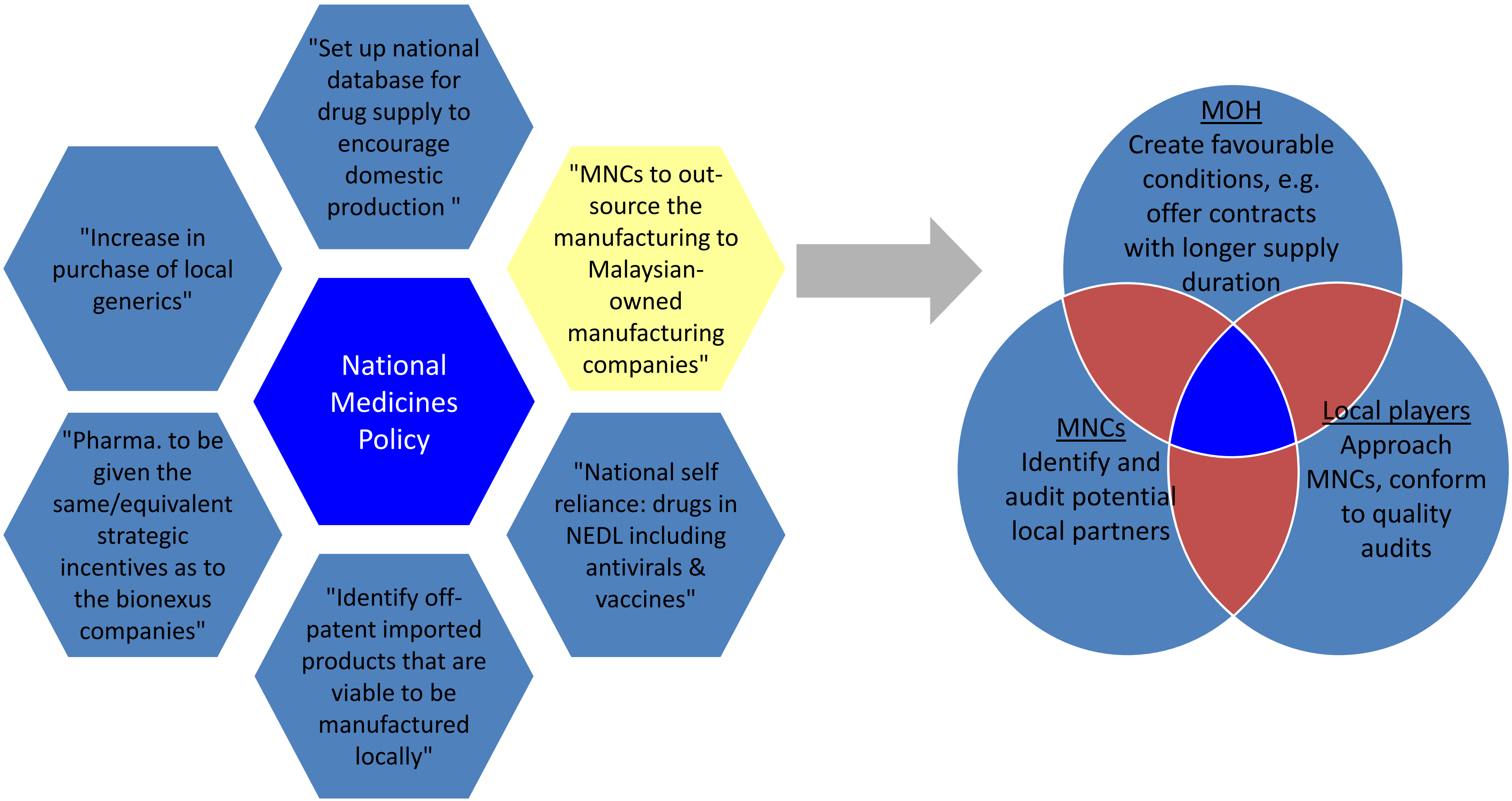


...but product fragmentation among imported generics limit potential for import substitution



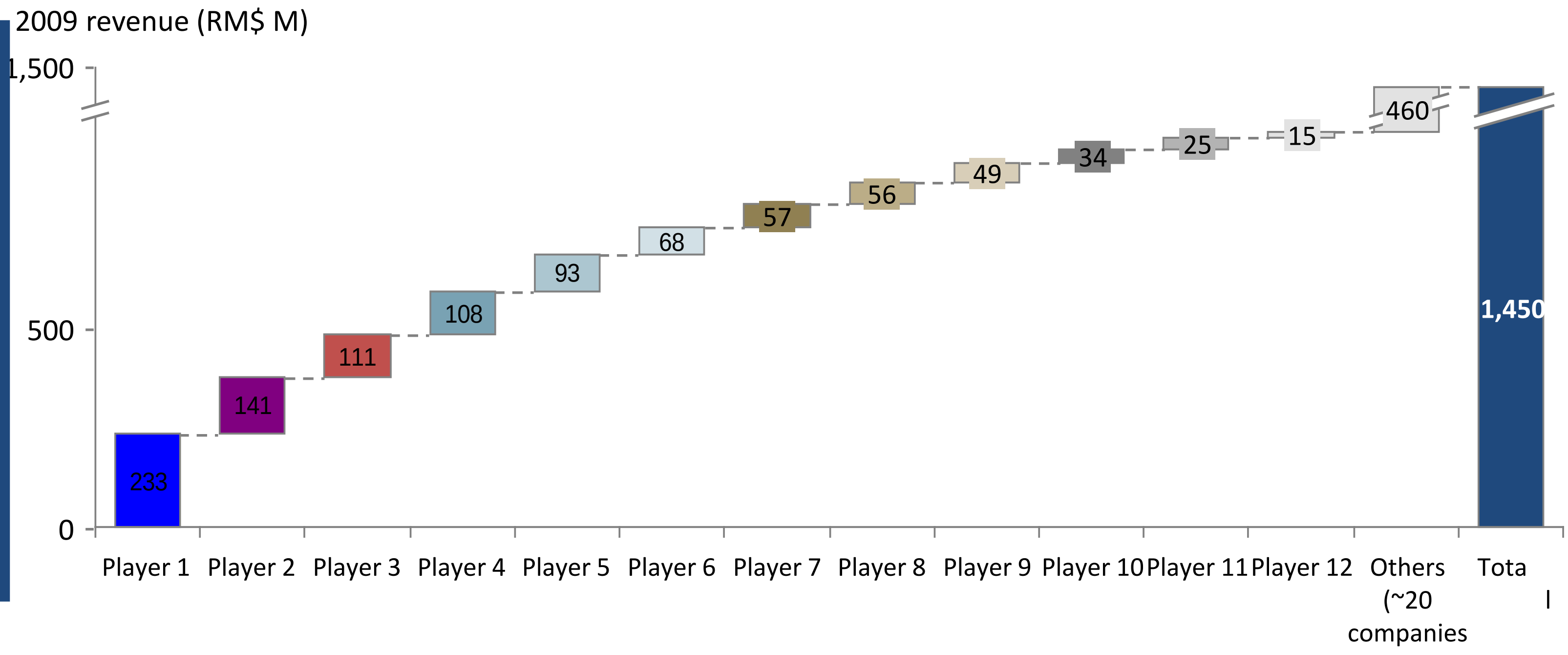
1. Approved Pharmaceutical Purchase List
Source: MOH procurement

Localisation policy already in place, partnerships with MNCs need to be formed



Local industry fragmented, production should be rationalised
Only 4 players have sales exceeding RM$100 M

Current status



Game plan

Migrate to a more focused set of domestic players. Potential levers include:

- Bundle multiple adjacent products (e.g. same dosage form, same TA) into large tenders that need to be fulfilled in its entirety → *encourage production rationalization and partnerships to fulfill tenders, laying the groundwork for mergers and acquisitions*
- Require a minimum % of sales to be ploughed back into R&D, as well as a minimum absolute amount of R&D spend → *build innovation capabilities and decrease number of players concentrating on lower value-added commodity products*

Note: Manufacturer's name masked due to data confidentiality. Revenue figures include prescription drugs, over-the-counter drugs, animal health products, TCM, nutraceuticals, and cosmeceuticals
Source: IMS; MOPI; BCG analysis

BE in it.

InnoHerb

mesti ambil tahu!

citrex

Thank You

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