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Opportunities for Pharmaceutical Manufacturers in GCC/ MENA

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Opportunities for Pharmaceutical Manufacturers in GCC/ MENA

The growing global and regional demand for generics pharmaceuticals, driven by costs and government policies, creates a significant opportunity for generics manufacturers worldwide. Add to this the high proportion of imports and the increasing expenditures on healthcare in the GCC, which creates a significant opportunity for GCC and MENA pharmaceutical companies. A range of operating models are possible for pharmaceutical manufacturers and distributors. The presentation will discuss global and regional facts, and explore alternative models for establishing such businesses.

Dr. Anil Khurana, Dinkar Saran, Maheshwar Singh, and Marc Webster

Outline for Presentation

- I. Pharmaceutical Demand in GCC and MENA**
- II. Pharmaceutical Supply Patterns in GCC and MENA**
- III. Global Pharmaceutical Overview and Generics Trends**
- IV. Opportunities for MENA Pharmaceutical Manufacturers and Investors, and Operating Models**



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- ✓ 4:1 business model is industry differentiator

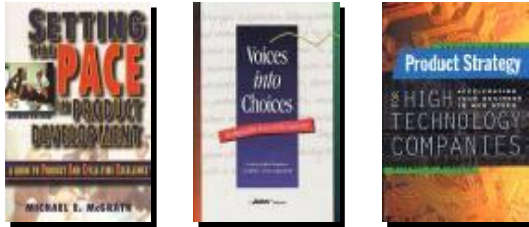


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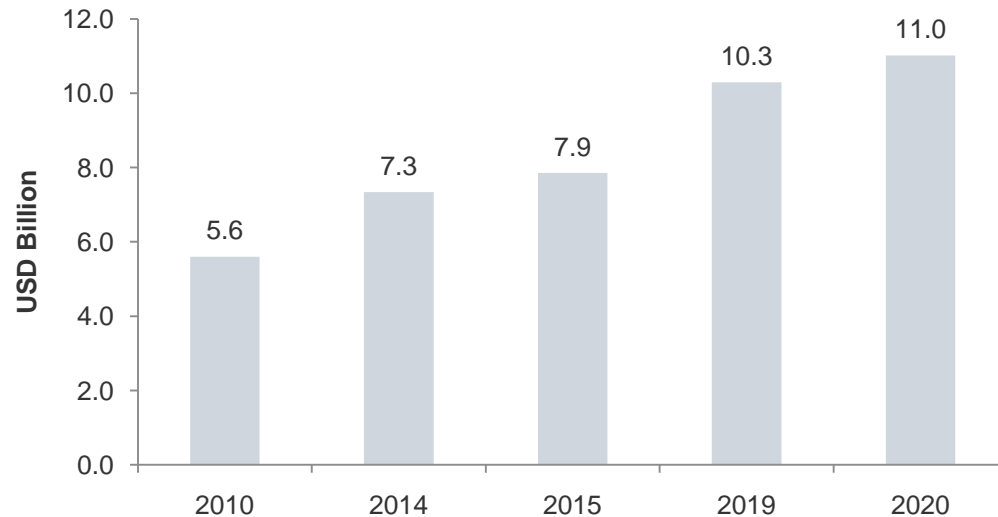
Industry Experience – Life Sciences and Healthcare

Industry Sectors	Description	Type of clients
Pharmaceuticals	<ul style="list-style-type: none"> • Ethical drugs • Generics and OTC • Consumer products • Distributors and Direct 	             
Biotechnology	<ul style="list-style-type: none"> • Vaccines • Biologics • Biomaterials 	          
Medical Devices and Diagnostics	<ul style="list-style-type: none"> • Medical Devices • <i>In-Vitro</i> Diagnostics • Point-of-Care 	       



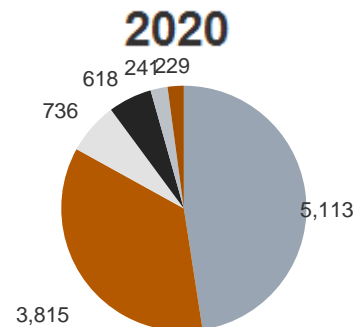
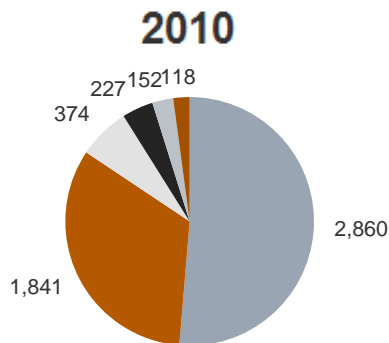
Pharmaceutical Demand in GCC and MENA

GCC Pharmaceutical Sales were \$5.6 Billion in 2010, and Expected to Grow at 6-8% to Reach \$11B by 2020



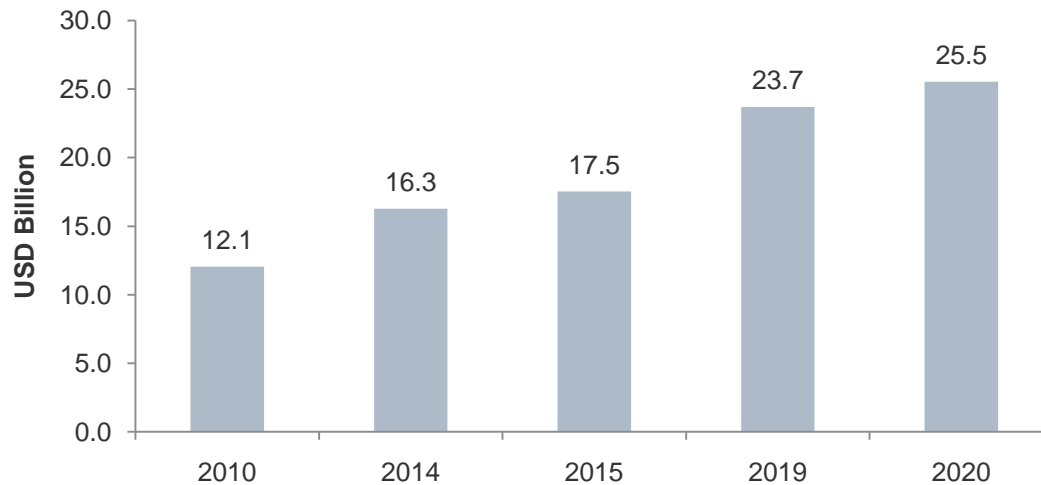
Source: Alpen Capital and PRTM Analysis

- Imports constitute 80% of sales
- Saudi is the largest market (~51% of sales)
- Exceptionally low investment in R&D in the region compared to international levels



■ Saudi Arabia ■ UAE ■ Kuwait ■ Qatar ■ Oman ■ Bahrain

Similarly, MENA Sales (including GCC) Were \$12 Billion in 2010, and Expected to Grow @ 10% to \$25+B by 2020



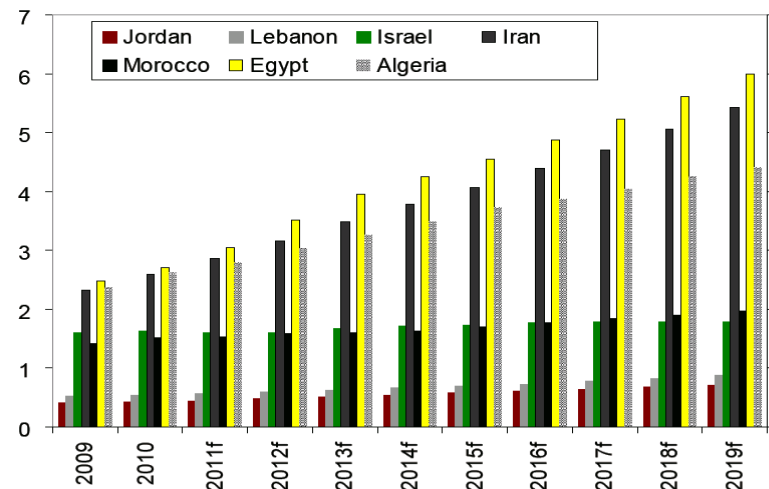
Source: BMI, TVM Capital MENA, GSK and PRTM Analysis

- CAGR of 10% is one of the highest in the world
- Yet, MENA is only 1.5% of global pharma sales

- Non-GCC MENA constitutes about half of MENA sales
- Amongst non-GCC MENA, Egypt and Iran are the largest markets and will more than double

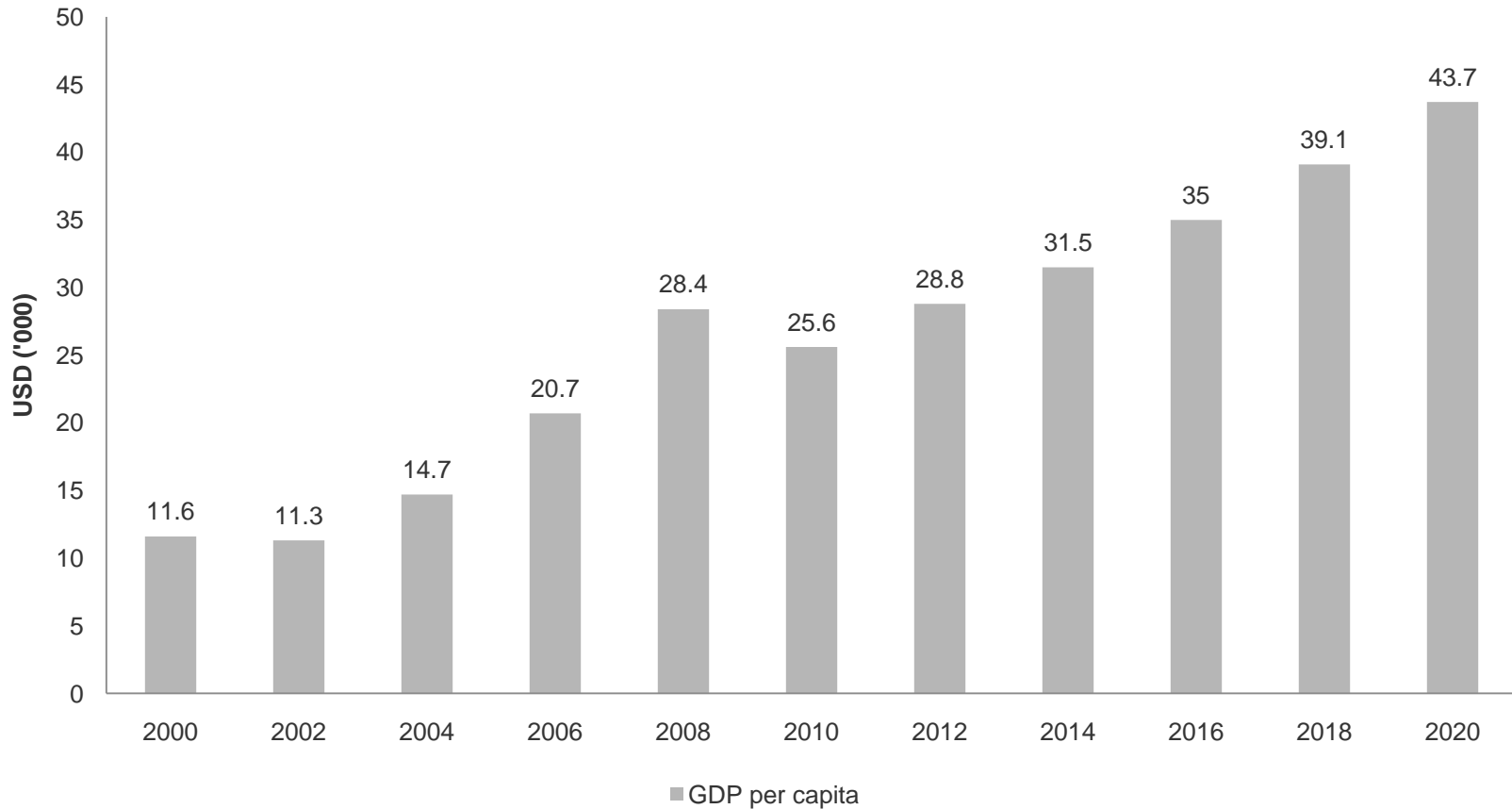
Non-G.C.C Contribution

Total Pharmaceutical Market Spending (US\$bn)



The Drivers for Growth Will be Population, GDP Per Capita, Lifestyle, and Higher Healthcare Standards

Between 2000-2020 the GCC GDP per capita will grow at 7%, and healthcare spend as a % of GDP will grow from ~4% to 6-7%

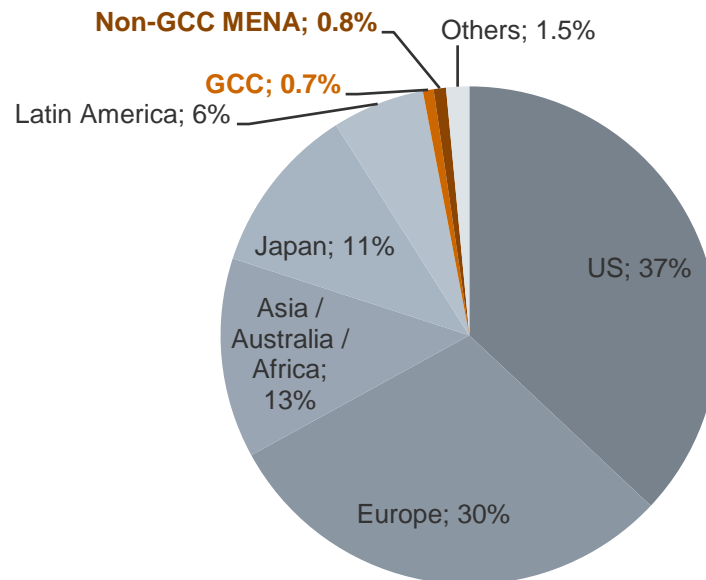


Source: World Bank, Alpen Capital and PRTM Analysis

Globally, US and Europe Continue to be the Largest Pharmaceutical Markets

In 2009, pharmaceutical sales in MENA accounted for 1.5% of the global market

Pharmaceutical Market 2009
(approx. \$950B, growing to \$1.1T by 2014)



Source: TVM Capital, IMS Health Market Prognosis, Alpen Capital and PRTM Analysis

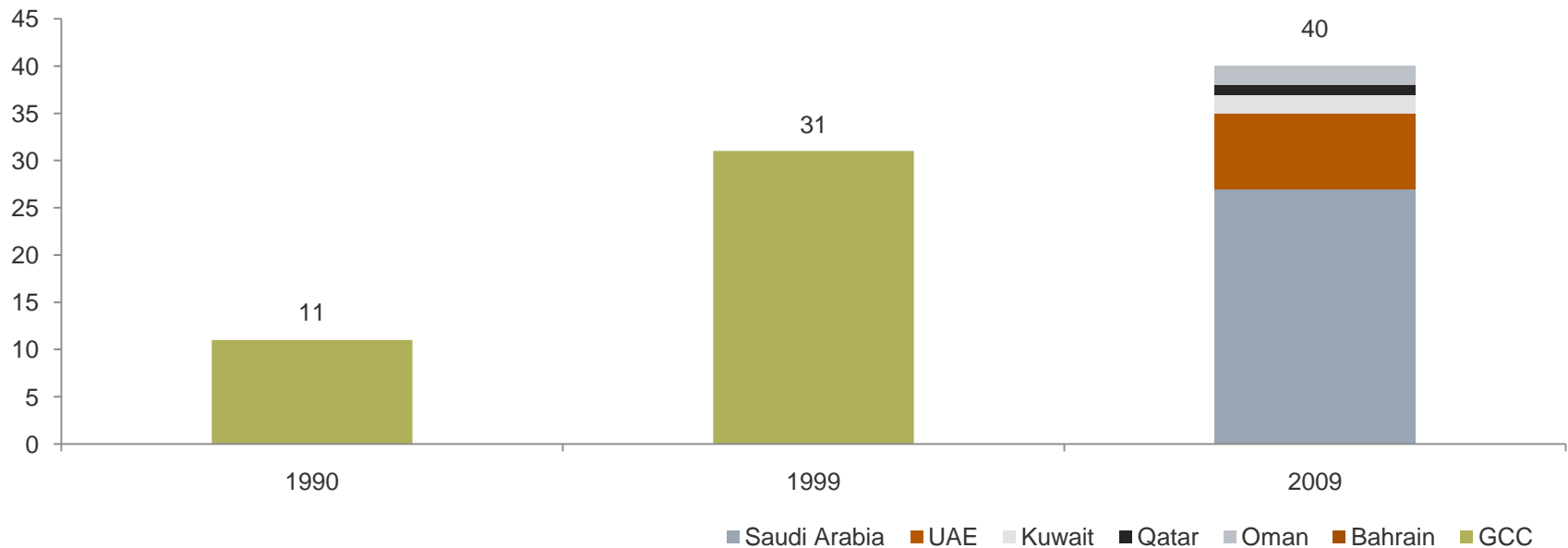


Pharmaceutical Manufacturing & Supply in GCC and MENA

The Number Of Pharmaceutical Factories In The GCC Grew From 11 In 1990 To 40 In 2009

- **The majority of the factories are in Saudi Arabia and UAE**
(In comparison, India had more than 20,000 manufacturing units in 2002)
- **Few companies are publicly listed which creates opportunities for Private Equity and Venture Capital investors**

GCC Pharmaceutical Factories



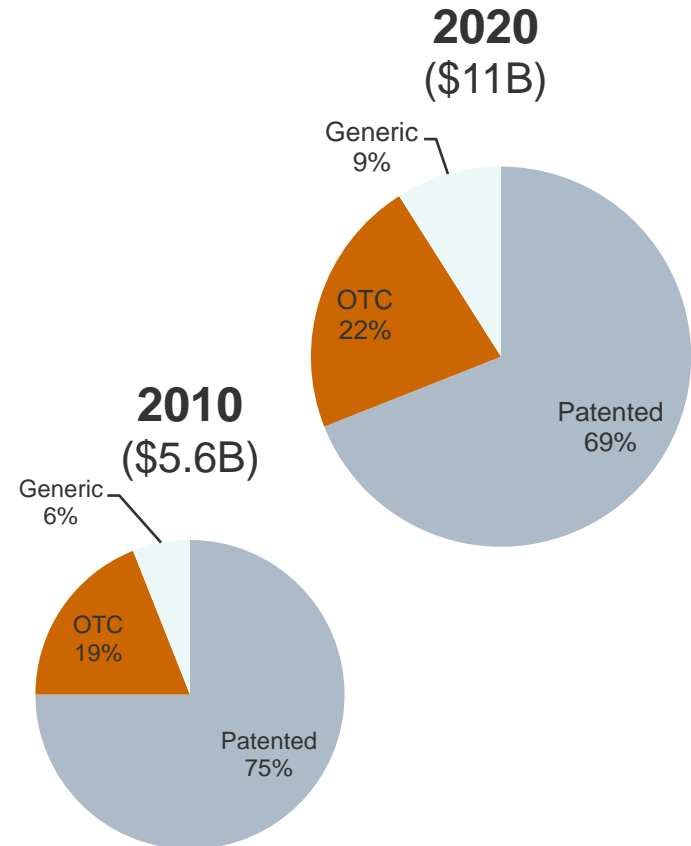
Source: IPR Strategic Business Information DB, GOIC, Pharmaceutical Drug Manufacturers, and PRTM Analysis

Domestic Manufacturers Have a Limited Share of the GCC Market Compared to Imported Products

GCC Supply Factors

- Every year, ~80% (\$4+B in 2010) are imported from Europe, US & Asia
- India and Japan are setting up JVs with local firms; Ranbaxy was the first Indian company to penetrate the Saudi market
- The GCC main players are Abbott, Novartis, GlaxoSmithKline, Astra Zeneca, Johnson & Johnson, and Pfizer
- Leading manufactures in the region like SPIMACO (Saudi) and Julphar (UAE) have less than 10% of the market
- Patented drugs are the major products with generics constituting 5-6% market share, but increasing
- GCC generics demand will grow from \$300M to \$1B by 2020 (+ MENA)

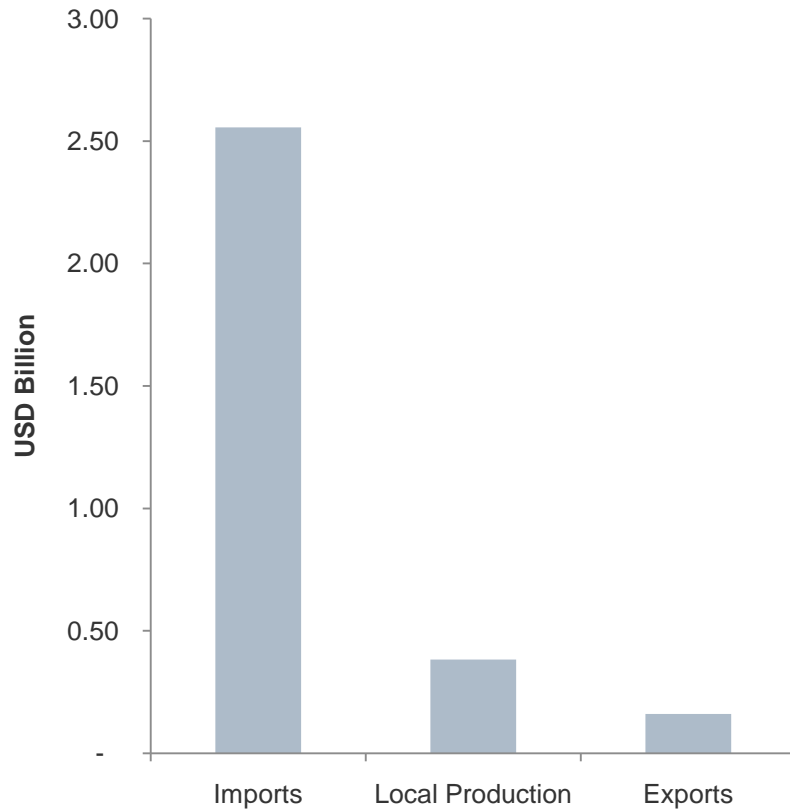
GCC Pharmaceutical Market



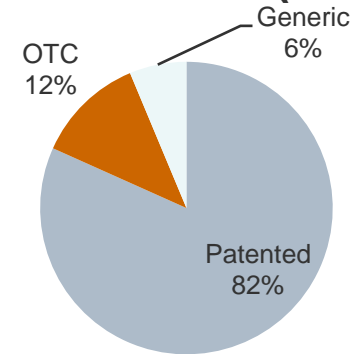
Source: WHO, International Diabetes Federation, Alpen Capital and PRTM Analysis

Local Production and Exports are a Small Fraction Even in Saudi Arabia

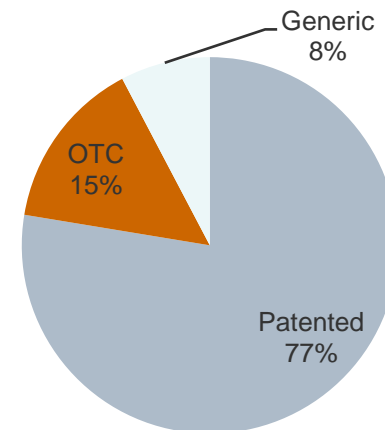
Saudi Pharmaceutical Supply (2008)



Saudi Market (2008)



Saudi Market (2014)



Source: NCB and PRTM Analysis

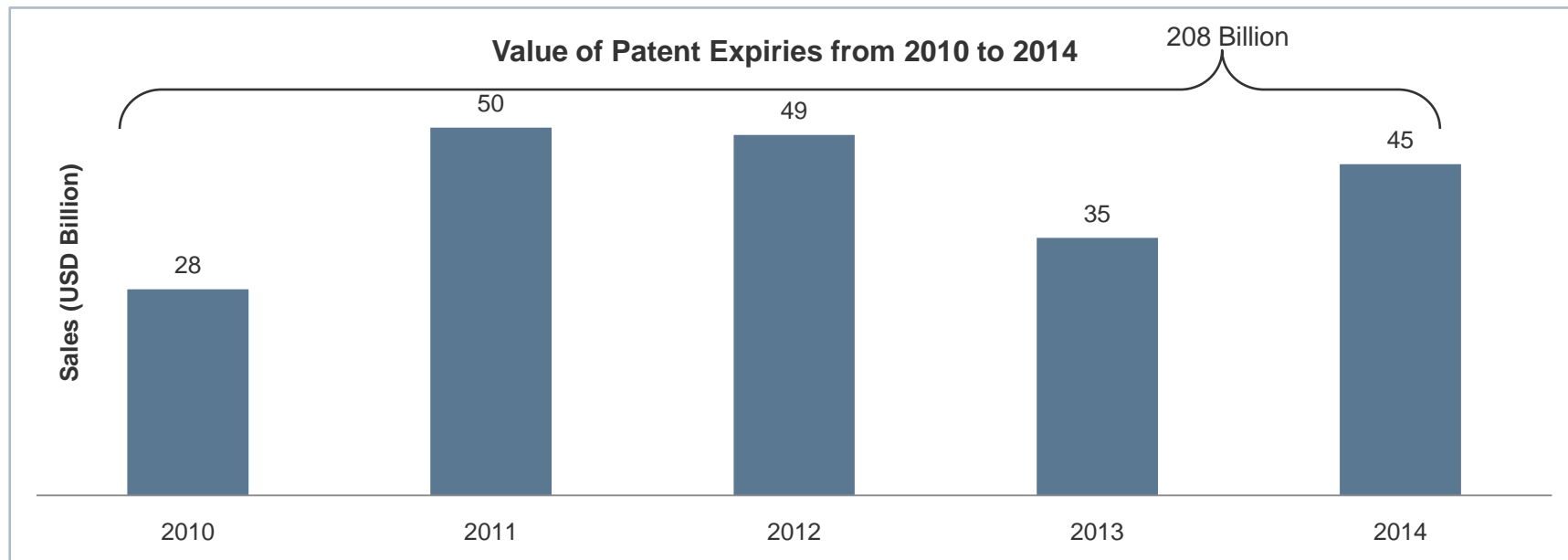


Global Pharmaceuticals – Trend Towards Generics

Key Biopharmaceutical Industry Trends

- ✓ **Move to networked or “selectively integrated” or “open innovation” operational models**
 - Mitigate risk, access innovation, expand into new markets, reduce costs
- ✓ **Increased mergers, acquisitions, and partnerships**
 - Trend of divestitures, in particular in small molecule manufacturing
- ✓ **Globalization of the industry**
 - Increased focus on Emerging Markets, in particular on BRIC-MT and MENA
- ✓ **Health Care reform**
- ✓ **Rise of generics and bio-similiars**
- ✓ **High / increased level of regulatory scrutiny and focus on Quality**

Over \$208 billion of patented pharmaceutical products will experience sales loss between 2010 & 2014



Top 10 drugs by value going off patent in year of expiry

- Cozaar
- Aricept
- Taxotere
- Protonix
- Eloxatin
- Xalatan
- Gemzar
- NovoSeven
- Sifrol/Mirapex

- Lipitor
- Plavix
- Seretide/Advair
- Zyprexa
- Actos
- Avapro
- Levaquin
- Zoladex
- Femara
- Avelox

- Enbrel
- Diovan
- Seroquel
- Singulair
- Lovenox/Clexane
- Lexapro
- Viagra
- Atacand
- Blopress
- Avapro

- Cymbalta/Xeristar
- Procrit/Epex
- Epogen
- Aciphex/Pariet
- Avonex
- Rebif
- Prograf
- Humalog
- Zometa
- Neupogen

- MabThera (Rituxan)
- Nexium
- Insulin Analogues
- Celebrex (63%)
- Symbicort
- Copaxone
- Micardis
- Actonel
- Risperdal Consta
- Kogenate

Source: Evaluatepharma, Product forecasts from analyst reports, PRTM Analysis

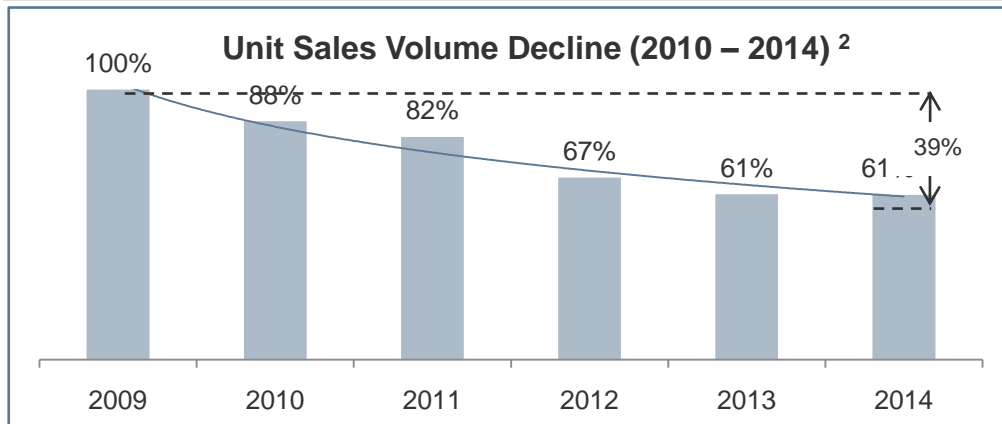
The top 15 firms account for 79% of the total worth of patent expiries¹

Innovator Firm	Total Value of Products losing Protection (USD Bn.)	% Of Industry Levels	Top 5 Drugs losing patent protection ²
Pfizer - Wyeth	27	13%	Lipitor, Enbrel, Celebrex, Viagra, Xalatan
AstraZeneca	17	8%	Seroquel, Nexium, Symbicort, Atacand, Arimidex
GlaxoSmithKline	15	7%	Advair, Avolve, Lovaza, Kivexa, Combivir
SanofiAventis	15	7%	Lovenox, Plavix, Taxotere, Eloxatin, Avapro
Merck Schering Plough	14	7%	Singulair, Cozaar, Nasonex, Temodar, Clarinex
Novartis	13	6%	Diovan, Zometa, Femara, Exelon, Aclasta
Eli Lilly	12	6%	Zyprexa, Cymbalta, Humalog, Gemzar, Cymbyx
Roche	10	5%	Rituxan, Xeloda, Boniva, Fuzeon, Cardene
Johnson & Johnson	8	4%	Risperdal, Procrit, Levaquin, Prezista, Aciphex
BristolMyers Squibb	8	4%	Plavix, Avapro, Sustiva, Avalide
Amgen	7	3%	Enbrel, Epogen, Neupogen, Kineret
Takeda	7	3%	Actos, Blopress, Velcade, Amitiza, Integrilin
Eisai	5	2%	Aricept, Aciphex, Dacogen, Ontak, Gliadel
Boehringer Ingelheim	4	2%	Micardis, Mirapex, Viramune, Glucagen, Viramune ER
Forest Laboratories	2	1%	Campral, Lexapro
All Others (~ 170 firms)	45	21%	Insulin Analogues, Avonex, Copaxone, Rebif, Oxycontin
Total	208	100%	

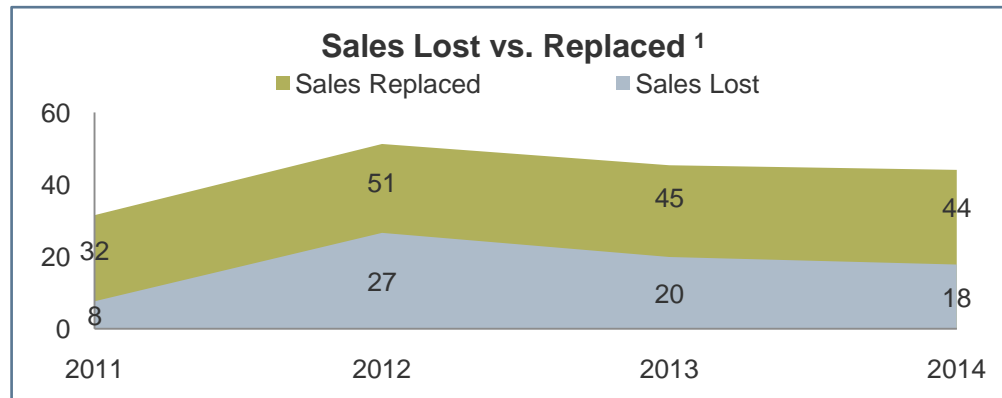
- *The “blockbuster syndrome” is in evidence as key losers are heavily dependent on few top products*
- *For each firm , the top 5 drugs accounted for 88% ³ of total value of products losing patent protection*

1. Sorted by expected sales loss
2. Top 5 drugs by value in year of expiry
3. Estimates of sales of top 5 drugs as a percentage of total value of patent expiry

Innovator firms will have 39% underutilized capacity by 2014; will be tough to redeploy with the new product mix



Yet the Innovator Pharma industry has projected net positive growth



1. Source: Analyst Reports, PRTM Analysis

2. PRTM Analysis: Assuming constant innovator prices

Sales Lost: Decline in innovator sales of products losing patent protection

Sales Replaced: Sales added through new products and growth of established products

- Products coming off patent are 34% injectables, 49% solid orals and 17% other formulations by sales

- Products are predominantly small molecule at 72% by sales

- While firms are able to replace sales, trends indicate increased % of biologics vs. small molecules

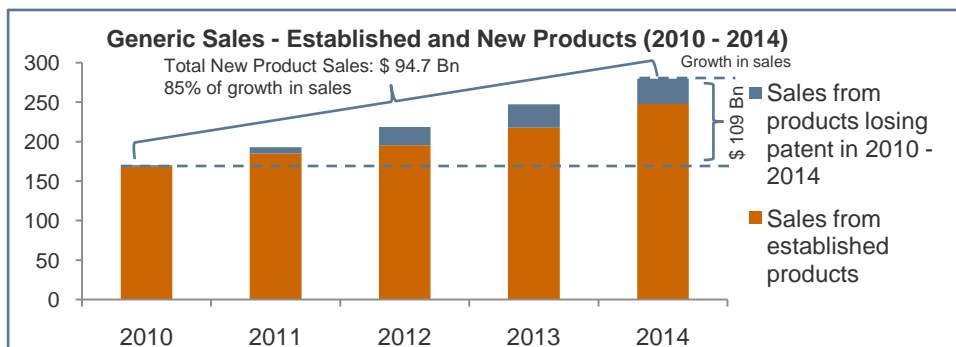
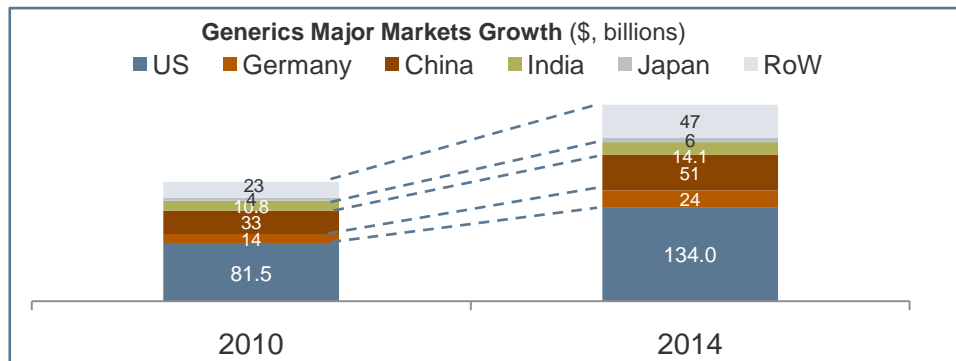
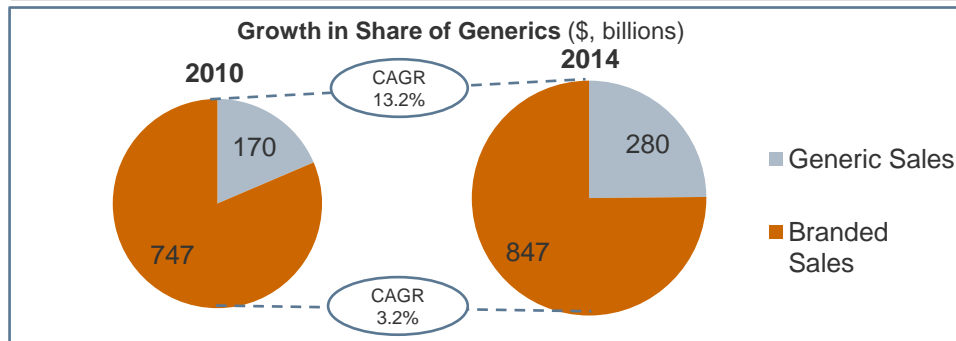
- At 42% of pre-clinical candidates and 26% of submissions, the share of biologics is expected to grow to 23% of world pharma in 2014

- This will also result in an increase in the share of injectable formulations



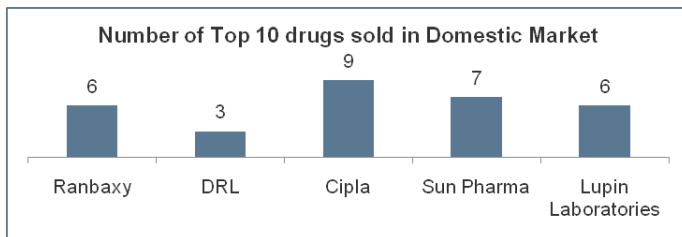
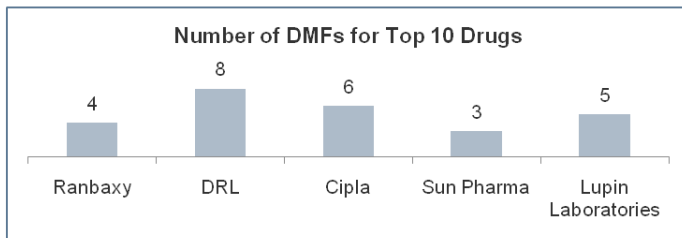
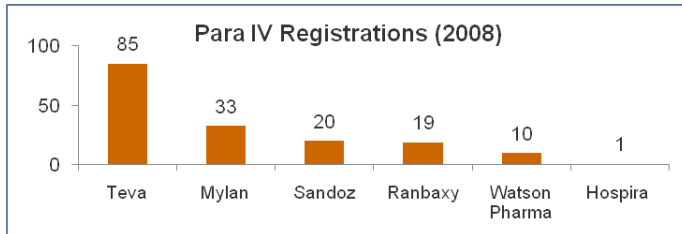
Assets will be hard to reassign

Generics will play a significant role in the global pharmaceutical market with a 2010-2014 CAGR of 13.2%



- **Generics are expected to increase their contribution from 19% in 2010 to 25% in 2014 of the global pharmaceutical market**
- **Generics show a much faster growth rate (13.2%) than branded products (3.2%)**
- **Generics growth is driven by key markets of US, Germany and China growing at 13%, 14% and 11% respectively**
- **Sales from products losing patent between 2010 and 2014 will contribute 11% of total industry sales**
- **Of the yearly growth in generics, 85% comes from products losing patent between 2010 and 2014, while 15% is from growth of established products**

Generics firms are preparing for patent expiries and scale through acquisitions and capacity addition



- Of the 60 drugs set to lose patent over the next 4 -5 years, generic manufacturers have filed Para IVs on at least 70% of them¹
- Para IVs filings are concentrated among a few firms: Among those filed for products with patent expiry in 2009, 41% were filed by Teva¹
- Generics players have also developed capabilities to manufacture drugs: 9 of the top 10 drugs have DMF registrations filed²
- LCC generic firms possess adequate chemistry capabilities: Many firms are currently selling innovator products in their domestic markets; All of the top 10 drugs are being sold in the Indian market by local players³

Consolidation/M&A Activity Among Top Generics Players



Planned Expansion Top Generic Players (Illustrative)

Teva	Plans to double capacity to 90 bn units by 2012
Mylan	Plant opened W. Virginia (2006) is expected to eventually double Mylan's capacity
Watson Pharma	Expansion of Goa facility from 1b units to 3bn to meet increased demand.
Stada-Arzneimittel	Shifting from CMOs to inhouse production in LCC . Eg. Vietnam, Russia and Serbia.

However, generic pharmaceutical margins will continue to be impacted by pricing pressures

However, HCC – Generic firm's margins will be worse impacted due to inability to respond to pricing pressures

Commoditization Of Drugs

Low Price Drivers

- When a patent expires, anywhere between 10 - 40 players enter the market
- Number of competitors affect price.
 - <10 competitors results in 40% drop
 - >10 competitors results in 50% drop

Adoption of Reference Pricing Systems

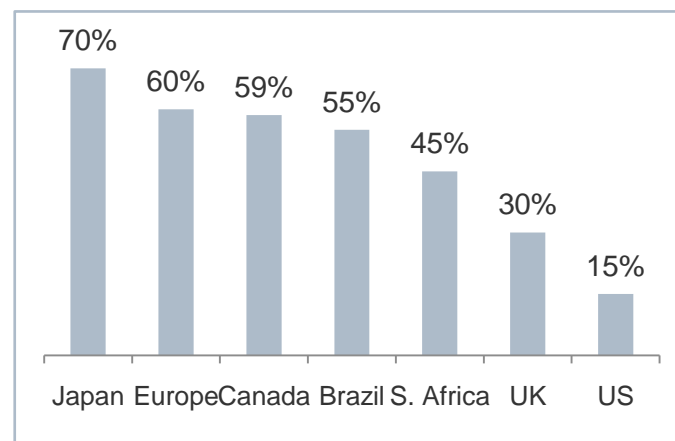
In order to contain healthcare expenditures, Govts are playing active role in pricing

- Japan - When a patent expires, ministry cuts price to 70% of branded drug.
- Key European markets base RPS on weighted average of generics price Eg: Italy, France.

Drug retailers wield price power

- Big box retailers (eg Walmart, Kmart) aggressively launch discount programs using volume purchases to undercut prices.
- Pharmacy industry consolidation, leaving price bargaining power to fewer players.
Eg: Top 6 pharmacies account for 50% of all dispensed medication in US

**Avg. Generic Prices
(as % of originator price)**



Source: IMS, EU Preliminary report, Press Search

Both Generics and Contract Manufacturers in High Cost Countries (HCC) will see pressures on margins

Company	HCC G Cost Structure*	LCC G Cost Structure+
Total Revenue	100%	100%
Cost Of Goods Sold	56%	45%
Gross Profit	44%	55%
Other Operating Exp., Total	28%	35%
Operating Income	16%	20%

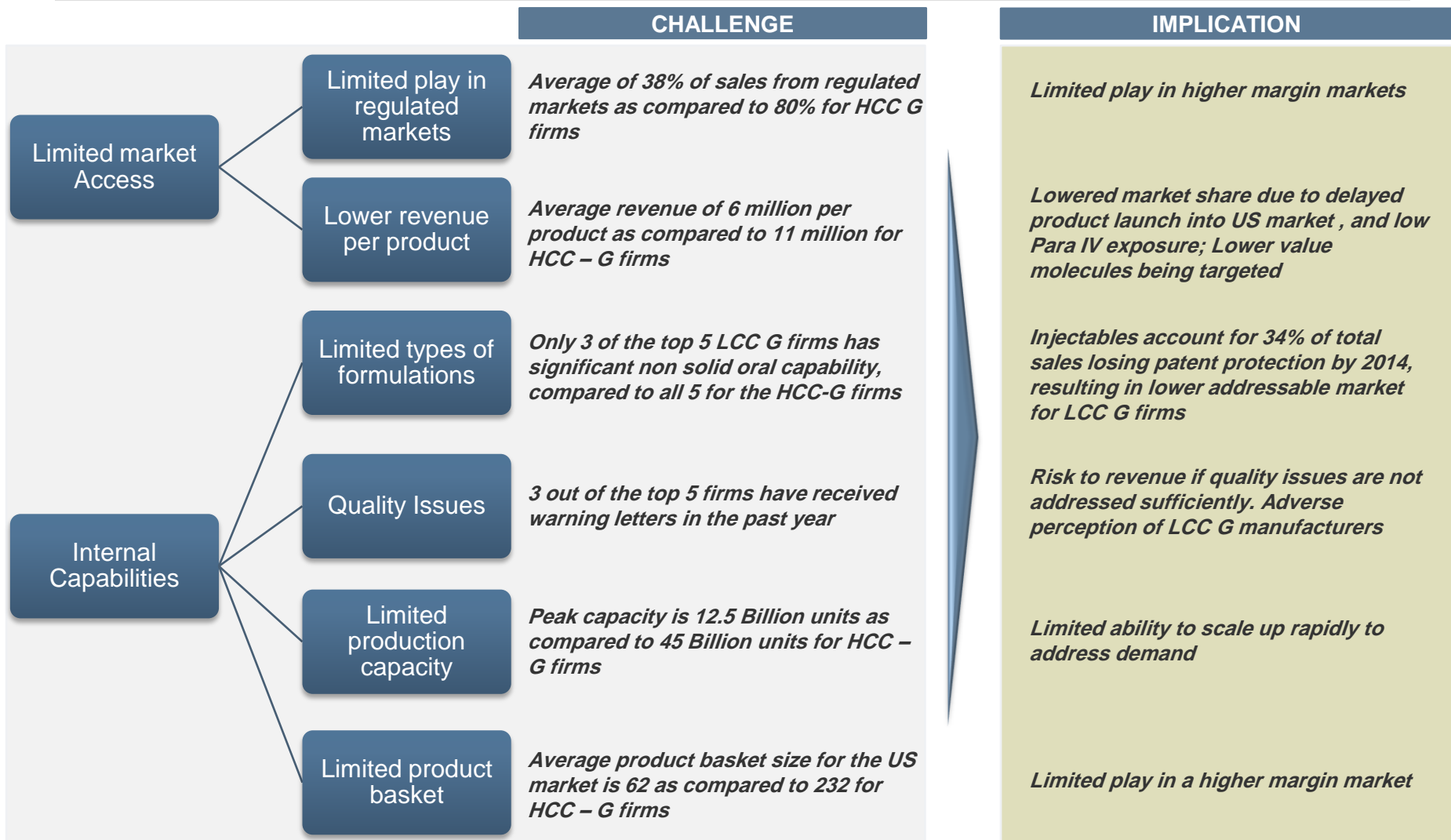
Key contributors to margin pressure

- 9% difference between LCC –G and HCC – G COGS, translating to a 7% operating margin difference
- 64% of the HCC – G assets are concentrated in HCC countries

	Average HCC CMO	Average LCC CMO
Revenue	100%	99%
Other Revenue		1%
Total Revenue	100%	100%
Cost Of Goods Sold	74%	51%
Gross Profit	26%	49%
Other Operating Exp., Total	18%	32%
Operating Income	8%	17%

- 23% difference between LCC –CMO and HCC – CMO COGS, translating to a 9% operating margin difference
- 74% of the HCC – G assets are concentrated in HCC countries
- This will translate into HCC CMOs facing challenges competing in the upcoming price sensitive environment









































LCC Generics will be stymied by a lack of market access and internal capabilities











































Generics players will use two strategic levers – alliances and restructuring – to win in the new environment

	Key Imperative to Win	M&A	Restructuring
Innovator	Smoothing earnings fluctuations from patent expiry	✓	
	Access to new markets / segments	✓	
	Access to new capabilities (biologics)	✓	✓
	Access to product pipelines	✓	✓
	Reduce cost base	✓	✓
Generic	Access to new markets	✓	✓
	Access to new capabilities (improved quality, systems, new manufacturing processes)	✓	✓
	Building scale of operations	✓	
CMO	Access to new markets	✓	✓
	Access to new capabilities (improved quality, systems, new manufacturing processes)	✓	✓
	Building scale of operations in LCC	✓	✓































Rationalization of the manufacturing network, SG&A and R&D Portfolio are the best options for Innovator Pharma

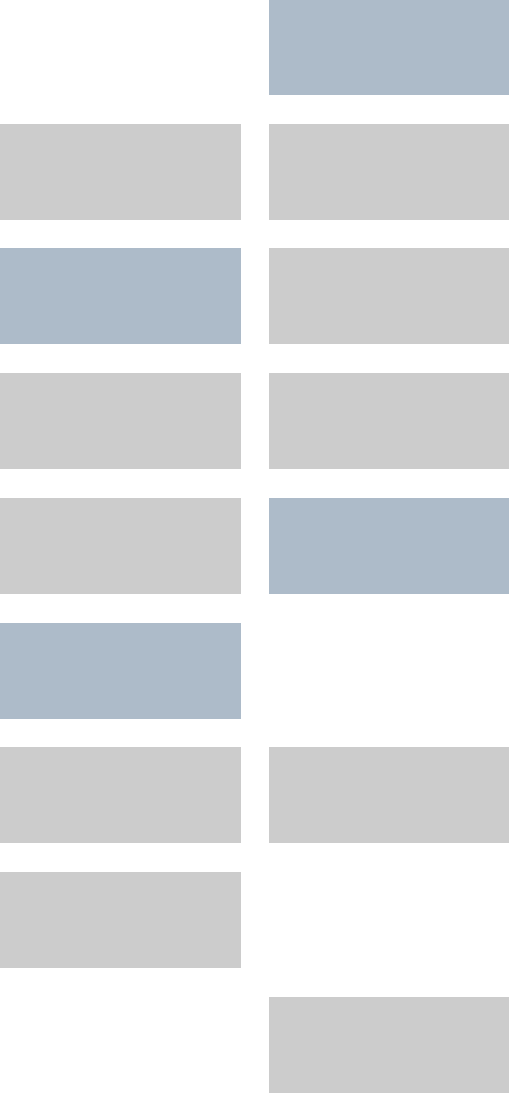
			Details			
Restructuring Area	Description	Overall Impact	Revenue Growth	Revenue Protect.	Cost Saving	Implemt. Risk
Manufacturing facility rationalization	Optimize manufacturing network by relocating/closing manufacturing facilities					
	Optimize internal versus external manufacturing and outsource non-core manufacturing					
Cost restructuring	Reduce headcount and SG&A costs					
	Optimize sourcing and distribution network					
R&D process restructuring	Functional restructuring: focus on core competencies while contracting out secondary R&D)					
	Project base restructuring: outsource development on project basis					
Product portfolio rationalization	Focus on high value and high probability of success drug projects (higher barrier to entry drugs and high profit areas)					
	Entry into branded generics					

Building manufacturing excellence and scaling up capacity in LCC are the best options for Generic Pharma

Restructuring Area	Description	Overall Impact	Details			
			Revenue Growth	Revenue Protect.	Cost Saving	Implemt. Risk
Build manufacturing excellence capabilities	Implement quality systems such as initiatives to comply with regulatory requirements and six sigma					
	Implement lean manufacturing					
Build R&D capabilities	Rapid R&D and technology transfer					
	Focus on differentiated generics and high value drugs					
Build capabilities to scale up manufacturing	Expand existing facilities					
	Expand footprint in LCC					
Build capacities to access to new market	Expand footprint in target markets (manufacturing facilities in highly regulated markets or distribution network)					
Build marketing capability	Market branded generics					

Transitioning production to LCCs and acquiring innovator assets are the best options for CMO

			Details			
Restructuring Area	Description	Overall Impact	Revenue Growth	Revenue Protect.	Cost Saving	Implemt. Risk
Build capabilities to scale up manufacturing	Transition production to LCCs					
	Acquire unutilized innovator assets					
	Expand existing facilities					
Build manufacturing excellence capabilities	Implement quality systems such as initiatives to comply with regulatory requirements and six sigma					
	Implement lean manufacturing					
Build capacities to access to new market	Expand footprint in target markets					



Opportunities for GCC/ MENA Pharmaceutical Manufacturers and Investors, and Operating Models

So, Where Are The Opportunities for GCC Pharmaceutical Manufacturers and Investors?

Let's recap a few facts and trends:

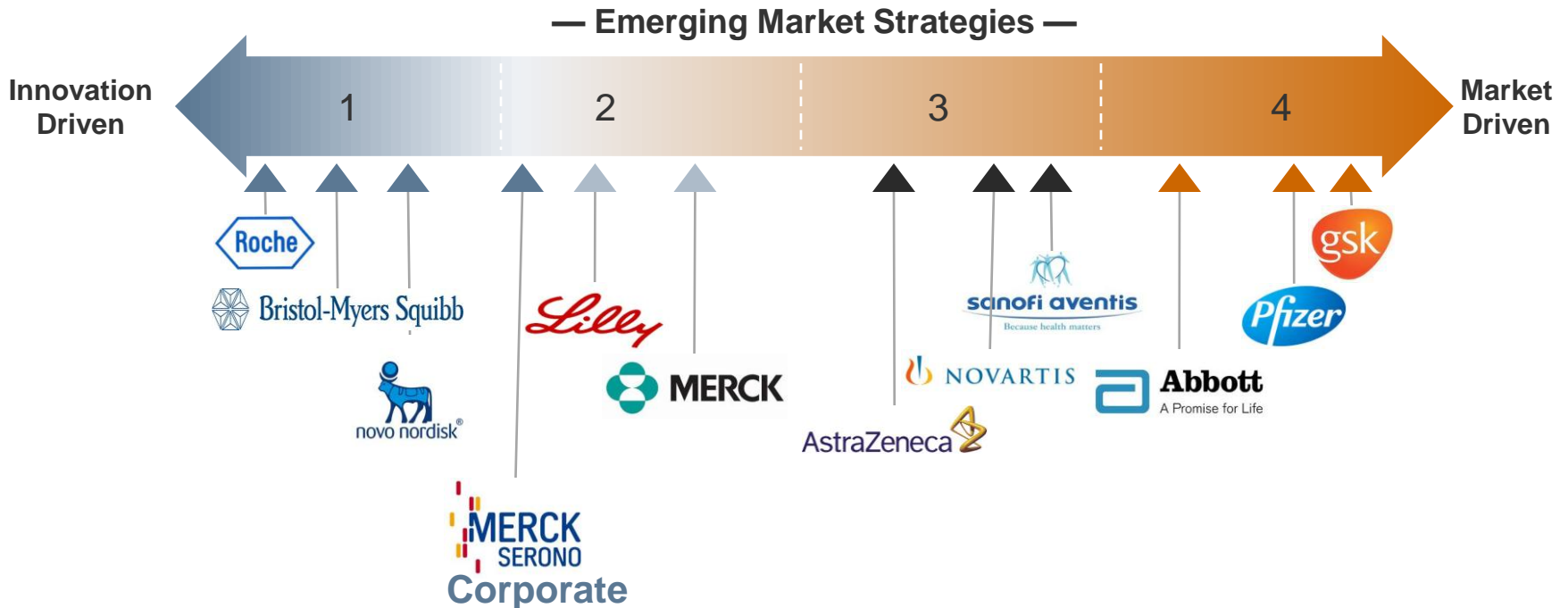
- Globally, generics pharma demand is growing dramatically – CAGR of nearly 12% - driven by patent expirations and healthcare costs
- GCC generics demand will grow from \$300M to \$1B by 2020, and from approximately \$500M to \$2.5B by 2020 for MENA – a CAGR of greater than 15%, which could be higher depending on GCC/ MENA government healthcare policies
- Generics manufacturers are looking to achieve market access by acquiring HCC-based generics companies, and to expand production capacity through greenfield facilities or acquisitions in LCC locations
- GCC governments are seeking to encourage domestic production (and R&D) to ensure import substitution, and, as generics demand increases, may find ways to encourage domestic production (GCC countries are not yet members of WTO)

The Opportunity in Generic Drugs is Significant

Globally, over \$208 billion of patent protected pharmaceuticals will be replaced by generics between 2010-2014; in the next 5 years, \$77 billion of patent drugs will expire for cardiovascular drugs alone.

This will create an opportunity for generic drugs manufacturers, including in the GCC and MENA, to expand sales and manufacturing, if supported by health plans, regulatory simplifications, and trade incentives.

Amongst Innovator (Branded) Pharma, Companies Are Using One of Four Strategies in Emerging Markets



Legend:

1. Innovation Driven: Leveraging Proprietary Portfolio into Emerging Markets

2. Augmentation: Limited Augmentation of Proprietary Portfolio into Emerging Markets

3. Focused: Focused Market Presence with Selective Market Expansion

4. Market Driven: Broad, Aggressive Market Driven Expansion into Emerging Markets

Innovator vs. Generics Development

R&D Specific Operating Model Differences

	Innovator R&D	Generics R&D
R&D Org. Construct	Mostly organized by therapy area and/or customer segment <ul style="list-style-type: none"> ▪ “Disease” and “patient” focus 	Mostly organized by market (region) , typically by regulated vs. emerging <ul style="list-style-type: none"> ▪ “Regional requirement” focus
Portfolio & Pipeline Management	Therapy Area led , with proactive pipeline management <ul style="list-style-type: none"> ▪ Research driven ▪ “Outcome based”, with no-go decisions based on pre-clinical and clinical results 	Chemistry and/or formulation type led (Therapy Area agnostic), focused on maximizing “shots on goal” <ul style="list-style-type: none"> ▪ Load pipeline with as many opportunities ▪ “No kill” philosophy (unless IP issues)
Development Paradigm	“First in class”, “fast to optimize”, etc. , assuring submissions are robust <ul style="list-style-type: none"> ▪ Ensure repeatability in commercial manufacturing ▪ Benefit of learnings from clinical batches 	“Fast to file” : Minimum required development prior to filing ... refine after filing / approval <ul style="list-style-type: none"> ▪ Smaller & fewer batches in development ▪ Limited clinical batches (BE / BA only)
Development Standards	Typically, uniform development standards , irrespective of market <ul style="list-style-type: none"> ▪ Harmonized standards / practices for all target markets 	Typically, disparate development standards , based on region / market <ul style="list-style-type: none"> ▪ Differentiated standards / practices across target markets ▪ Managing global quality standards can be an issue






Innovator vs. Generics Development

R&D Specific Operating Model Differences

Continued

	Innovator R&D	Generics R&D
Capabilities / Expertise	<p>Research driven, with extensive focus on Pre-Clinical and Clinical development</p> <ul style="list-style-type: none"> Strong lead generation & optimization, pre-clinical development, and clinical development capabilities 	<p>CMC driven, with extensive focus on formulation dev, process chemistry, and analytical characterization</p> <ul style="list-style-type: none"> Rapid API and formulation & process development capabilities Strong Intellectual Property expertise, if focused on first-to-files
Team Organization	<p>Program- / product- based, with dedicated resources on programs</p> <ul style="list-style-type: none"> “Cradle to grave” philosophy 	<p>Function-based (i.e. formulation, process, analytical), with resources spread across multiple programs</p>
Partnering	<p>Need-based partnering</p> <ul style="list-style-type: none"> In-license, partner, and/or outsource based on pipeline gaps, technology gaps, and/or non-core activities 	<p>Extensive partnering</p> <ul style="list-style-type: none"> Aggressive in-licensing, outsourced development, etc to achieve capture market opportunity

Given the preceding choices, GCC Pharma companies need to assess operating model and mode

	Pros	Cons	GCC Fit
GCC Greenfield			
Technology License			
Minority Investment/ Alliance			
Acquisition			
Joint Venture			

Thank You

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R&D Focus across Different Types of Generics

	First-to-File Generics	Follow-on Generics	Authorized Generics	Branded Generics	Differentiated Generics	Innovator Drugs
Product Portfolio	<ul style="list-style-type: none"> Chemistry led 	<ul style="list-style-type: none"> Chemistry led 	<ul style="list-style-type: none"> Formulation Type led 	<ul style="list-style-type: none"> Formulation Type led 	<ul style="list-style-type: none"> Formulation Type led 	<ul style="list-style-type: none"> Therapy Area / Customer Segment led
CMC Focus	<ul style="list-style-type: none"> High velocity, high throughput in API and formulation & process development 	<ul style="list-style-type: none"> Non-infringing API and formulation development, with highest commercial yields 	<ul style="list-style-type: none"> Technology integration capabilities 	<ul style="list-style-type: none"> Formulation or packaging development, without altering basic PK or PD characteristics (e.g. packaging material change, tablet shape or color changes, etc.) 	<ul style="list-style-type: none"> Enhanced drug delivery systems Advanced formulation development, without impacting PD characteristics (e.g. novel dosage formulations – TDD, inhalation, extended release etc). 	<ul style="list-style-type: none"> Novel molecules Novel drug delivery systems and/or formulations
Clinical Focus	<ul style="list-style-type: none"> BE and BA studies 	<ul style="list-style-type: none"> BE and BA studies 	<ul style="list-style-type: none"> BE and BA studies 	<ul style="list-style-type: none"> BE and BA studies Limited pre-clinical development 	<ul style="list-style-type: none"> Late-stage clinical development 	<ul style="list-style-type: none"> Pre-clinical, early stage, and late stage clinical development
Dev. Cycle Time and Costs	<ul style="list-style-type: none"> Few months to 1 – 2 years \$1 – 3 MM 	<ul style="list-style-type: none"> 1 – 2 years \$1 – 3 MM (may be lower for certain markets) 	<ul style="list-style-type: none"> < 1 year < \$1 MM 	<ul style="list-style-type: none"> < 1 year \$1 – 3 MM (may be lower for certain markets) 	<ul style="list-style-type: none"> 2 – 5 years \$3 – 10 MM (may be higher for certain products) 	<ul style="list-style-type: none"> > 5 years > \$100 MM