

The Global Generics Market - Key Facts & Challenges -

Position Paper

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The Global Generics Market – Key Facts & Challenges

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1. Introduction

This presentation highlights the key issues regarding dynamics and strategies in the generics business

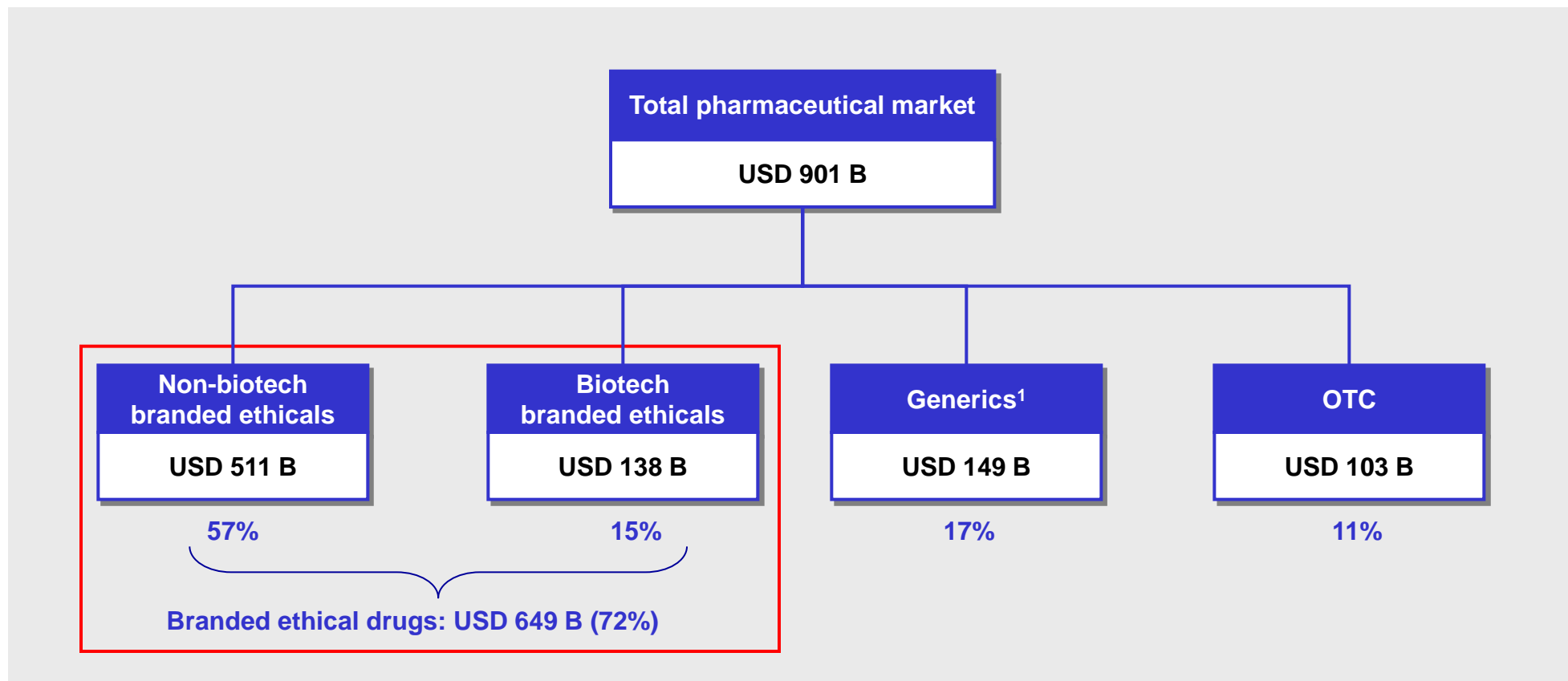
Key issues addressed

- How is the global generics market structured?
- What are the dynamics of key generics markets?
- What are the most attractive generics markets?
- What are the key players of the generics industry?
- What are the current strategies of the key players?

2. Generics market structure & dynamics

Generics drugs accounted for 17% of the global pharmaceutical market in 2010, representing the second largest segment after the non-biotech branded ethicals

Global Pharmaceutical market segmentation (2010)



2. Generics market structure & dynamics

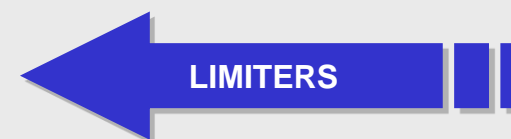
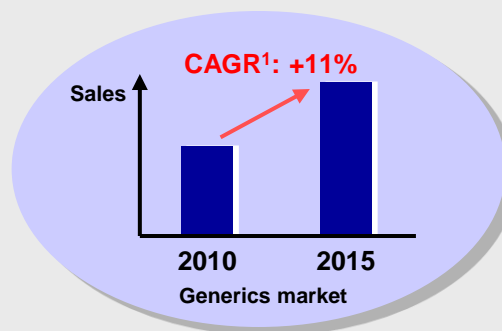
The key drivers and limiters of the generics market are well identified, as well as their impact on sales trends

Generics market drivers and limiters (2010–2015)



1. Growing healthcare expenditure
2. Population increase and ageing
3. Growing demand for low prices
4. Increasing public acceptance for generic products
5. High growth potential in countries with low current generics penetration (e.g. Italy, Spain, France, Japan, etc.)
6. Faster and simpler registration procedures for generic drugs
7. Key brands patent expiries

Key forces (2010-2015)

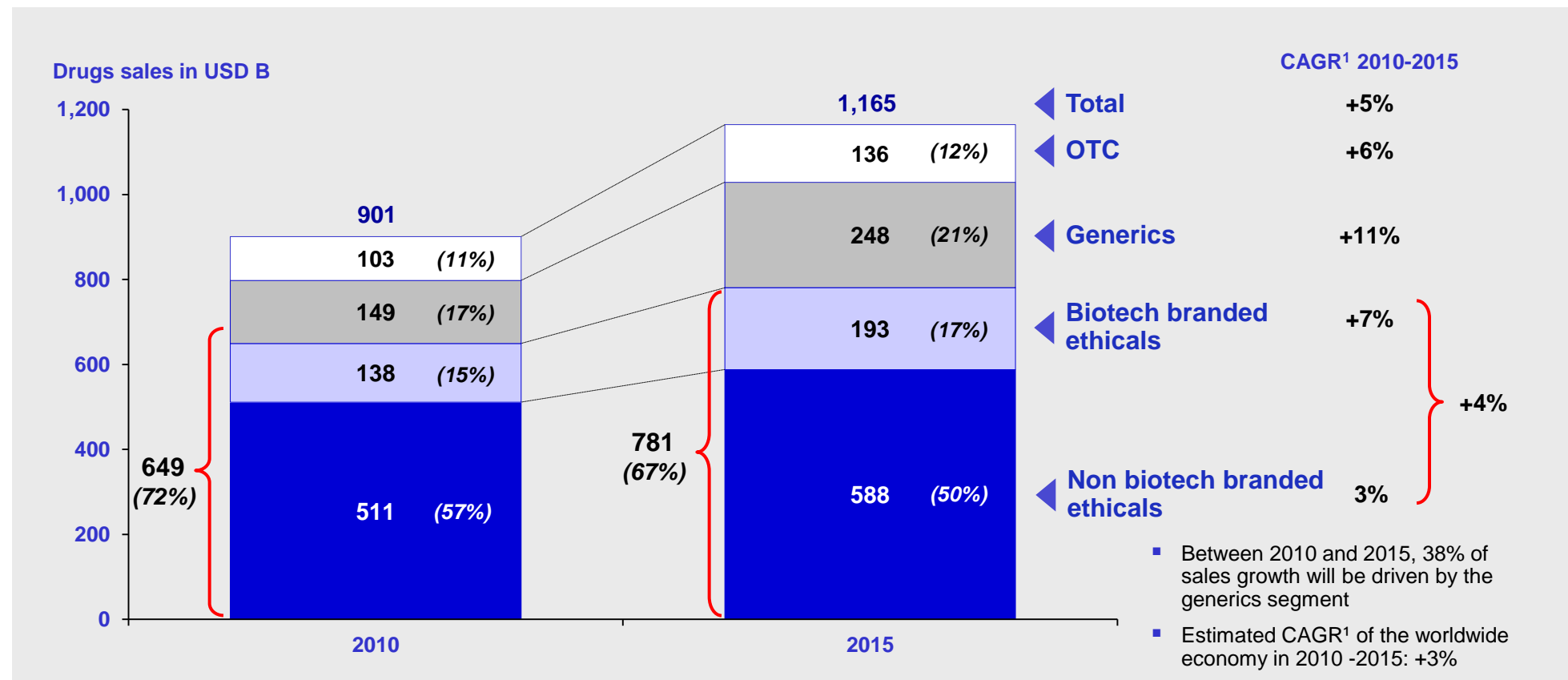


1. Dependence on patent expiries and thinning pipelines
2. Defense generics strategies of R&D-based companies:
 - Life-cycle management / Evergreening²
 - Commercial offers to distributors
 - Price equalization
 - OTC switching (to ensure brand loyalty after patent loss)
 - IP protection / litigations
3. Saturation of generic penetration
4. Profits reduced by increasing competition amongst generics players

2. Generics market structure & dynamics

If branded ethical drugs (non-biotech + biotech) will remain the largest strategic segment, generics segment share will increase due to major brands patent expiries

DRIVERS → Growth by key pharmaceutical strategic segment (2010–2015)



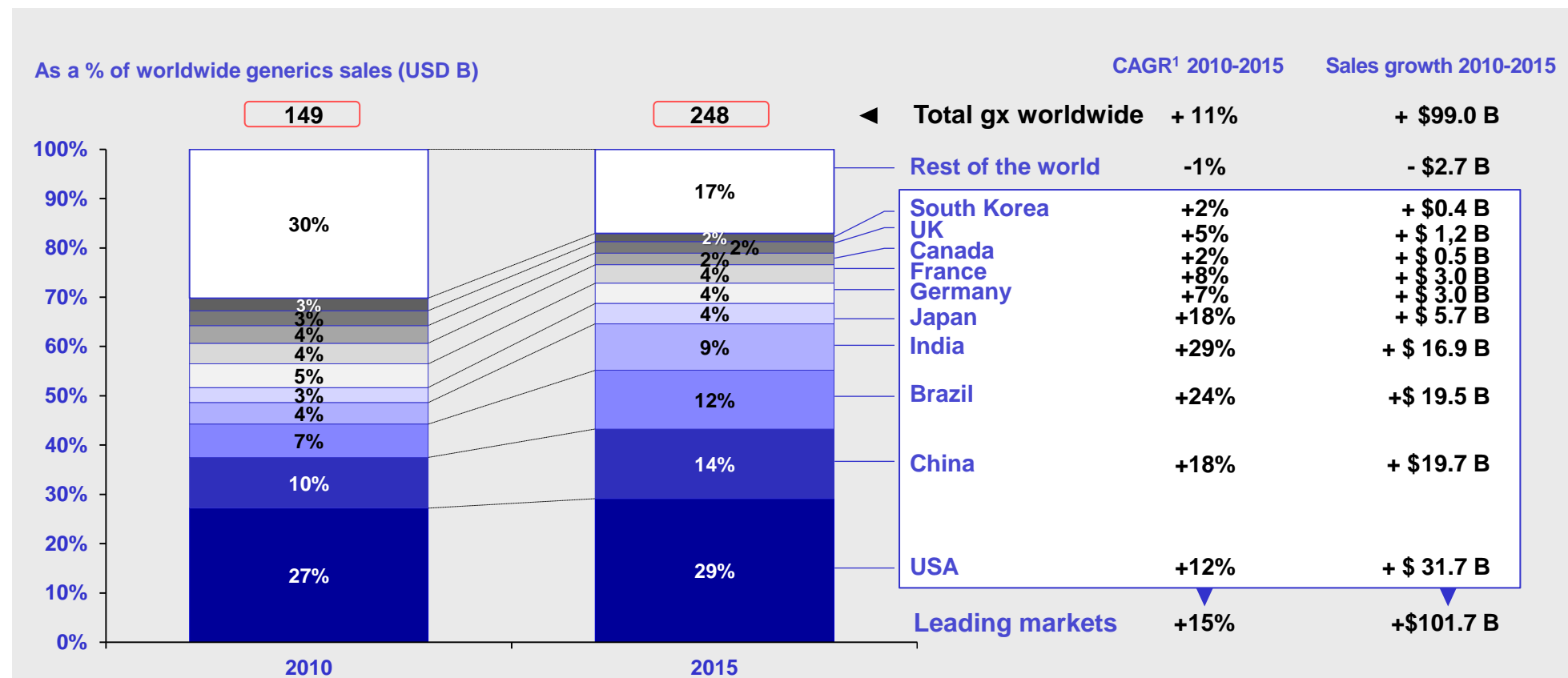
Source: IMS Market Prognosis, Sept. 2011- Nicholas Hall's OTC Yearbook 2011 – Smart Pharma Consulting analyses

¹ Compounded annual growth rate

2. Generics market structure & dynamics

In 2015, the top 5 generics markets should account for more than 2/3 of the global generics market, making them strategic of leading generics players

DRIVERS → Dynamics of generics markets (2010–2015)



Source: IMS Market Prognosis, Sept. 2011 – IMS Worldwide Top 10 Generic Country, Q42010 – IMS : the global use of Medicines Outlook: Through 2015

- What Lures the Attention of Global Generic Drug Makers towards China? (Frost & Sullivan) – "India Pharma 2015" (McKinsey) – BMI (Brazil) - Smart Pharma Consulting analyses

¹ Compounded annual growth rate

2. Generics market structure & dynamics

USA, China, Brazil and India will offer the highest perspective of growth on the generics segment over the period 2010 – 2015



	Specific drivers	Specific limiters	Attractiveness
USA	<ul style="list-style-type: none"> Good acceptance of generics and vast market Many high value drugs coming off patent in the next coming years Very probable pro-generic new reforms Biosimilar legislation passed in 2010 Drug purchasers keen to reduce costs 	<ul style="list-style-type: none"> Very competitive market, once 180-day exclusivity is lost High cost/duration of litigation with branded companies that easily fight to extend patent life Complex regulatory system, approval delays due to FDA backlog Unclear scope for biosimilar products 	H
China	<ul style="list-style-type: none"> Most medicines payments are out-of-pocket (although private health insurance and drug coverage is available) Increasing adherence to the state FDA and good manufacturing practices (GMP) Inexpensive manufacturing capabilities 	<ul style="list-style-type: none"> Strict patent laws are being introduced Since 2011, launch of across-the-board price reviews and price cuts with emphasis on high costs reimbursed drugs (including generics) Domination of local producers (98% of the Chinese generics market is controlled by local producers) Complex drug distribution system 	H
Brazil	<ul style="list-style-type: none"> Low fixed costs & fast supply of raw materials Enforced bioequivalence, generics packaging, generics prescribing and substitution are new regulatory measures to expand generics 10 bestselling pharmaceuticals with patent expiring between 2006 and 2013 (~ USD 358 M market) 	<ul style="list-style-type: none"> Lack of generics awareness among all targets Due to high competition among local producers, generics prices have fallen dramatically, diminishing profits Opening of “popular pharmacies” where original drugs are sold with up to 90% discounts, to increase access to medicines 	H
India	<ul style="list-style-type: none"> Increasing awareness and access to medicines Increasing private investments to develop generics Increasing health insurance leading to better market's affordability for medicines Wide market (1/6 of the world population) 	<ul style="list-style-type: none"> Patented drug sales are expected to increase, owing to an improvement in the implementation of patent laws and spread of health insurance Lack of medicines awareness in the rural areas Increasing of health insurance coverage leading to price reduction 	H

H: High – M: Moderate – L: Low attractiveness, integrating impact on sales, and profits of generics players

Source: Espicom Business Intelligence 2011 – World Generics Market 2009-2024 (Visiongain) - Smart Pharma Consulting analyses

2. Generics market structure & dynamics

Japan, Germany and France attractiveness are relatively moderate, the former market being quite resistant to generic penetration and the two later rather mature



	Specific drivers	Specific limiters	Attractiveness
Japan	<ul style="list-style-type: none"> Promotion/incentives to favor generics by Government: <ul style="list-style-type: none"> New prescription pad formats, Increased dispensing fees for pharmacists if generics account for >30% of their sales Improvement of pharma industry image thanks to the Stable Supply agreement Ambition of Government to reach a market share of generics of 8% in 2015 	<ul style="list-style-type: none"> Strong IP protection Low consumer awareness of and trust in generics Physicians usually prescribing by brand Competition by cheap branded products Pricing policy is not very pro-generics (2 price cuts p.a.) Lack of consistent government policy towards generics 	M
Germany	<ul style="list-style-type: none"> High acceptance of generics (the largest generics market in Europe) Health reforms seeking to reduce pharmaceuticals costs (should further boost generics usage) Strong local manufacturing base 	<ul style="list-style-type: none"> Mandatory rebates and discounts apply to generics, placing pressure on manufacturers' margins Increasing price competition among generic manufacturers Greater competition from overseas manufacturers 	M
France	<ul style="list-style-type: none"> Government initiatives to increase: physicians prescription in INN, physicians prescription of generics and generics acceptance by patients High pharmacy substitution rate (economic benefit) Loss of patent protection for several blockbusters 	<ul style="list-style-type: none"> Increasing reluctance of patients towards prescription of generics and substitution for complex/severe diseases Physicians used to switch prescriptions of genericized products in favor of patented me-toos Regular price cuts over generics drugs Risk of reference price system extension 	M

H: High – M: Moderate – L: Low attractiveness, integrating impact on sales, and profits of generics players

Source: Espicom Business Intelligence 2011 – World Generics Market 2009-2024 (Visiongain) – The Pharma Letter (for India)– PharmaHandbook (IMS Health) - What Lures the Attention of Global Generic Drug Makers towards China? (Frost) - Smart Pharma Consulting analyses

2. Generics market structure & dynamics

Due to the limited size of the generics markets in Canada, the UK and the South Korea, their potential growth in absolute terms will remain relatively limited, by 2015



	Specific drivers	Specific limiters	Attractiveness
Canada	<ul style="list-style-type: none"> Relatively high generic prices (on average 30% more than the international median) Rich market, close to the USA Large, experienced local generics manufacturing sector Relatively new market for non-Canadian companies to enter 	<ul style="list-style-type: none"> Possibility of reforms aiming to reduce generic prices Decentralized reimbursement system (pricing and rebate rules set in a territory can be circumvented in other provinces) Patent law was tightened in 2003 and again in 2006 	L
UK	<ul style="list-style-type: none"> Generics prescribing is encouraged by Government Political and public willingness to accept generic versions of off-paten drugs is high The role of pharmacists in generics dispensation is increasing 	<ul style="list-style-type: none"> Generics prices have declined since 2005 A significant number of generic prescriptions are not dispensed as such (for example, 26% of all generics prescriptions in 2005 were dispensed as brands) High competition between generics manufacturers 	L
South Korea	<ul style="list-style-type: none"> Population is aging more rapidly than any other country with healthcare spending by those over 65 years old growing by 10% to 20% annually Increasing medical tourism Imminent patent expiries Expertise in product reformulation to produce super-generics and biosimilars Strong government support, both in terms of financing and policy development, for the domestic biosimilars industry 	<ul style="list-style-type: none"> Data exclusivity laws have tightened, inhibiting new product opportunities for generics producers Increasingly crowded domestic market Growing pressures on generic prices and margins 	L

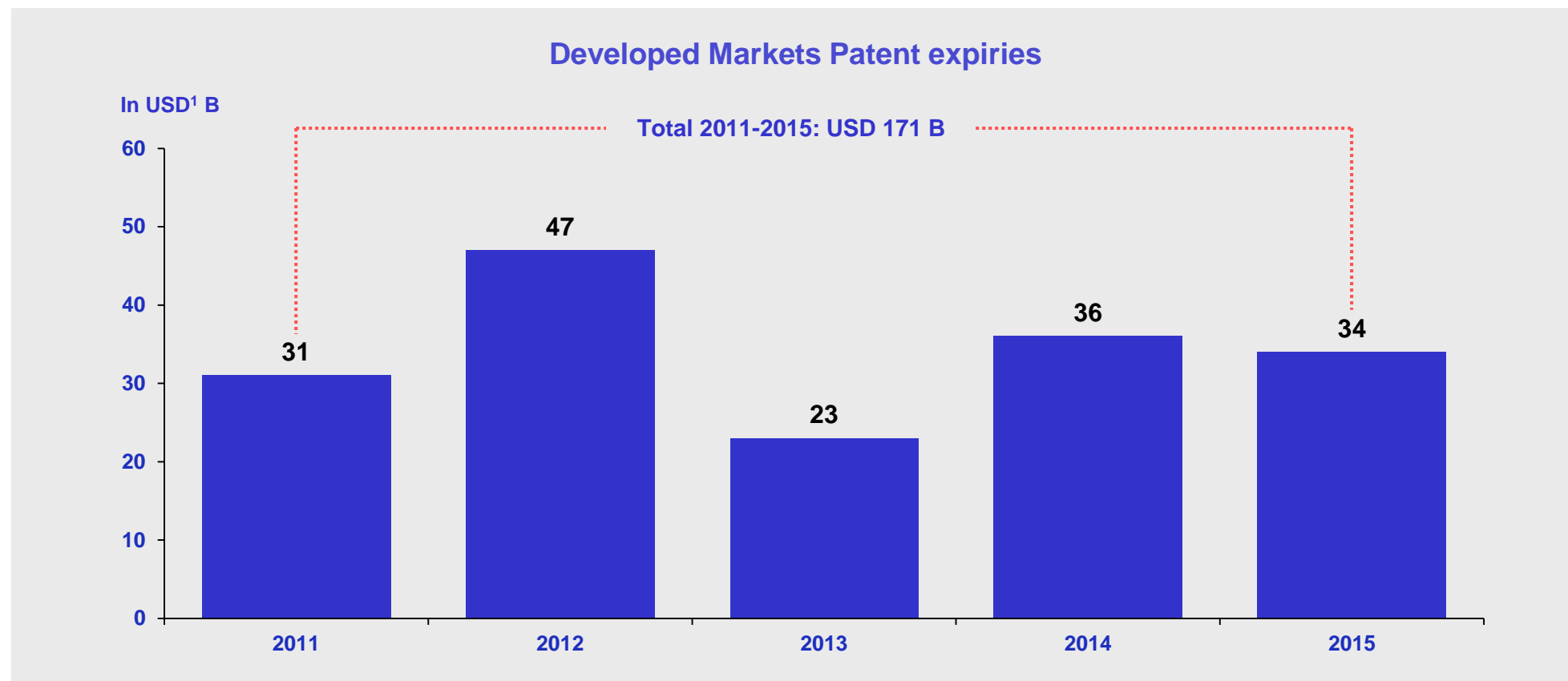
H: High – M: Moderate – L: Low attractiveness, integrating impact on sales, and profits of generics players

Source: Espicom Business Intelligence 2011 – World Generics Market 2009-2024 (Visiongain) - Smart Pharma Consulting analyses

2. Generics market structure & dynamics

2011-2015 will be key in generics development, as ethicals sales exposed to patent expiry are projected to total USD 171 B, including major brands such as Lipitor

DRIVERS → Value of patent expiries (2011-2015)



2. Generics market structure & dynamics

Biosimilars are expected to grow to USD 2.3 B and to represent a share of total biologicals of only 1.2% in 2015

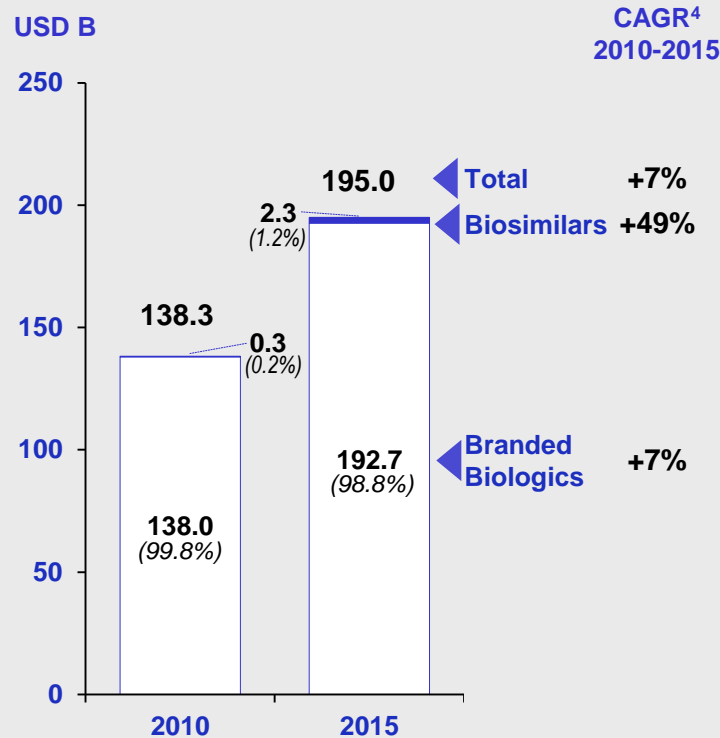


Biosimilar drugs offer

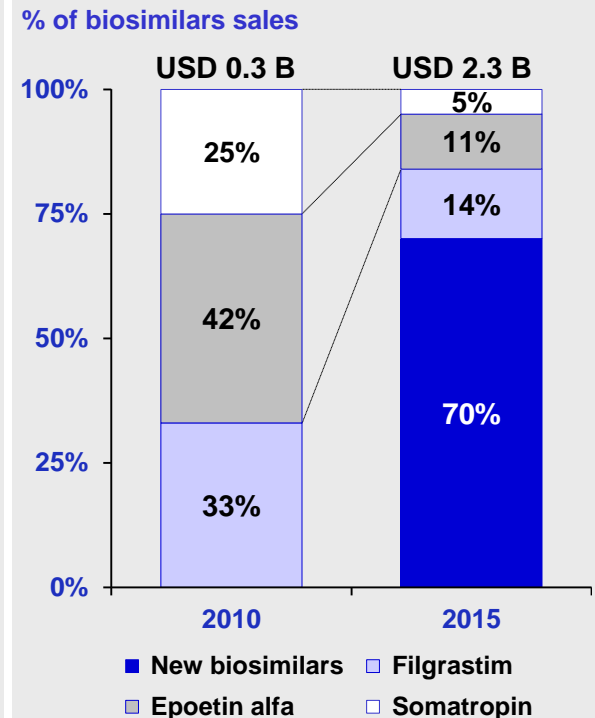
Context

- Biopharmaceuticals are defined by their production process, knowing that any change can impact their safety and efficacy profile
- Proof of bioequivalence in an abbreviated process is not accepted for “copies” of biopharmaceuticals which are named biosimilars
- Development timelines for biosimilars are not very different from new entity development, but the risk of failure is smaller¹
- EMA (European Medicines Agency) CHMP (Committee for Medicinal Products for Human Use) have released “final regulatory guidelines” for insulins, G-CSF², growth hormone and ESA³

Sales Forecast 2010-2015



Market share 2010-2015



Note: Patents of 37 drugs with cumulative sales of USD 55 B are due to expire between 2011 and 2015. New biosimilars would include: Insulin-Glargine (Lantus), Interferon alpha 2a (Roferon & Intron) in 2014, Interferon beta 1a (Avonex). 12 mAbs (mono-clonal antibodies) would also lose their patent protection

Source: IMS Institute for healthcare informatics - IMS Midas December 2010 - Pharmaceutiques, September 2009 - Smart Pharma Consulting analyses

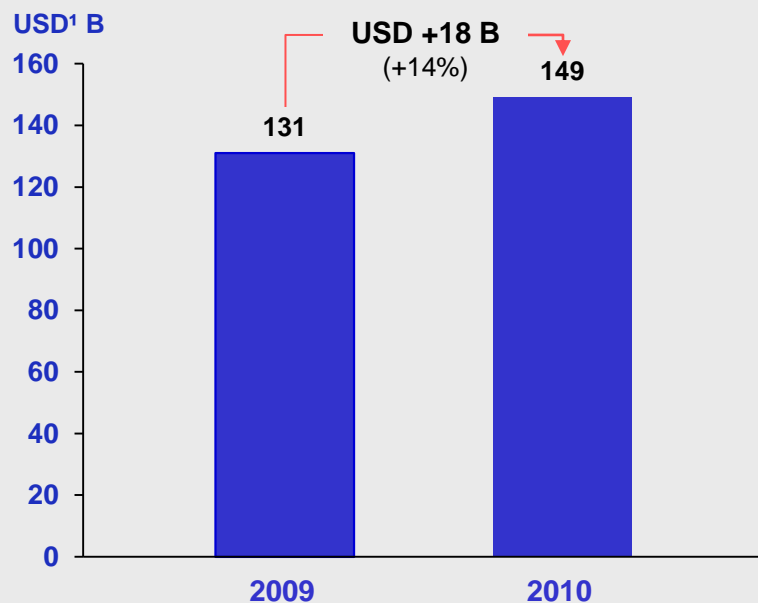
¹ Development costs estimated at \$ 100 to 150 M - ² Granulocyte-colony stimulating factors - ³ Erythropoiesis stimulating agents - ⁴ Compounded annual growth rate

3. Key generics players performance & strategies

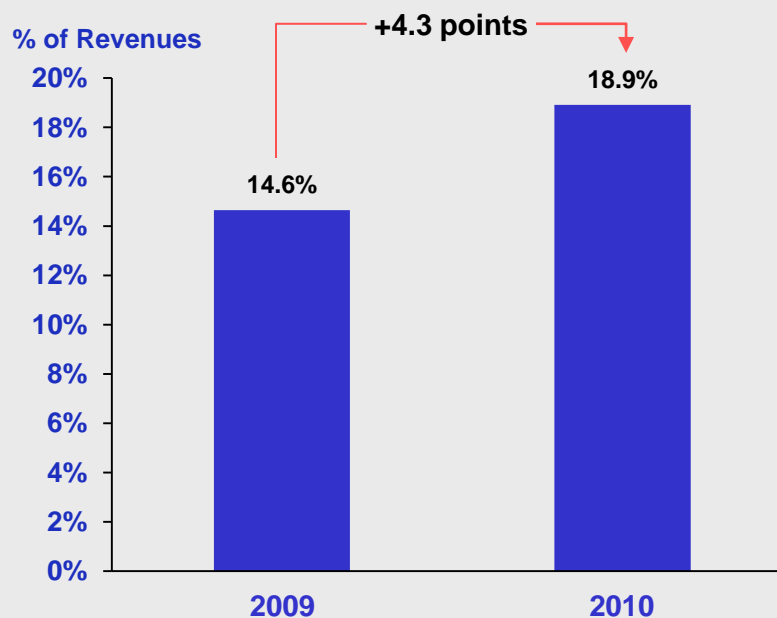
In 2010, the generics market registered 14% growth to reach \$149 Million, while the average profitability of generics companies grew from 15% in 2009 to 19% in 2010

Generics market performance dynamics (2009–2010)

Revenues



Weighted operating profitability (based on 20 leading generics companies²)



(Weighted operating profitability for 2008: 11.4%)

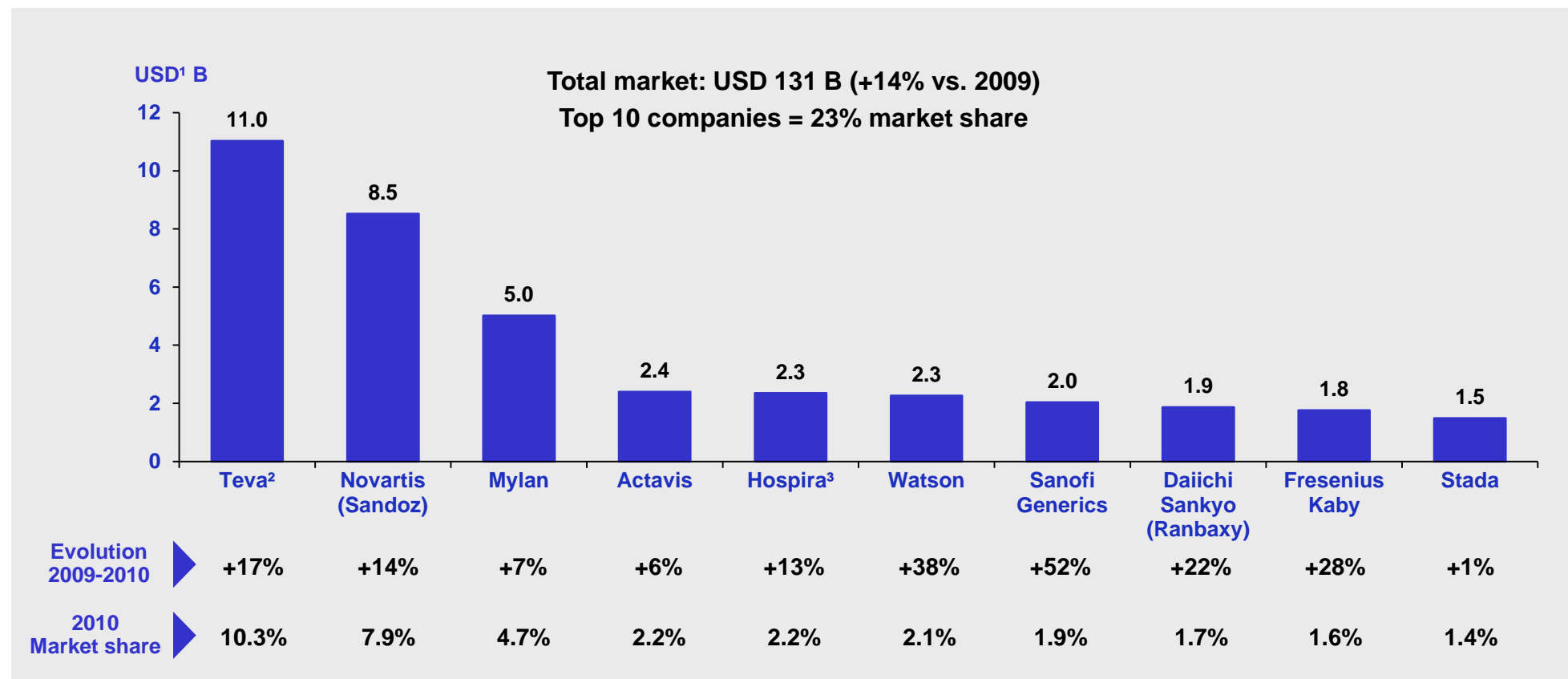
Source: Companies annual reports (2010) - Smart Pharma Consulting analyses

¹ Average 2010 Federal Reserve exchange rate - ² As per annual reports of the top 20 generics companies publishing annual reports

3. Key generics players performance & strategies

Despite recent M&A operations (e.g. Mylan-Merck Generics, Teva-Ratiopharm, Sanofi-Zentiva, Actavis-Alpharma, etc.), the generics market remains fragmented

Revenues of leading generics companies (2010)



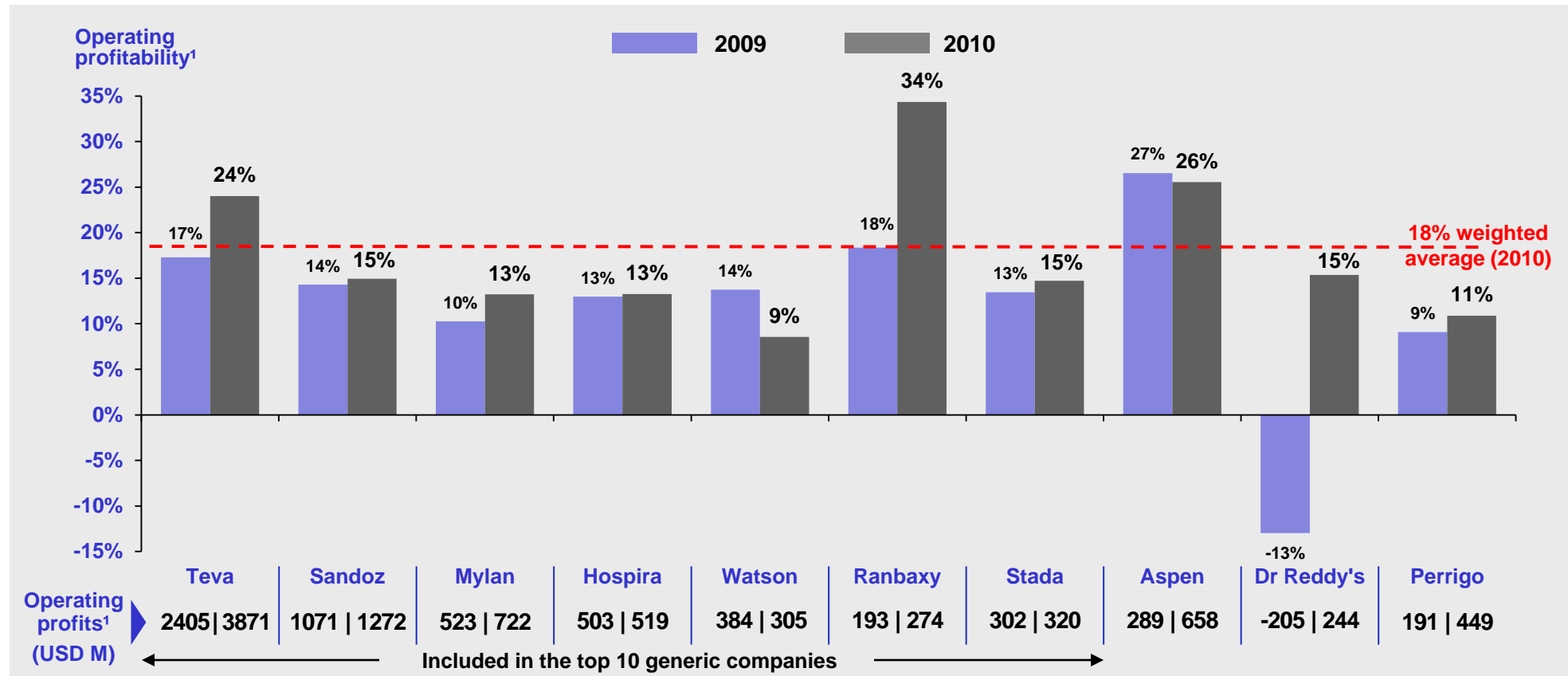
Source: Annual reports 2010 (for all companies but Actavis that is not publicly listed) - bloomberg.com and forexyard.com (Actavis) - IMS Health, MIDAS MAT December 2010 (total market) - Smart Pharma Consulting analyses

¹ Average 2010's USD exchange rates, as reported by the Federal Reserve - ² Generics sales only - ³ Including sales of Precedex (proprietary pharmaceutical)

3. Key generics players performance & strategies

The average operating profitability of leading generics companies was about 18% in 2010, but only three of them have managed to go past

Profitability and profit trends of 10 leading generics companies (2009–2010)



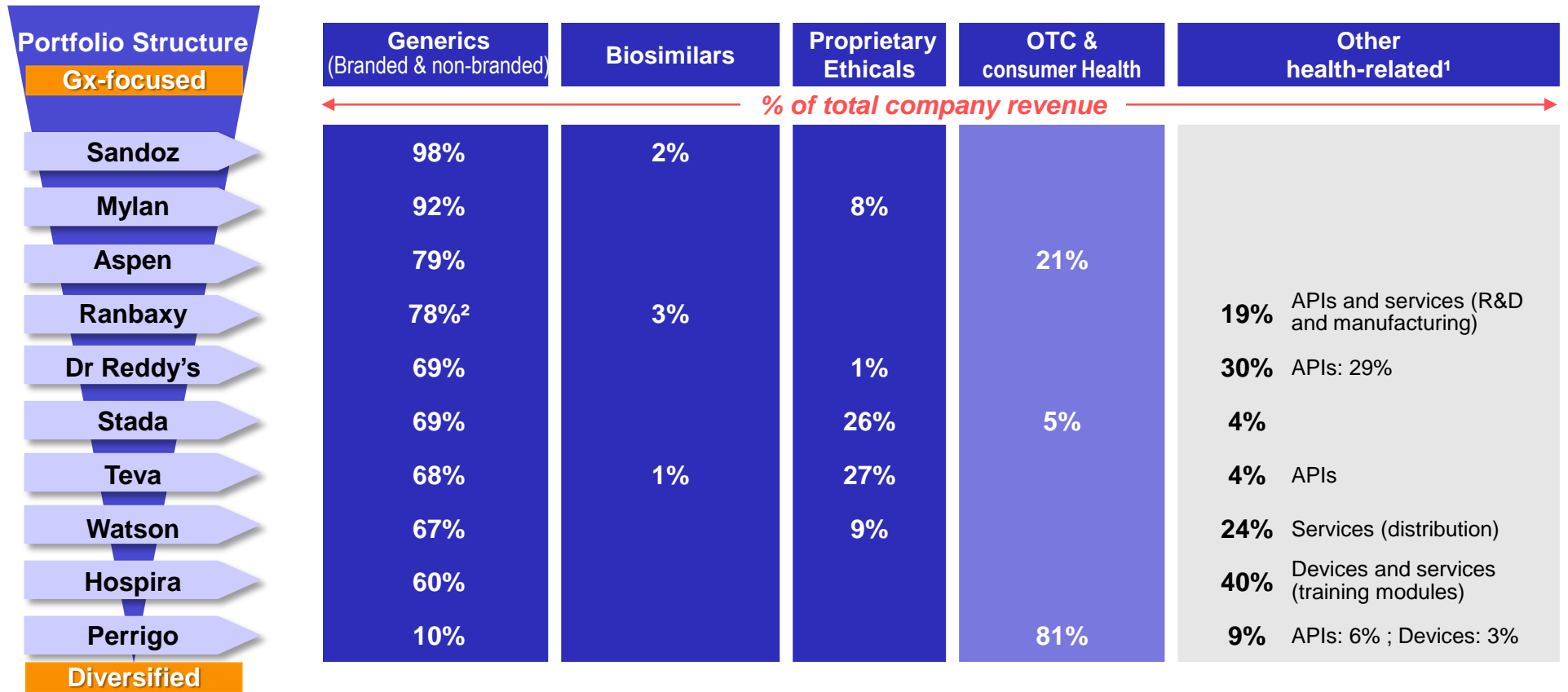
Source: Annual reports 2009-2010 (Exchange rates as at 31 December of each considered year) - Smart Pharma Consulting analyses

¹ Including profits from non-generics related businesses

3. Key generics players performance & strategies

Amongst the leading generics companies, only Sandoz and Mylan stay focused on generics, while others tend to develop hybrid business models to mitigate risks

Business structure of leading generics companies (2010)



Source: Annual reports 2010 - Smart Pharma Consulting analyses

¹ Includes APIs (Active Pharmaceutical Ingredients), devices, royalties, licensing fees, contract manufacturing etc.
² Estimates including undisclosed proprietary ethical sales which represent a minor share of pharmaceutical sales

4. Key challenges for generics players by 2015

Generics companies must develop strategies to increase their sources of revenues, prevent commoditization of their business, reinforce competitiveness and efficiency

Key challenges and strategic responses of generics companies

Key challenges	Strategic responses
<ul style="list-style-type: none">▪ Increase revenues through geographical expansion	<ul style="list-style-type: none">▪ Footholds in new markets through affiliates establishment, acquisitions or partnerships
<ul style="list-style-type: none">▪ Increase revenues through market share development	<ul style="list-style-type: none">▪ Broader portfolio: more products and wider business coverage▪ More attractive offer in terms of prices, quality and related services
<ul style="list-style-type: none">▪ Anticipate the future dearth of patent expiries	<ul style="list-style-type: none">▪ Business diversification (proprietary drugs, OTCs, contract manufacturing, etc.)
<ul style="list-style-type: none">▪ Increase revenues through higher value products	<ul style="list-style-type: none">▪ Development of complex generics and biosimilars
<ul style="list-style-type: none">▪ Strengthen competitive advantages	<ul style="list-style-type: none">▪ First to file¹ / first to market competencies▪ Development of innovative, and differentiated generics (e.g. branding strategy)
<ul style="list-style-type: none">▪ Drive profitability through operational efficiency	<ul style="list-style-type: none">▪ Vertical integration▪ Costs reduction, synergies and economies of scale▪ Elimination of non-strategic assets

5. Key strategic options for generics players

Rationales for M&As vary from acquisition of a product portfolio in other therapeutic areas to the development of activities in other geographical markets

Rationale for M&As in the generics market segment

Rationales	Examples
<ul style="list-style-type: none">▪ Broaden portfolio or pipeline with products in other business segments (proprietary ethicals, OTC, biosimilars, etc...) or in other therapeutic areas	<ul style="list-style-type: none">▪ Sandoz acquisition of Oriel which has broadened its portfolio with generic respiratory products▪ Hospira broadening its portfolio with Orchid's generic injectables
<ul style="list-style-type: none">▪ Strengthen of leading positions in some strategic segments or therapeutic areas	<ul style="list-style-type: none">▪ Watson acquisition of Andrx (patented sustained-release drug delivery technologies and solid pipeline of difficult-to-replicate generic products) to strengthen and broaden product portfolio
<ul style="list-style-type: none">▪ Get a foothold in new geographical markets	<ul style="list-style-type: none">▪ Watson acquisition of Arrow to enter in Europe▪ Teva acquisition of Ratiopharm to reinforce its presence in Europe and especially in Germany
<ul style="list-style-type: none">▪ Acquire manufacturing capabilities	<ul style="list-style-type: none">▪ Mylan acquisition of Matrix in India▪ Acquisition of Eden Biodesign by Watson, offering expertise and capabilities in biotherapeutics manufacturing

Source: Smart Pharma Consulting analyses

5. Key strategic options for generics players

M&A operations lead to improvement of competitive positions through a broader product portfolio and/or a wider geographical coverage, while mitigating risks

Major Merger & Acquisitions operations (2008–2011)

Acquirer	Acquired	Strategic objectives ¹			
		Portfolio diversification	Strengthening	Geographical expansion	API manufacturing
Teva	<ul style="list-style-type: none"> ▪ Cephalon (Oncology & CNS) ▪ Barr (USA & Eastern Europe) ▪ Ratiopharm (Europe) 	✓	✓	✓ ✓	
Sandoz	<ul style="list-style-type: none"> ▪ Oriel (Generic respiratory products) ▪ Ebewe (Generic injectables) 	✓ ✓			
Mylan	<ul style="list-style-type: none"> ▪ Bioniche (Generic injectables) ▪ Matrix (API) 	✓			✓
Hospira	<ul style="list-style-type: none"> ▪ Orchid (Generic injectables) 	✓			
Watson	<ul style="list-style-type: none"> ▪ Andrx (Generic drug maker) ▪ Specifar (generic development, Europe) ▪ Eden Biodesign (Biomanufacturing) ▪ Arrow (Europe) 	✓	✓ ✓	✓ ✓	✓
Perrigo	<ul style="list-style-type: none"> ▪ Paddock Labs (Generics) ▪ PBM Holding (Infant formula manufacturing) 	✓	✓		
Stada	(No major acquisition)				
Ranbaxy	(No major acquisition)				
Dr Reddy's	<ul style="list-style-type: none"> ▪ BASF's pharmaceutical contract manufacturing business 				✓
Aspen	<ul style="list-style-type: none"> ▪ Sigma's pharmaceutical business (branded, generics & OTC products, Australia) 	✓		✓	

Sources: Pharma Deals Review - Companies' press releases and financial information - <http://knol.google.com> - Smart Pharma Consulting analyses

¹ Diversification means entering new strategic segments/balancing minor segments; Strengthening corresponds to reinforcing major strategic segments; Expansion stands for geographical diversification

5. Key strategic options for generics players

The main strategic priorities of leading generics companies are to strengthen their positions, to make strategic deals and improve their operational efficiency

Strategic statements (2010–2011)

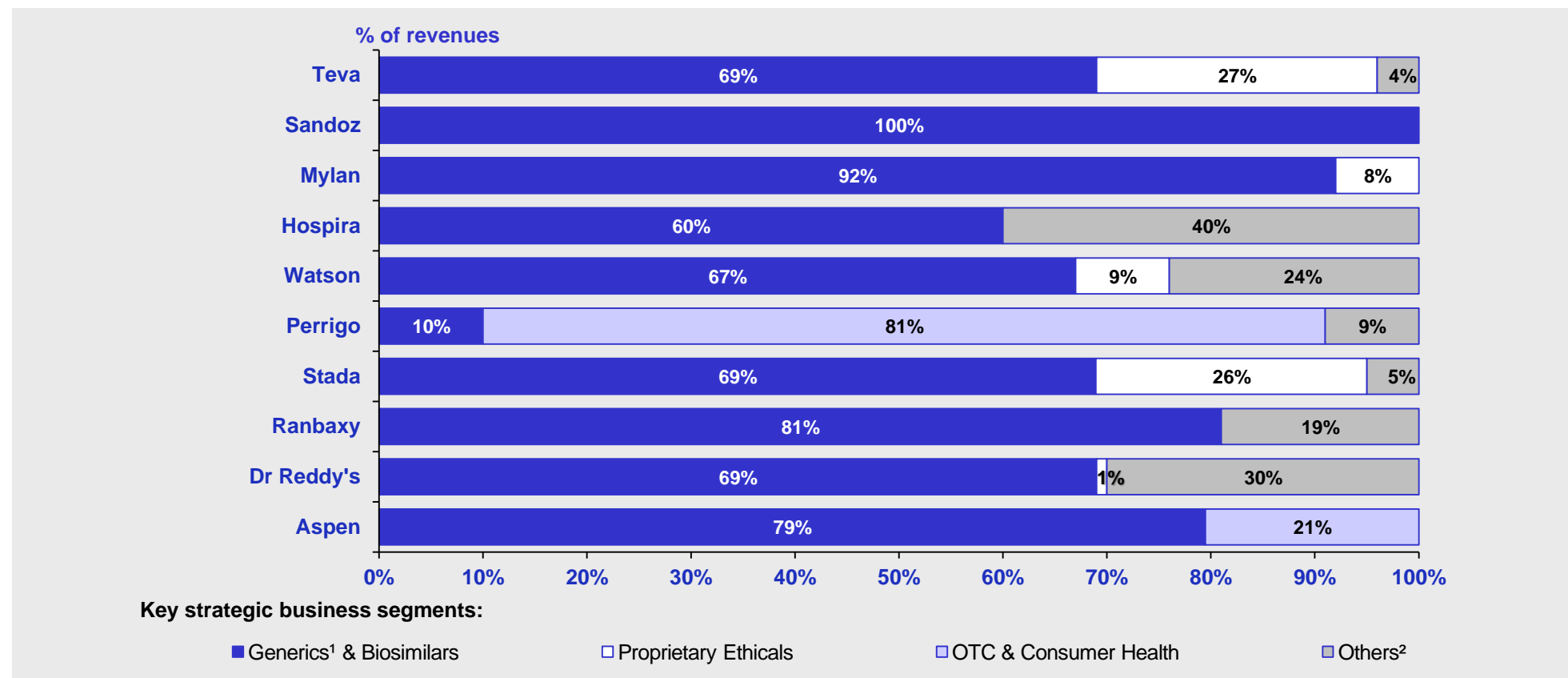
Strategic priority	Teva	Sandoz	Mylan	Hospira	Watson	Perrigo	Stada	Ranbaxy	Dr Reddy's	Aspen	TOTAL
Leading positions strengthening	✓	✓	✓	✓				✓		✓	6
Market Share Expansion	✓				✓					✓	3
Geographical Expansion					✓	✓				✓	3
Diversification through proprietary drugs	✓							✓			2
Diversification through biosimilars	✓	✓		✓	✓			✓			5
Strategic deals and acquisitions	✓		✓		✓	✓	✓		✓		6
“First to market” strategy and regulatory breakthroughs	✓	✓									2
Cost reduction & operational efficiency	✓		✓	✓				✓	✓	✓	6
Non-strategic assets elimination				✓							1

Source: Companies annual reports (2010) - Smart Pharma Consulting analyses

5. Key strategic options for generics players

Each generics company has developed its own diversification profile regarding business segment coverage...

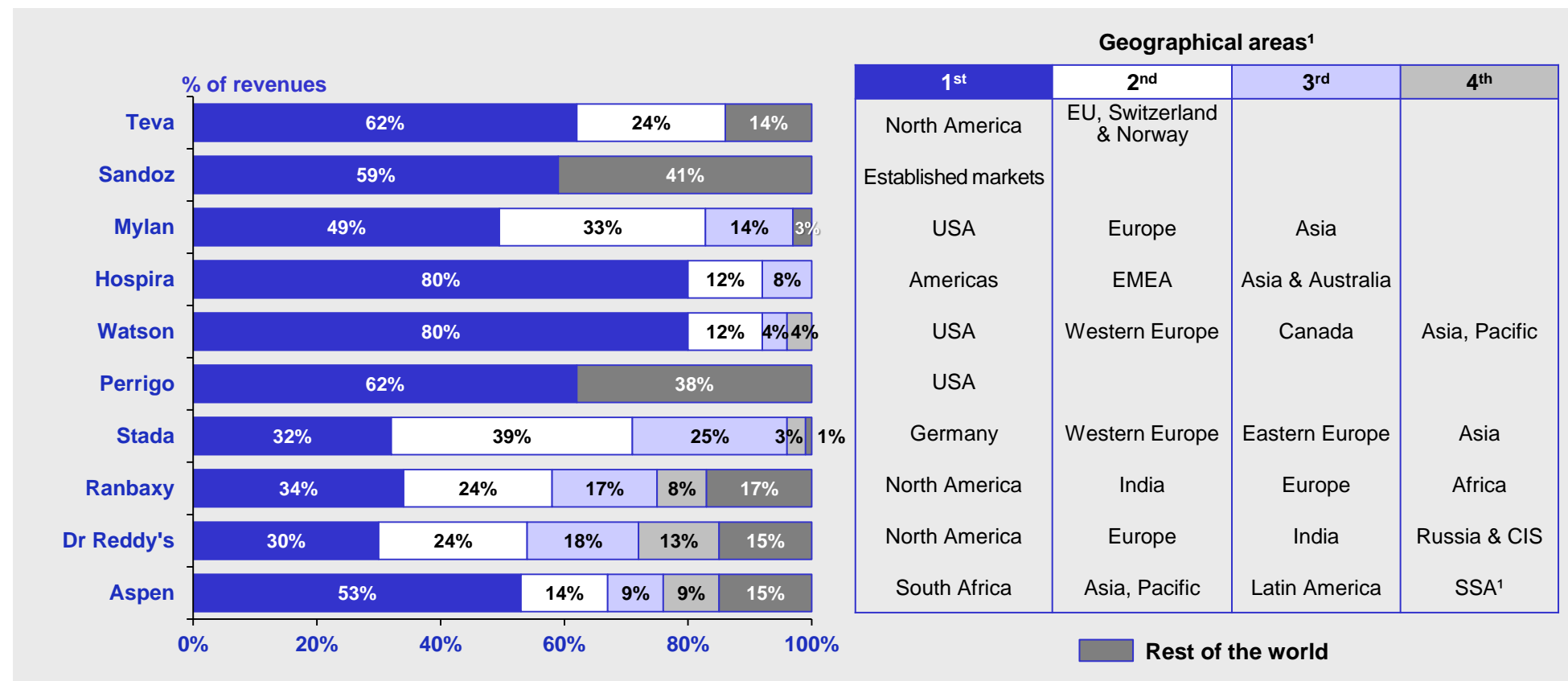
– Strategic orientations of leading generics companies (2010) – Strategic segment coverage –



5. Key strategic options for generics players

.... and also regarding geographical coverage

— Strategic orientations of leading generics companies (2010) – Geographical coverage —



Source: Companies annual reports (2010) - Smart Pharma Consulting analyses

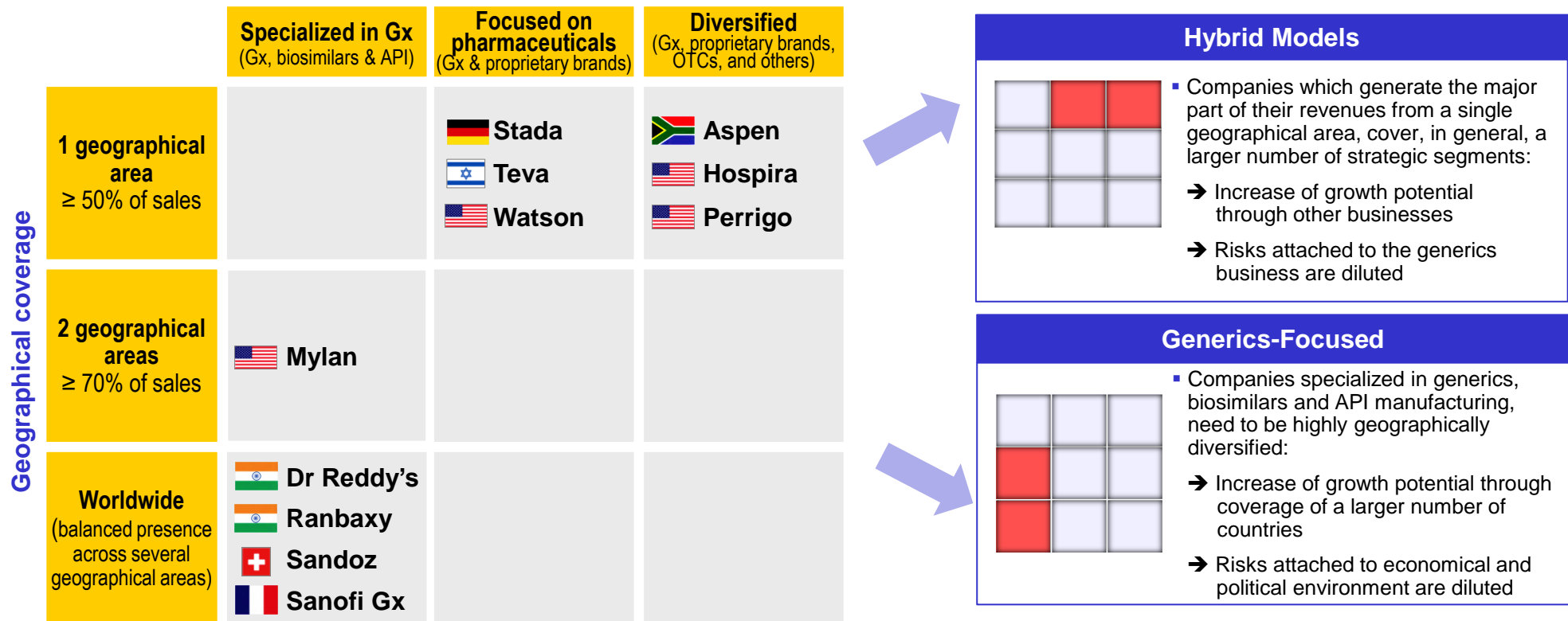
¹ Geographical segmentation as published in annual reports – ² Sub-Saharan Africa

5. Key strategic options for generics players

Among the generics leaders, there are basically two business models based either on business diversification or on geographical expansion

Generics companies strategic models (2010)

Strategic segments coverage



Specialized in Gx: Generics, Biosimilars and API sales ≥ 90% of total product sales

Geographically focused: >50% of sales in a single geographical region (e.g. USA, Europe, Japan, Asia, etc.)

6. Conclusions

Key learning for generics companies

- The generics development is driven by the growing need – in each country – to contain healthcare expenditure, but limited by the saturation of generics penetration and a decrease of patent expiries
- By 2015, the global generics market is expected to increase by a CAGR¹ of 11% (vs. +5% for the total pharmaceutical market) to reach \$248 billion
- USA, China, Brazil and India would offer the highest growth potential for generics (with USA remaining the largest and the most dynamic generics market in value)
- The current weighted average profitability of generics leaders is about 18% but could be affected by the increasing competition and new health authorities measures aiming to reduce prices
- One of the strategic response to avoid profitability erosion could be to develop more differentiated products like complex generics and biosimilars, which could offer higher value with lower competition
- With only 36% market share concentrated by ten leading players, the generics market appears to be fragmented and offers opportunities for M&A operations
- M&A operations have to be considered as a way to reinforce competitive position by focusing on current activities or geographical markets, or on the contrary, by diversifying activities in non generics-related businesses and/or by expanding geographical coverage to mitigate risks