



## *BIOTECHNOLOGY IN EUROPE: KEY TRENDS*

Eva Edery, Senior Principal, IMS Health Global Pharma Strategy

EGA Symposium on Biosimilars, London, May 2007



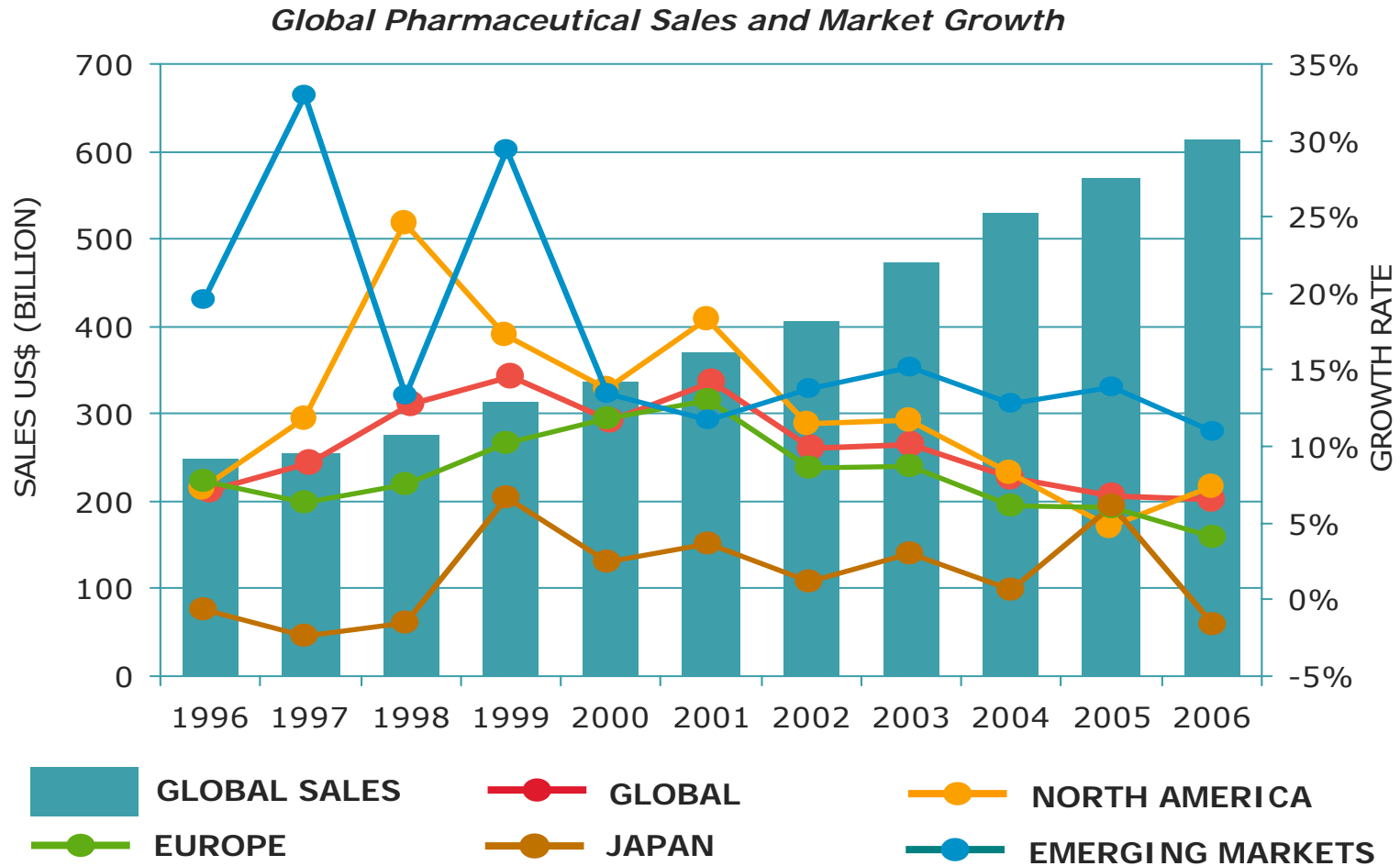


## Global pharmaceutical trends

- Biotech market dynamics
- Future Outlook

# The global pharmaceutical market stabilizes in 2006 with 6.5% growth

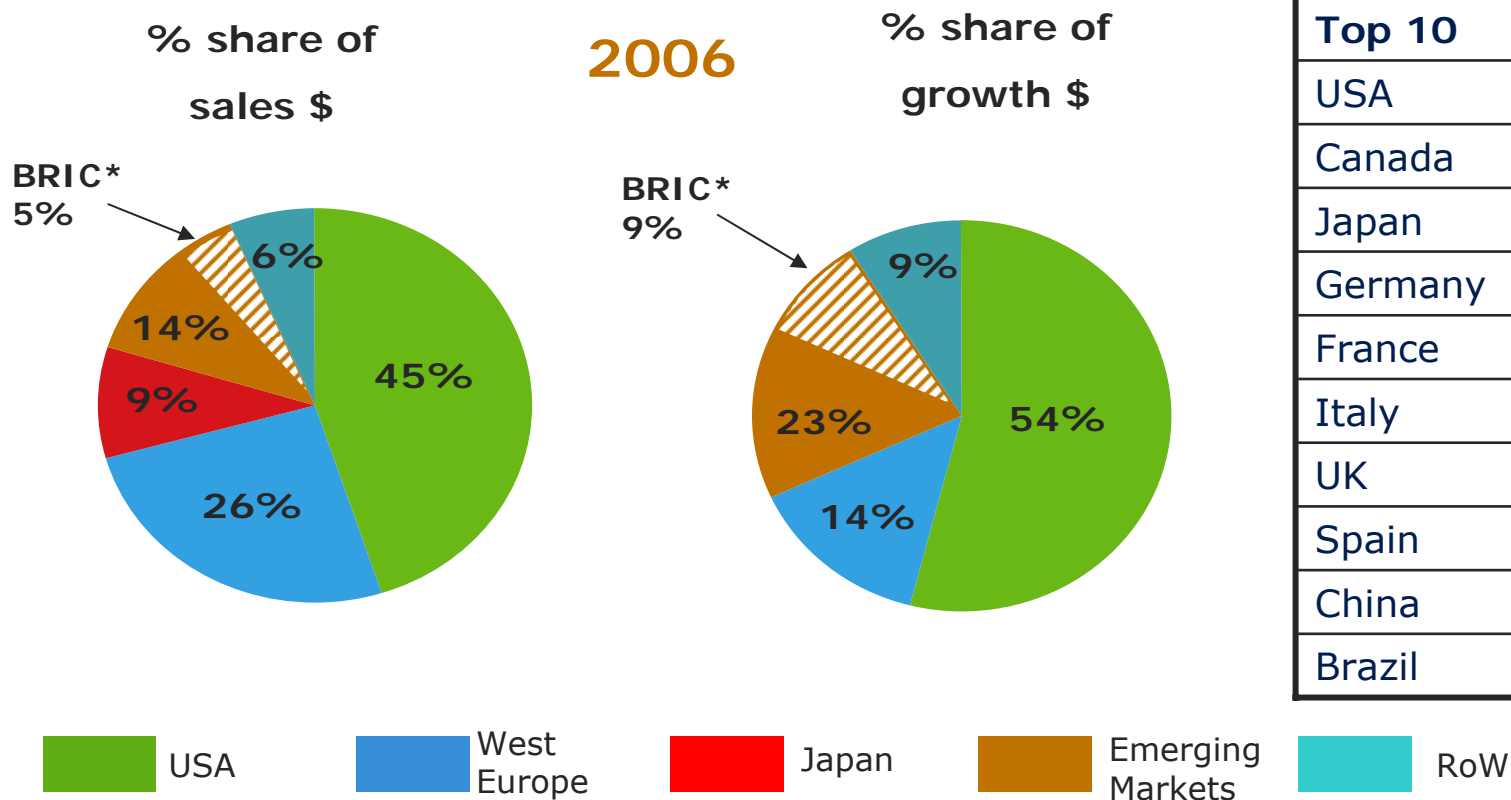
USA uplift benefits global growth; Europe slows down



Source: IMS Health MIDAS MAT December 2006

# Growth and sales dependent on USA and emerging markets

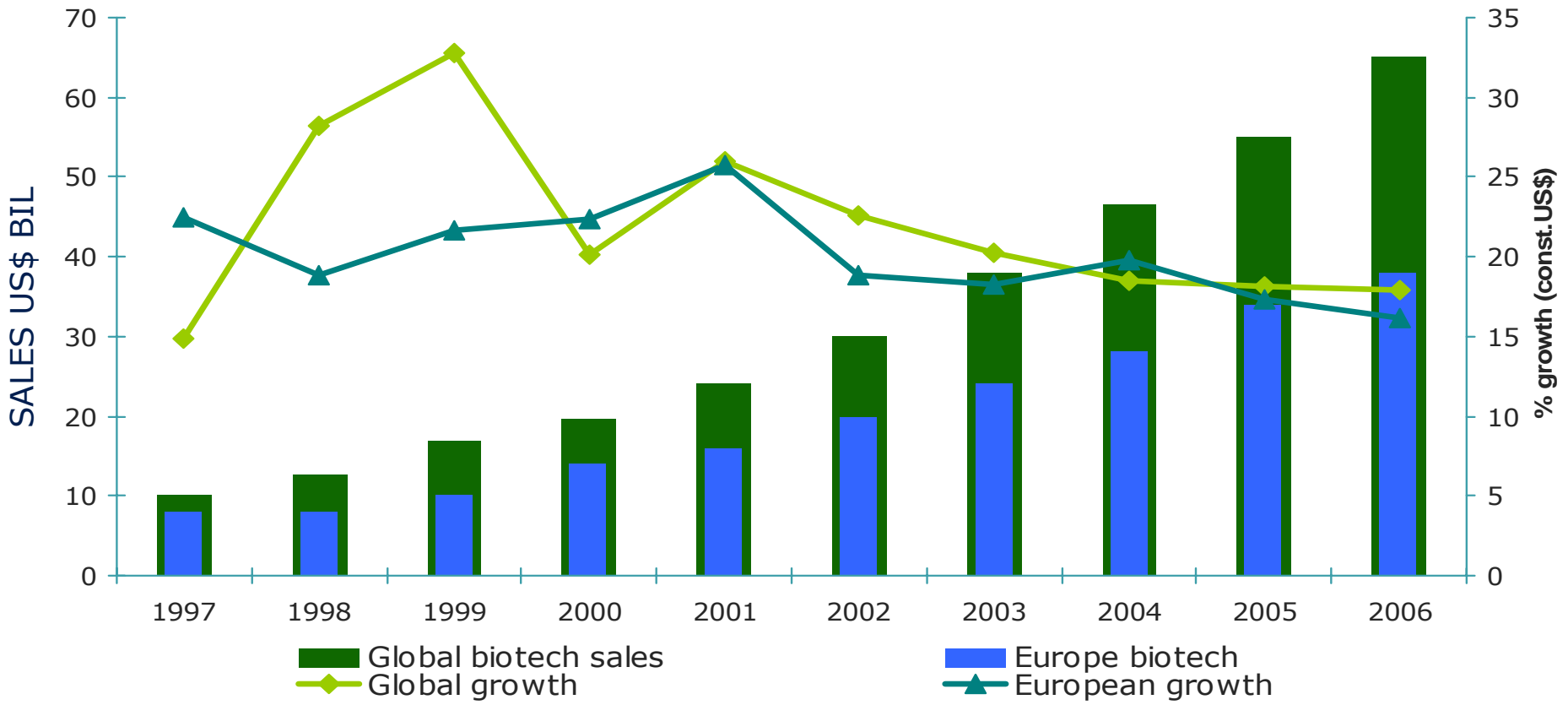
Top 5 Europe struggling; Japan suffers from biannual cut



Source: IMS Health: MIDAS, MAT Dec 2006. (\*) BRIC: Brazil/Russia/India/China



# Global biotech sales reach US\$65B but growth moderates to 18%-European growth slowing down

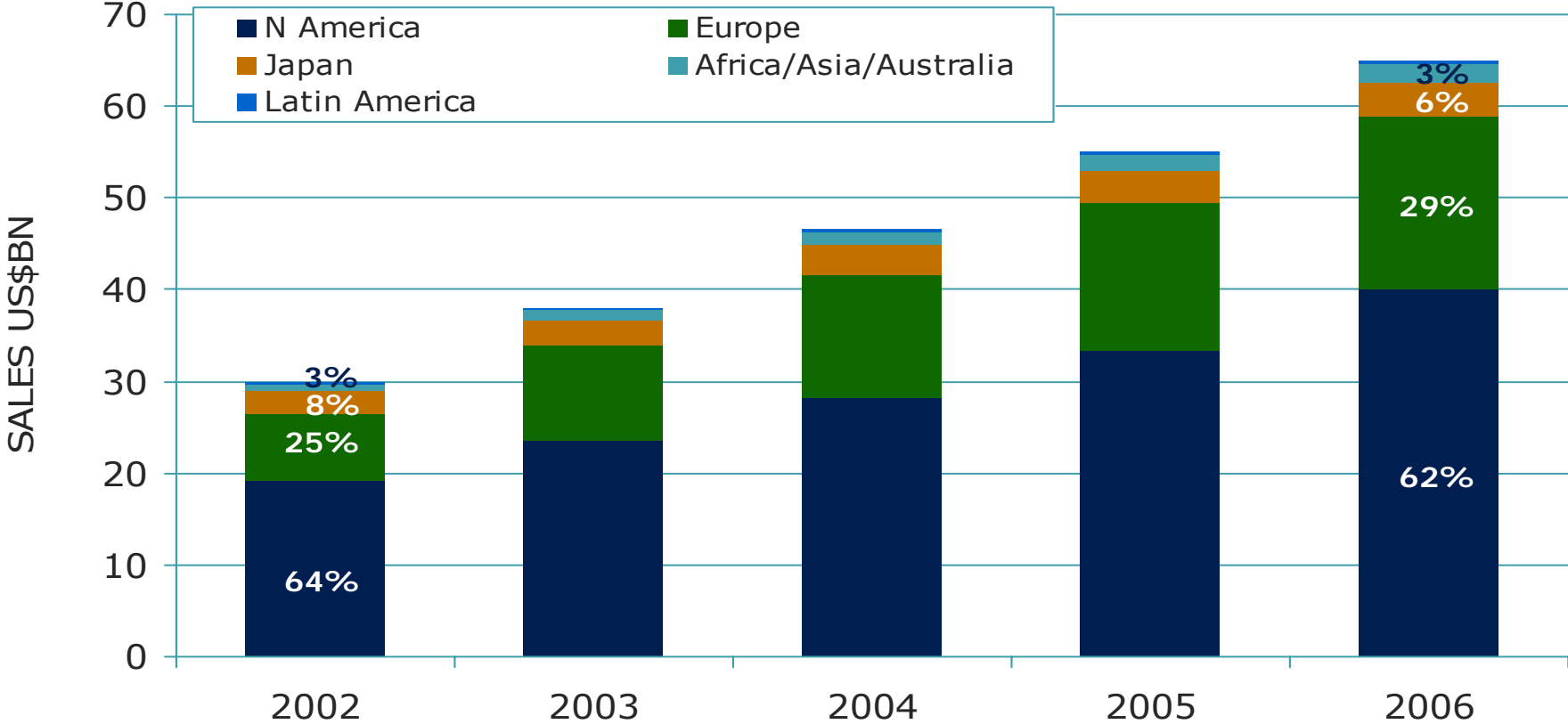


Source: IMS Health: MIDAS, MAT Dec 2006



# North America dominates biotech sales

## Europe increases its share

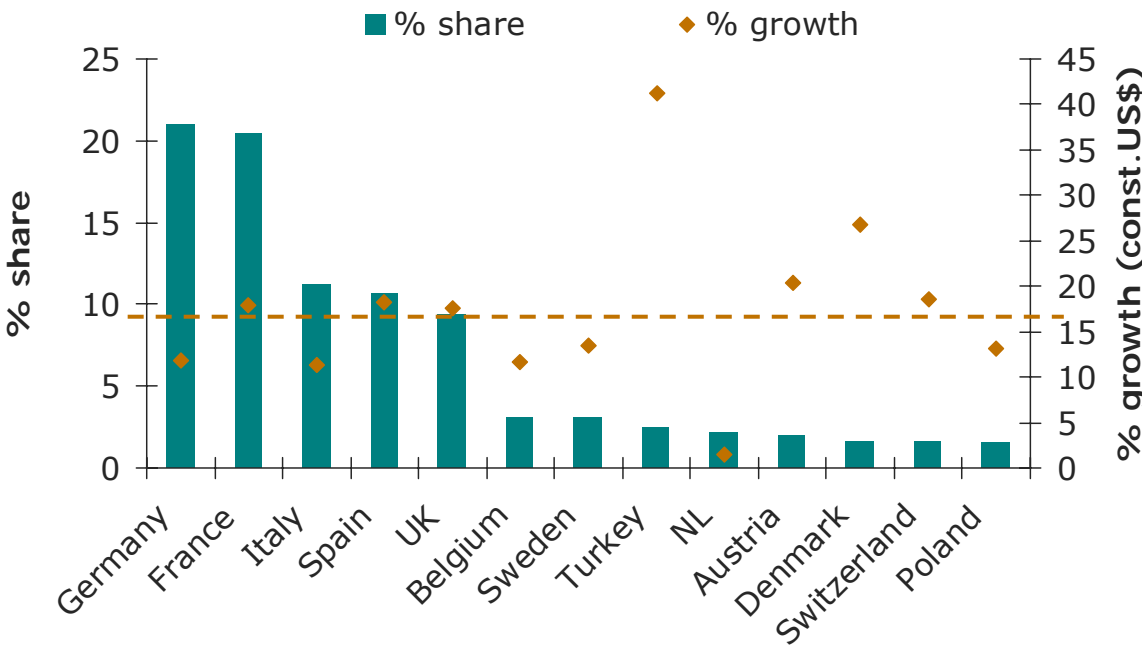


Source: IMS Health, MIDAS, MAT Dec 2006

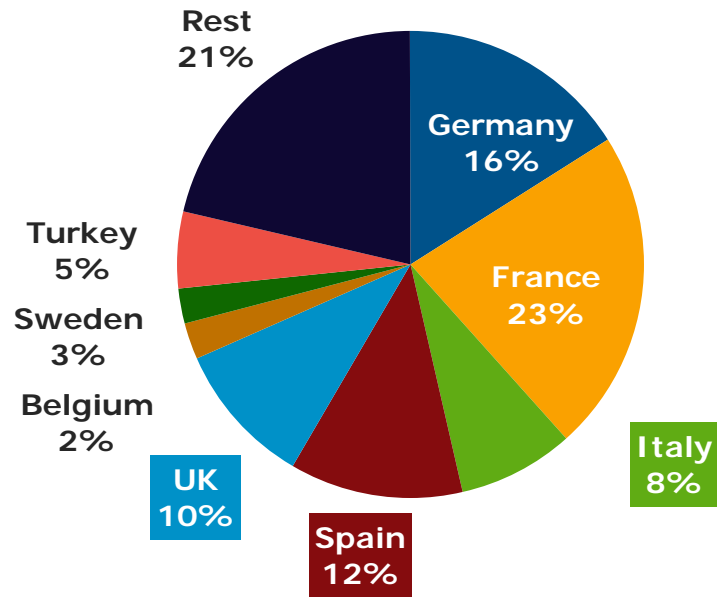
# Europe biotech sales and growth highly reliant on top 5 EU

## Germany & Italy underperforming the market

European biotech sales:  
Sales and growth by country (US\$)



% Regional contribution  
(const. US\$)

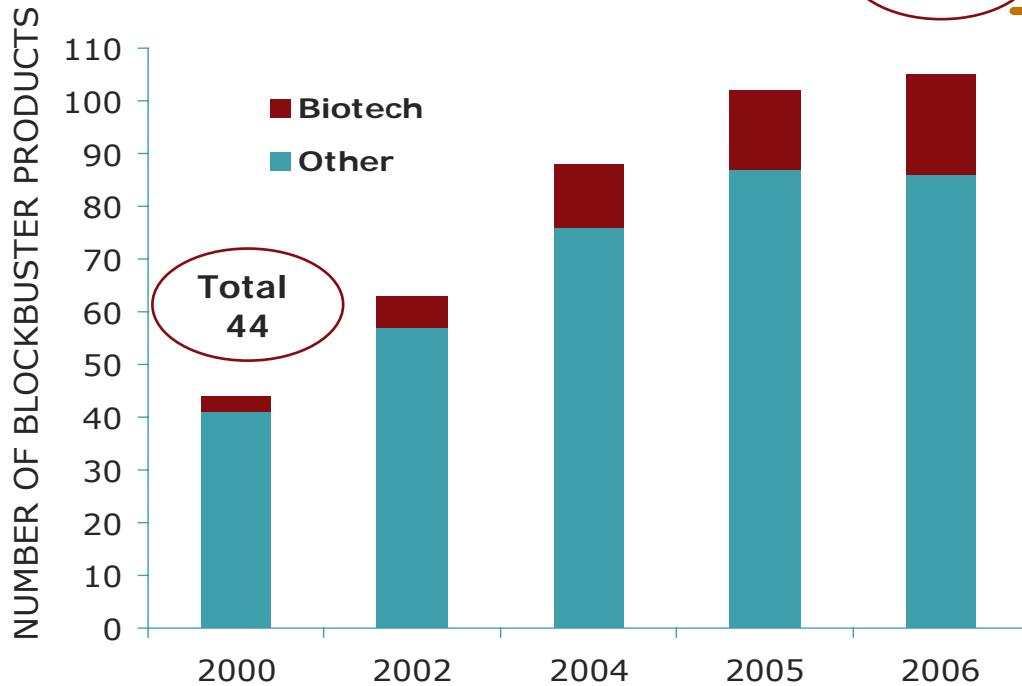


Source: IMS Health, MIDAS, MAT Dec 2006



# 20% of global blockbusters from biotech

Over 40% of biotech blockbuster volume sales from Europe



19 Biotech Blockbusters	US\$bn
Aranesp (Amgen)	5.0
Enbrel (Amgen/Wyeth)	4.5
Erypo/Procrit (J&J)	3.7
Remicade (J&J/SP)	3.6
Neulasta (Amgen)	3.2
Mabthera/Rituxan (Roche)	3.2
Epogen (Amgen)	3.1
Herceptin (Roche)	2.5
Lantus (Sanofi-Aventis)	2.0
Avastin (Roche)	2.0
Humira (Abbott)	1.8
Avonex (Biogen Idec)	1.7
Neorecormon (Roche)	1.5
Neupogen (Amgen)	1.4
Rebif (Serono)	1.3
Novorapid (Novo Nordisk)	1.0
Humalog (Lilly)	1.0
Betaferon (Bayer/Schering AG)	1.0
Synagis (Abbott)	1.0

Source: IMS Health, MIDAS, MAT Dec 2006



# Agenda

- Global pharmaceutical trends

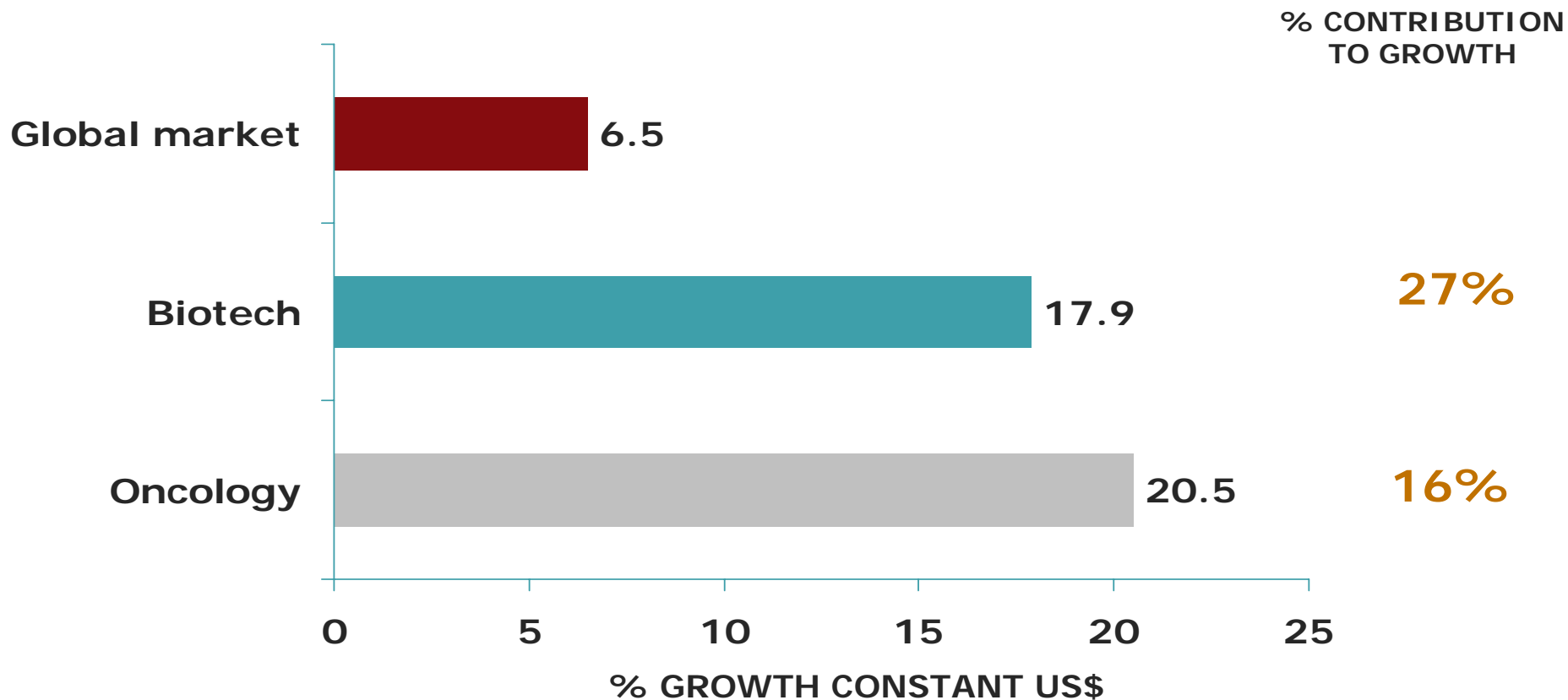


## Biotech market dynamics

- Future Outlook



# Biotech driving nearly a third of global growth

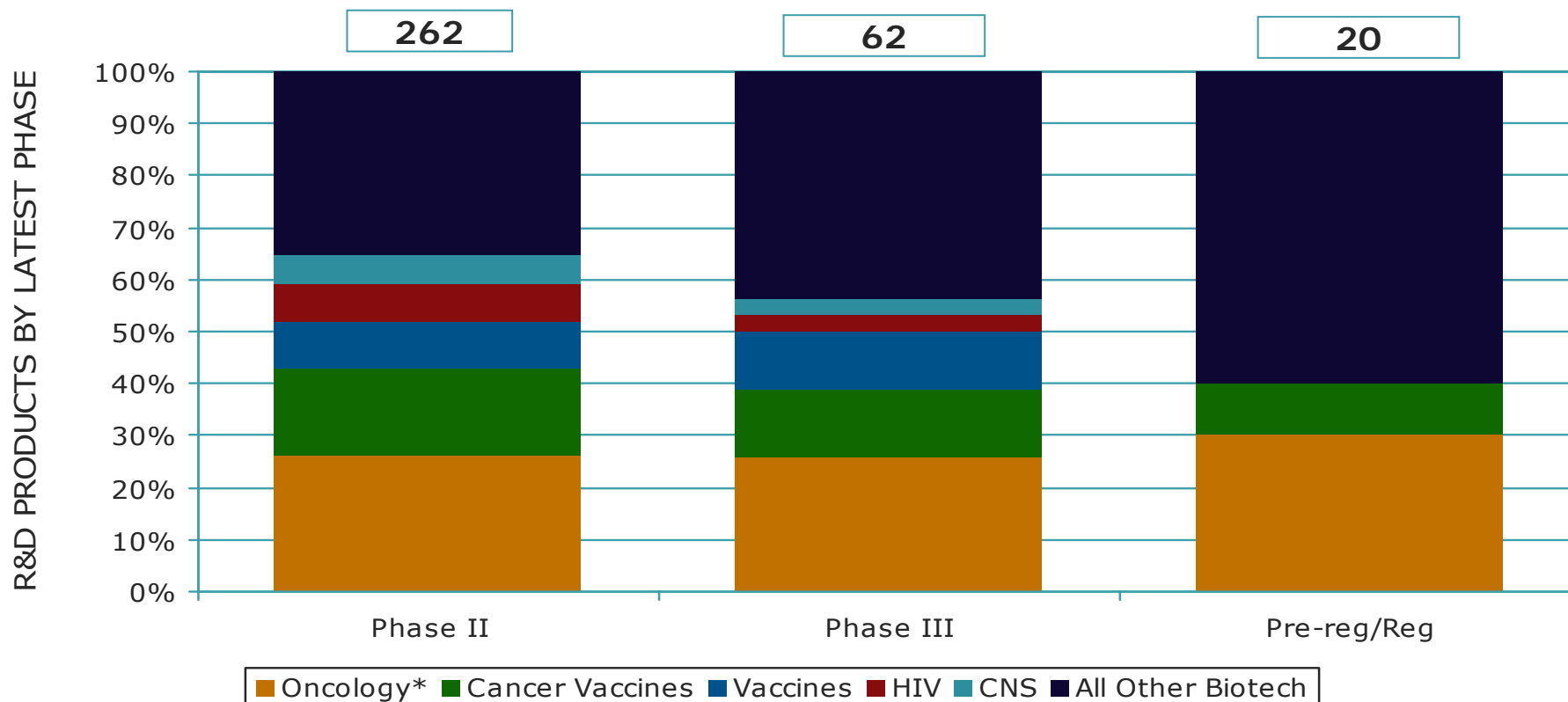


Source: IMS Health, MIDAS, MAT Dec 2006

# And a third of pipeline projects come from biotech

## Oncology is the largest area

### Biotech pipeline by therapy area



Source: IMS Lifecycle R&D Focus Dec 2006; Oncology is L1&L2, Cancer vaccines are vaccines with cancer indications



# Highly concentrated market among top 10 corps

## Underperformance for half of key players

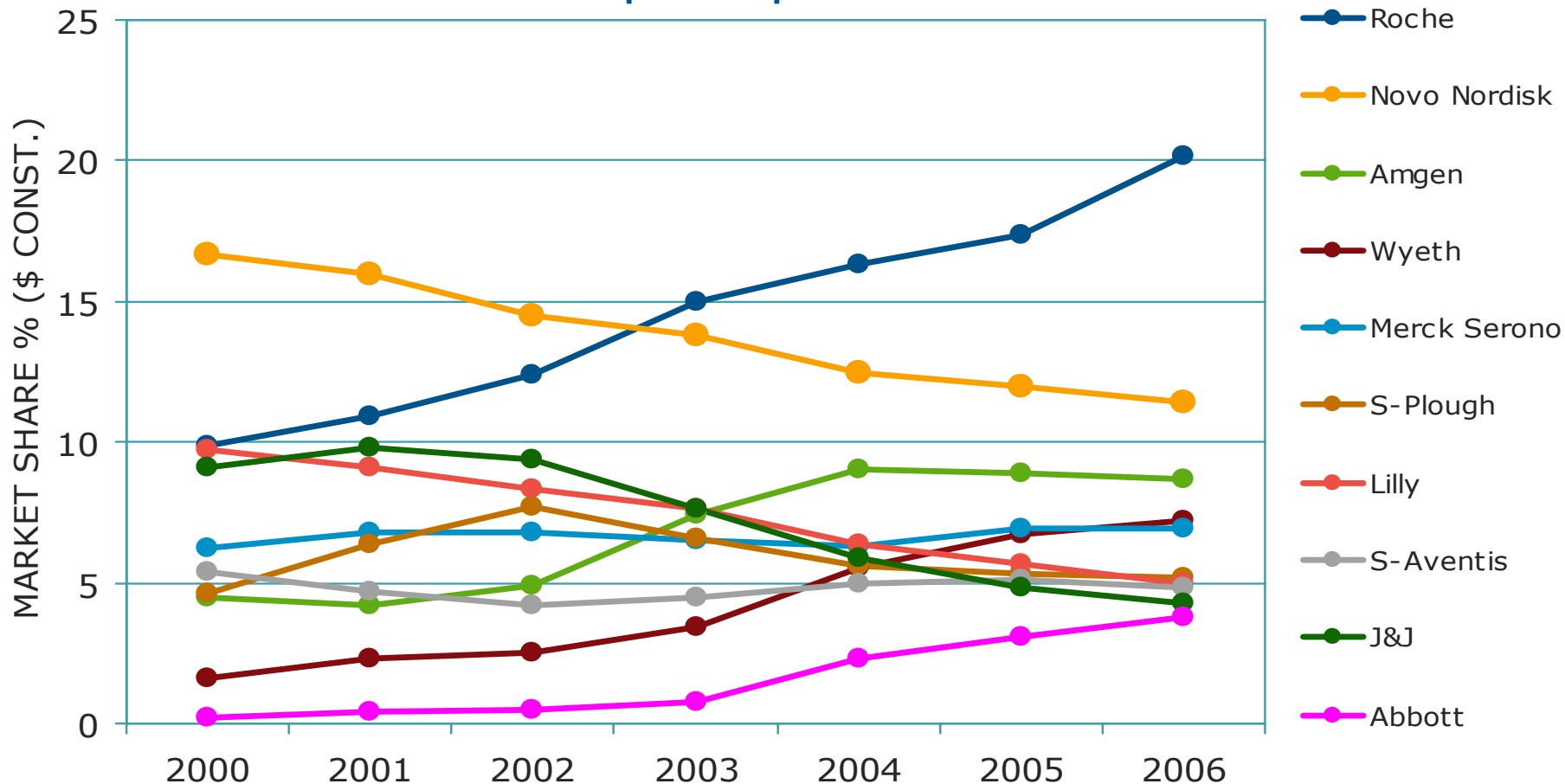
Rank	US\$m MAT Dec 2006	% Market Share 2006	% Growth Constant US\$	
			2006	CAGR 01-05
<b>Global Biotech Market</b>	<b>65,023</b>	<b>100.0</b>	<b>17.9</b>	<b>19.8</b>
1 Amgen	15,825	24.3	19.9	29.8
2 Roche/Genentech	12,498	19.2	35.5	32.8
3 Johnson & Johnson	6,416	9.9	0.9	9.8
4 Novo Nordisk	4,966	7.6	15.4	16.5
5 Lilly	3,575	5.5	0.5	6.9
6 Sanofi-Aventis	2,327	3.6	23.8	43.4
7 Abbott	2,076	3.2	42.0	126.5
8 Serono	1,974	3.0	10.9	15.6
9 Schering Plough	1,878	2.9	11.6	4.2
10 Wyeth	1,796	2.8	24.0	35.4
<b>Top 10</b>	<b>53,330</b>	<b>82.0</b>	<b>18.8</b>	<b>21.8</b>

Source: IMS Health, MIDAS, MAT Dec 2006

# Europe: Roche continues steaming ahead driven by oncology franchise

Diabetes players losing ground

Biotech: Top 10 corps = 77% share



Source: IMS Health MIDAS December 2006.



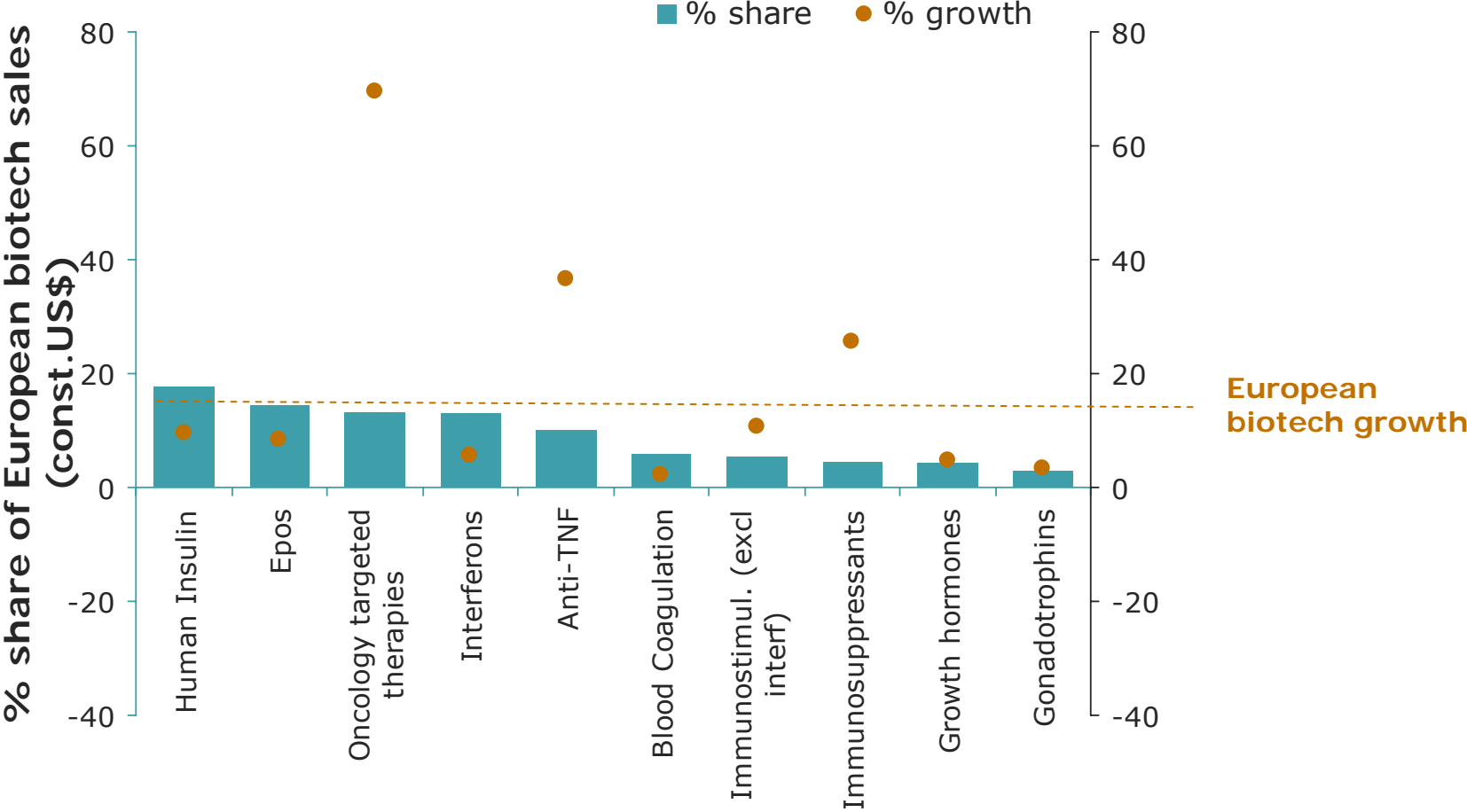
# Global: Oncology and anti-TNF key drivers of growth

Top 10 Therapy Classes	US\$m	% Market Share 2006	% Growth Constant US\$	Const US\$ CAGR 01-05
Global Biotech Market	65,023	100.0	17.9	19.8
B3C Erythropoietin Products	13,896	21.4	11.8	14.9
L1X All Other Anti-neoplastics	8,927	13.7	51.4	49.1
A10C Human Insulin+Analogues	8,618	13.3	14.5	15.6
M1C Spec Anti-rheumatic Agent	6,461	9.9	26.9	54.8
L3B Interferons	6,314	9.7	7.8	13.5
L3A Immunostim Ag Ex Intfron	5,622	8.6	15.4	18.4
L4A Immunosuppressive Agents	3,689	5.7	18.0	32.6
H4C Growth Hormones	2,250	3.5	3.2	9.6
B2D Blood Coagulation	2,179	3.4	3.9	19.1
G3G Gonadotrophins	971	1.5	10.9	4.9
<b>Total top 10</b>	<b>58,927</b>	<b>90.6</b>	<b>18.0</b>	<b>20.4</b>

Source: IMS Health, MIDAS, MAT Dec 2006

# Europe: oncology targeted therapies; anti-TNF and immunosuppressants drive growth

Insulins and EPOs hold a third of sales:key targets for biosimilars

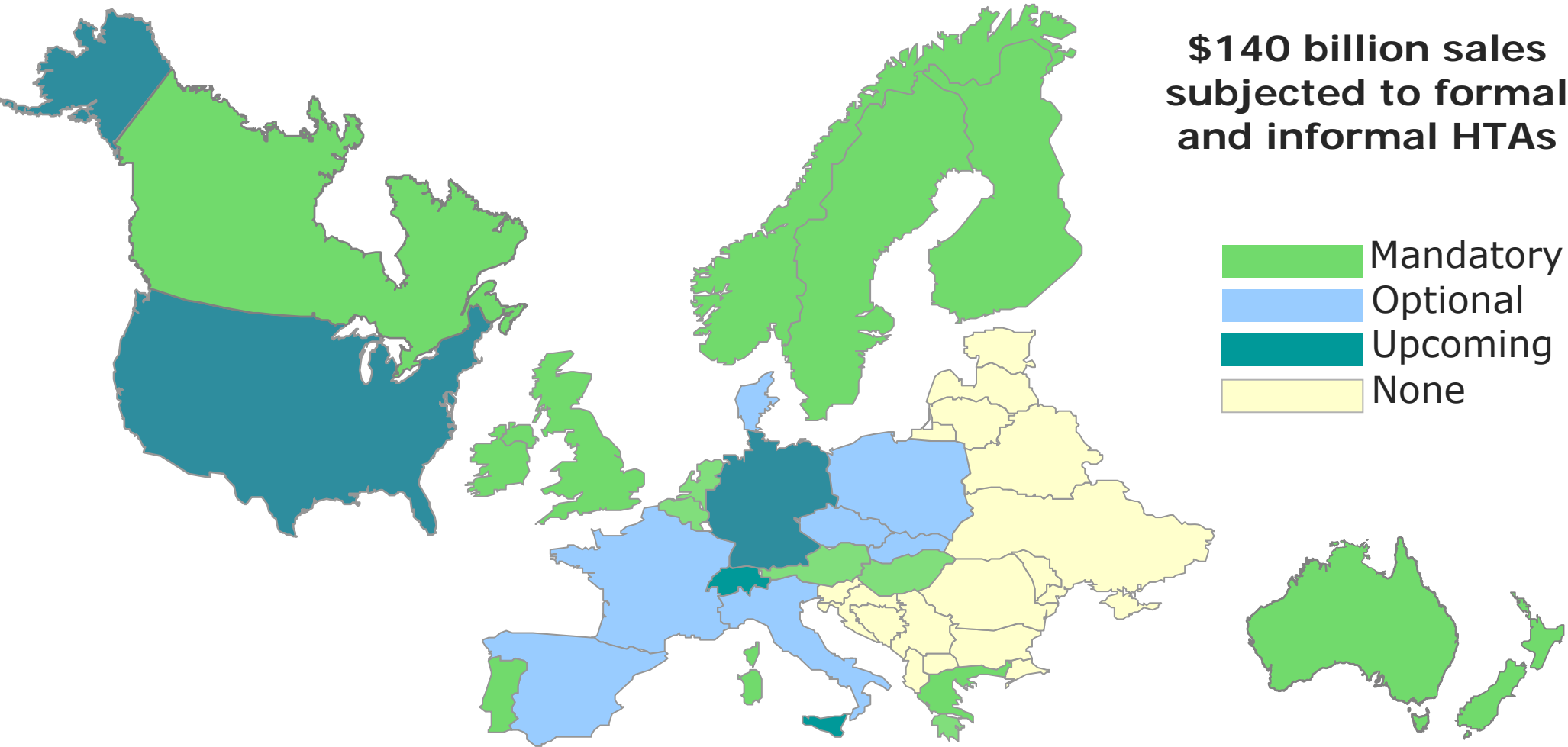


Source: IMS Health, MIDAS, MAT Dec 2006

# HTA fast global penetration: even in innovative areas like cancer

Impact has been particularly felt in Germany and UK

**\$140 billion sales  
subjected to formal  
and informal HTAs**

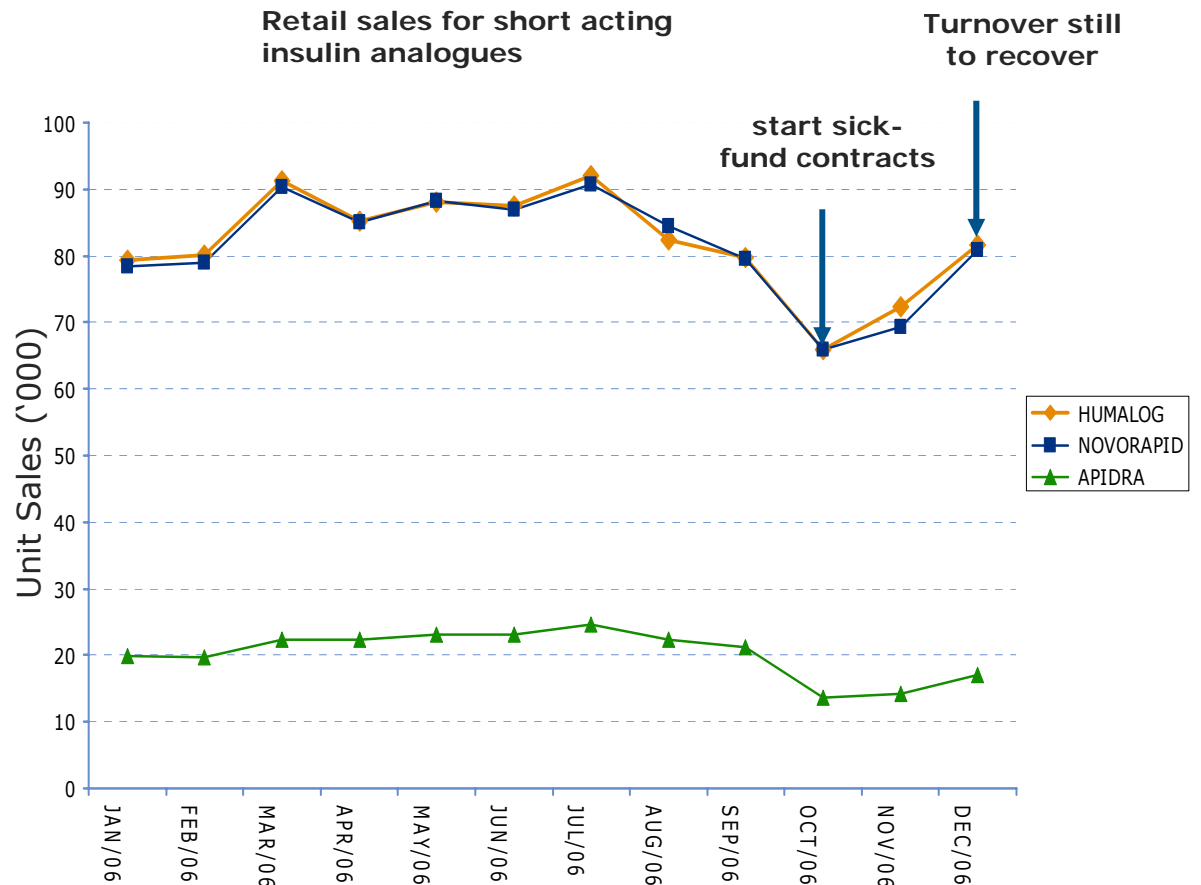




# Insulins: IQWIG in Germany stopped reimbursement of insulin analogues in type 2 diabetes

## Impact of IQWIG decision

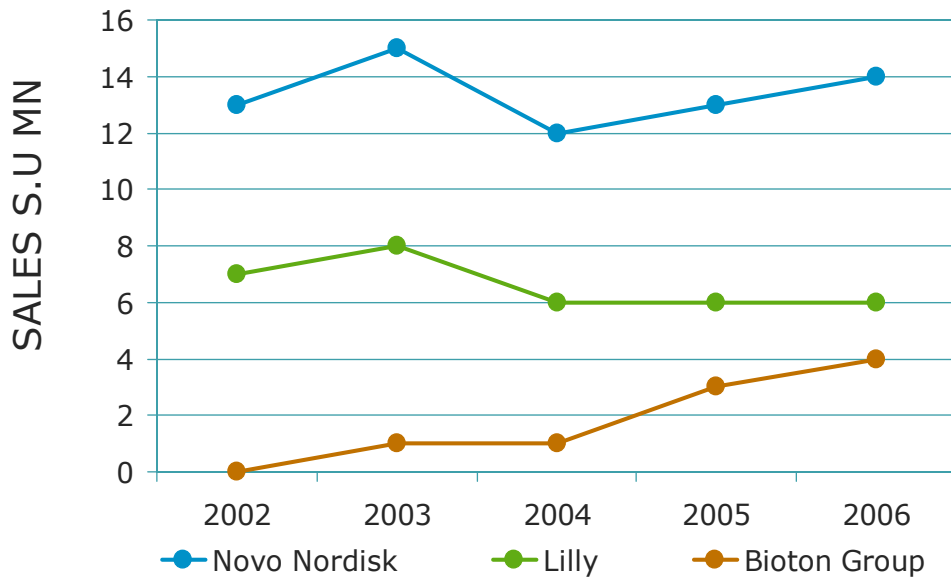
- 29th Sept' 2006 the IQWIG/G-BA ruling; Type 2 patients to receive short acting insulin **only in exceptional cases** or if no extra cost
- Resulting in leading diabetes players signing discount contracts with the large health insurers
- Glitazones currently under review by IQWIG/G-BA
- New drugs likely to undergo similar scrutiny before reimbursement assured



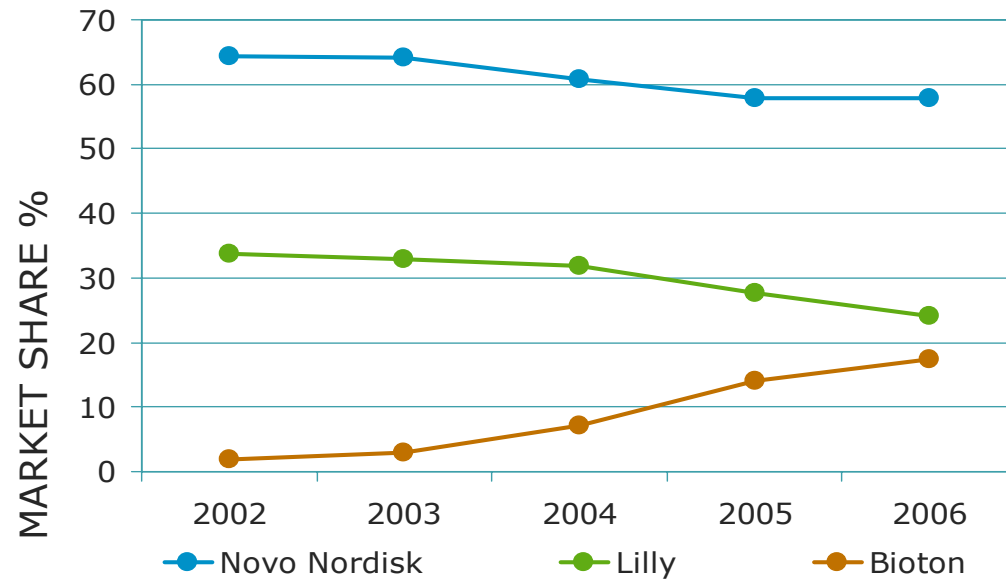
Source: IMS Health, Pharmascope Germany, 2006

# And biosimilar in the insulin space cannot be ignored as payors look for tradeoffs in managing cost growth

POLAND: HUMAN INSULIN SALES, VOLUME (S.U MN)



POLAND: HUMAN INSULIN MARKET SHARE %, VOLUME (S.U MN)



..and will affect regulated European markets before 2008

Omnitrope launched in Germany in 2006

Dynepo (ESA from Shire) launched at 30% discount but is an original brand

Source: IMS Health: MIDAS MAT Dec 2006



# Global: half of biotech sales among top 10 brands

## EPOs struggling

Top 10 Products	US\$m 2006 Sales	% Market Share 2006	% Growth Constant US\$	Const US\$ CAGR 01- 05
<b>Global Biotech Market</b>	<b>65,023</b>	<b>100.0</b>	<b>17.9</b>	<b>19.8</b>
<b>Aranesp (AMG)</b>	<b>4,964</b>	<b>7.6</b>	<b>35.6</b>	<b>308.6</b>
<b>Enbrel (AMG/WYE/TAK)</b>	<b>4,496</b>	<b>6.9</b>	<b>18.4</b>	<b>43.8</b>
<b>Erypo/Procrit (J&amp;J)</b>	<b>3,697</b>	<b>5.7</b>	<b>-2.2</b>	<b>2.3</b>
<b>Remicade (J&amp;J/S-P)</b>	<b>3,566</b>	<b>5.5</b>	<b>18.7</b>	<b>33.6</b>
<b>Neulasta (AMG)</b>	<b>3,249</b>	<b>5.0</b>	<b>28.9</b>	<b>***</b>
<b>Mabthera/Rituxan (ROC)</b>	<b>3,222</b>	<b>5.0</b>	<b>18.6</b>	<b>33.5</b>
<b>Epogen (AMG)</b>	<b>3,142</b>	<b>4.8</b>	<b>8.8</b>	<b>5.7</b>
<b>Herceptin (ROC)</b>	<b>2,545</b>	<b>3.9</b>	<b>78.1</b>	<b>49.4</b>
<b>Lantus (S-A)</b>	<b>2,001</b>	<b>3.1</b>	<b>30.6</b>	<b>***</b>
<b>Avastin (ROC)</b>	<b>1,997</b>	<b>3.1</b>	<b>99.5</b>	<b>102.5</b>
<b>Total top 10</b>	<b>32,878</b>	<b>50.6</b>	<b>24.9</b>	<b>31.4</b>

Source: IMS Health, MIDAS, MAT Dec 2006

# Erythropoietins FDA black box warning March 2007

Impact on sales is yet unknown

**New guidance:** use the lowest dose possible to maintain haemoglobin level necessary to avoid need for transfusions

- EPO drugs can result in a higher chance of death for cancer patients, and not shown to improve outcomes of chemo.
- In advanced head & neck or metastatic breast cancer can contribute to increased rates of tumor growth.
- No requirement to change treatment for reimbursement

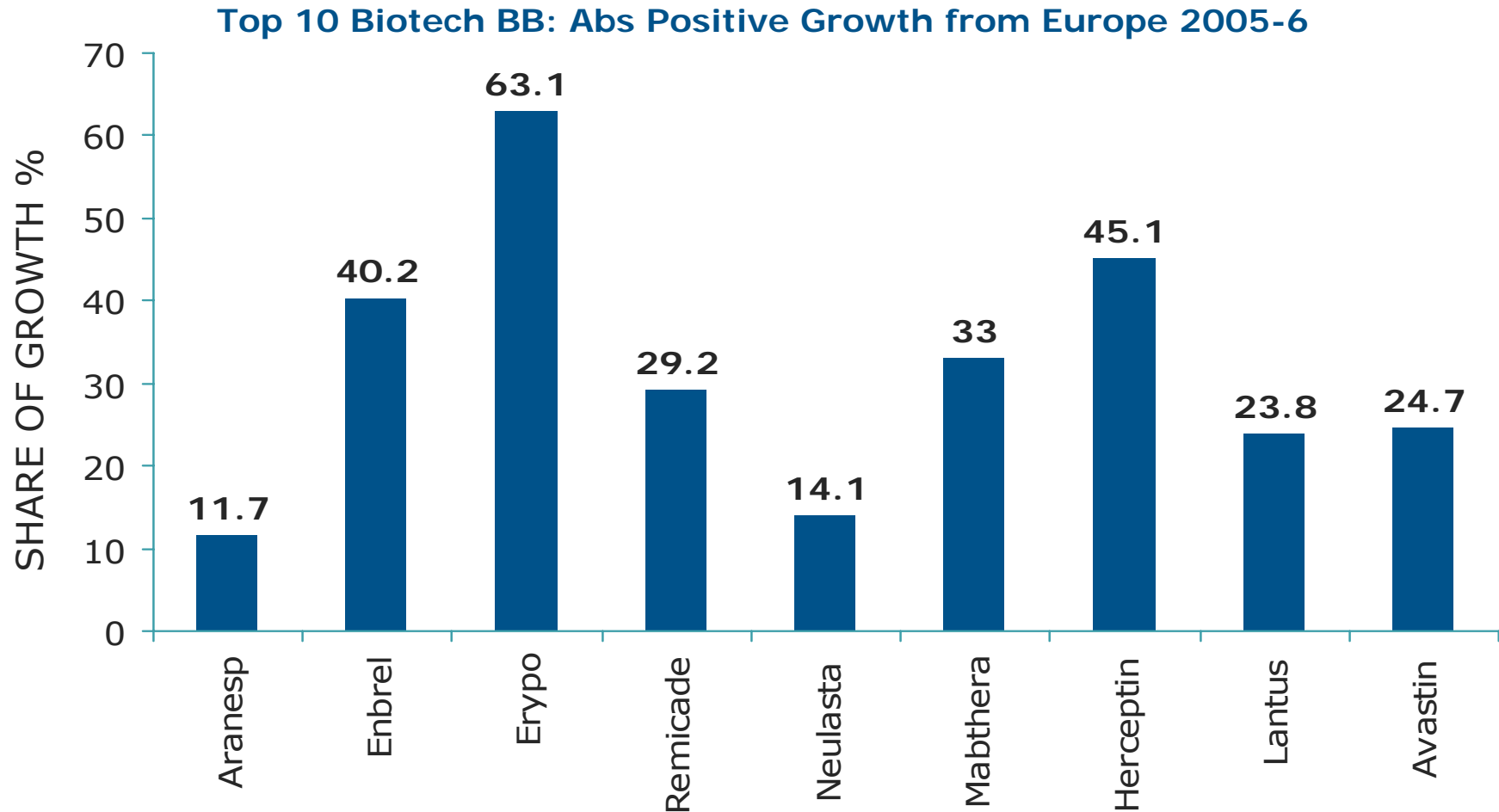


Guidance is not likely to change current treatment practices

Source: IMS Market Insights; IntrinsiQ

# Top 10 global brands: Europe contribution to growth varied

Europe main driver for Erypo; only driving 12% of Aranesp sales



Source: IMS Health, MIDAS, MAT Dec 2006

7 Key

## 7 major biotech molecules with \$10bn potential biosimilar exposure

Leading Substances	Brands	Marketer	2006 US\$m	% of Sales Expired or Expiring 06-10
Epoetin Alfa	Erypo/Procrit/Epogen	Johnson & Johnson/ Amgen	6,579	8%
Interferon Beta 1A	Avonex/Rebif	Biogen Idec/Serono	2,682	100%
Human Insulin	Ins. Protaphane HM/ Novolin N/ Actraphane HM/ Humulin NPH/ Humulin Mix/ Insuman Comb	Novo Nordisk/ Lilly/ Sanofi-Aventis	1,976	99%
Somatropin	Genotropin/ Humatrope/ Norditropin/Asellacrin	Pfizer/Lilly/Novo Nordisk/Serono	1,523	100%
Filgrastim	Neupogen	Amgen	1,250	100%
Interferon Beta 1B	Betaferon	Bayer/Schering AG	836	100%
Epoetin Beta	Neorecormon	Roche	646	100%

Source: IMS Health, MIDAS MAT Dec 2006; SMR Team Analysis, 2007

# Agenda

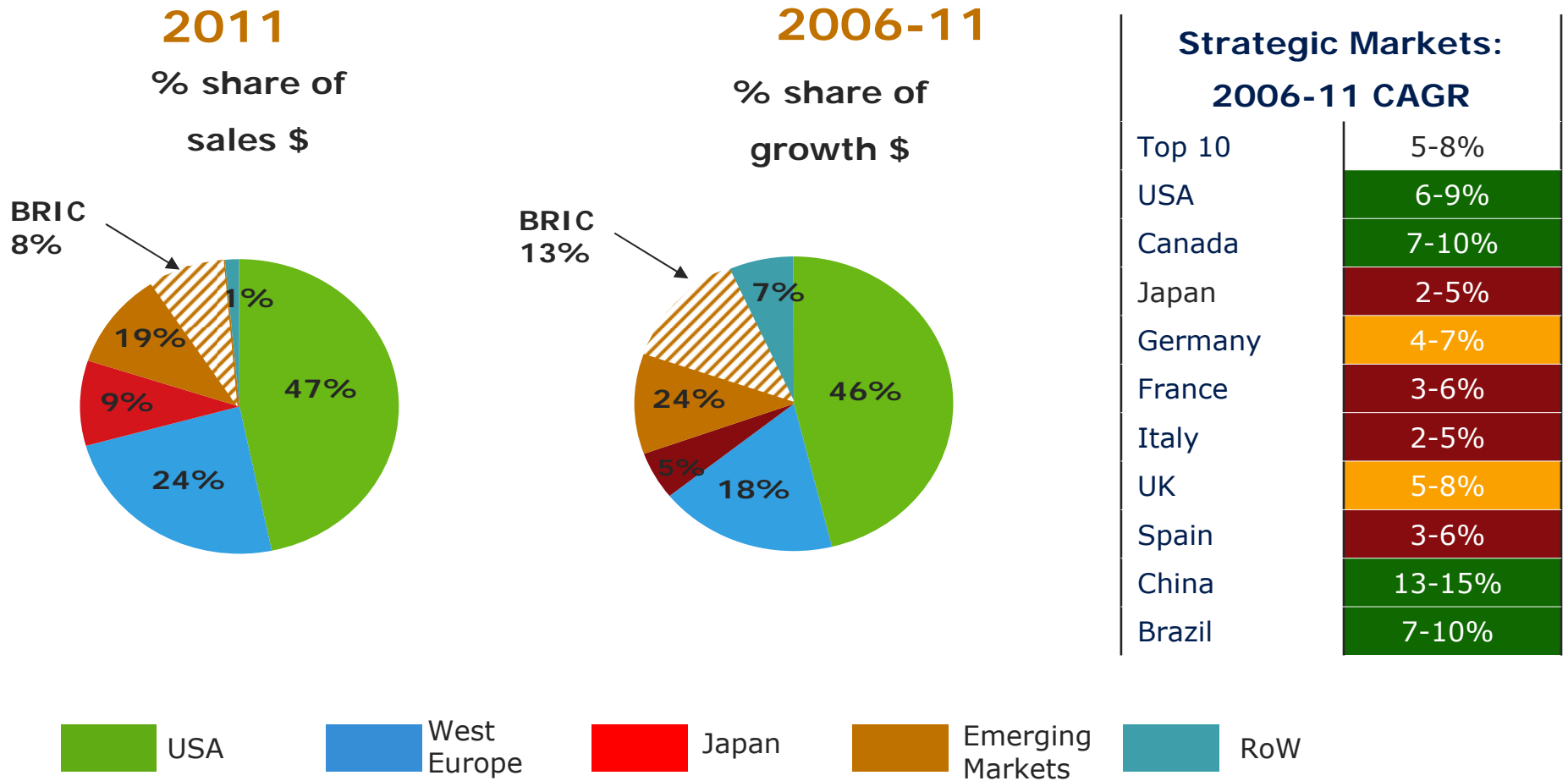
- Global pharmaceutical trends
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## Future Outlook

# Pharma forecast to grow 5-8% CAGR to 2011

USA will remain the key market; Western Europe loses ground

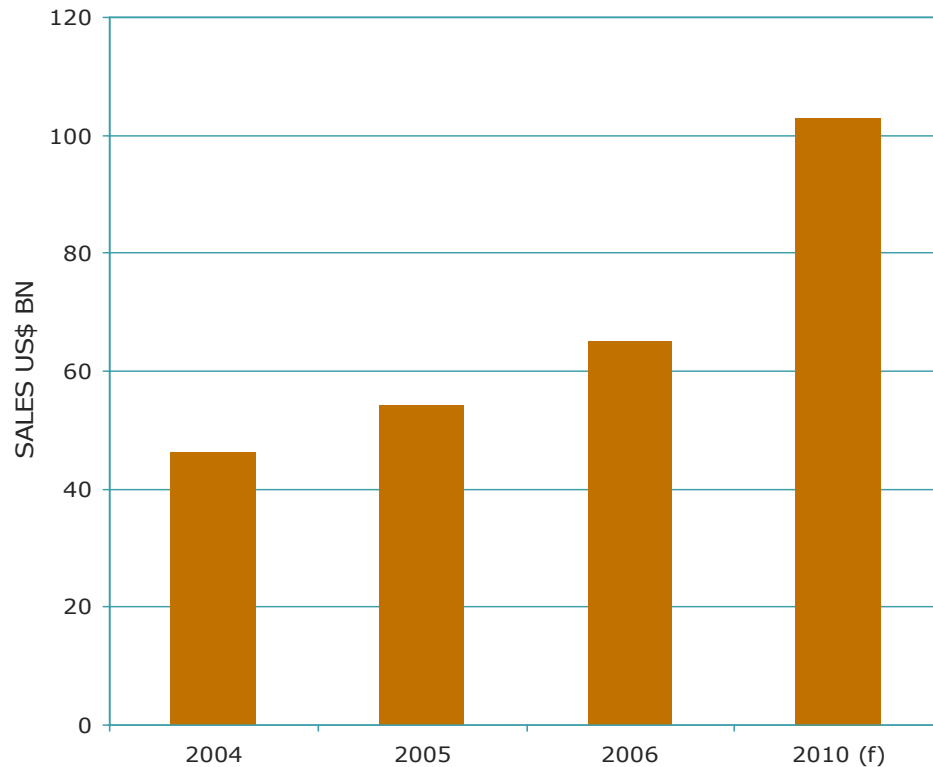


Source: IMS Health: MIDAS, MAT Dec 2006; Market Prognosis Global Forecast, March 2007 update





# Biotech market expected to growth 12-15% CAGR to 2010, reaching over \$100 Bn



## Key Events

- Oncology main driver of growth
- Expanded indications
- Nine biotech launches expected in 2007
- Fertile biotech pipeline
- Biosimilar Epos and interferons expected in Europe in 2008, but not in US before 2010

Source: IMS MIDAS, Therapy Forecaster, Market Insights, Sep 2006



# THANK YOU

Eva Edery

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