IMS HEALTH

Prospects for Generics Pharmaceuticals the USA and Europe

European Generics Association

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Graham Lewis, Vice President
Strategic Consulting
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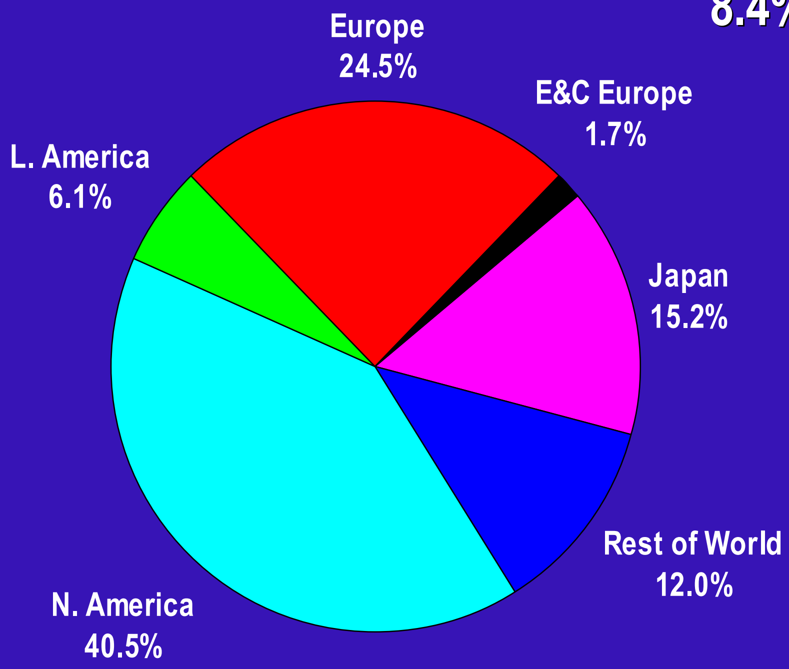
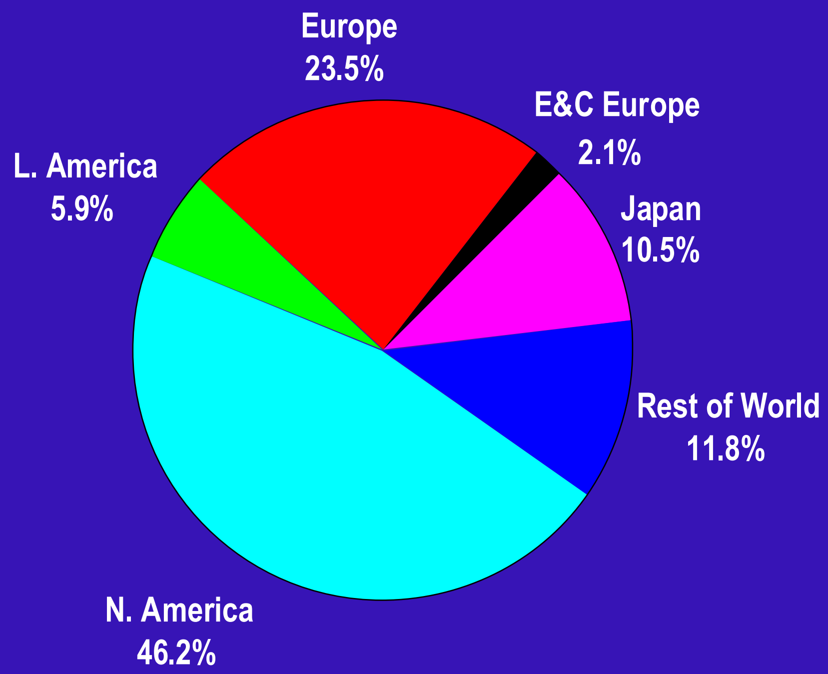
World Pharmaceutical Market by Region

CAGR 1999-2004
8.4%



US$ 337 billion



US$ 506 billion

Country Rank 1999 & 2004

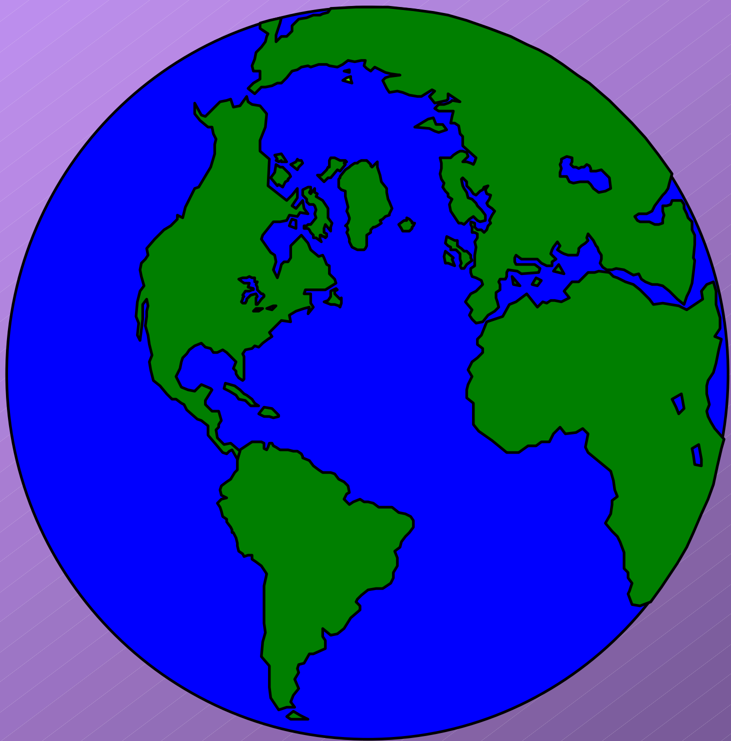
COUNTRY	99 RANK	2004 RANK
U.S.A.	1	1
Japan	2	2
Germany	3	3
France	4	4
Italy	5	6
U.K.	6	5
Spain	7	7
Brazil	8	11
China	9	8
Canada	10	9
Mexico	11	10
Argentina	12	13
India	13	12

Definition of Generics

- Varies depending on whether the products are handled as branded or unbranded

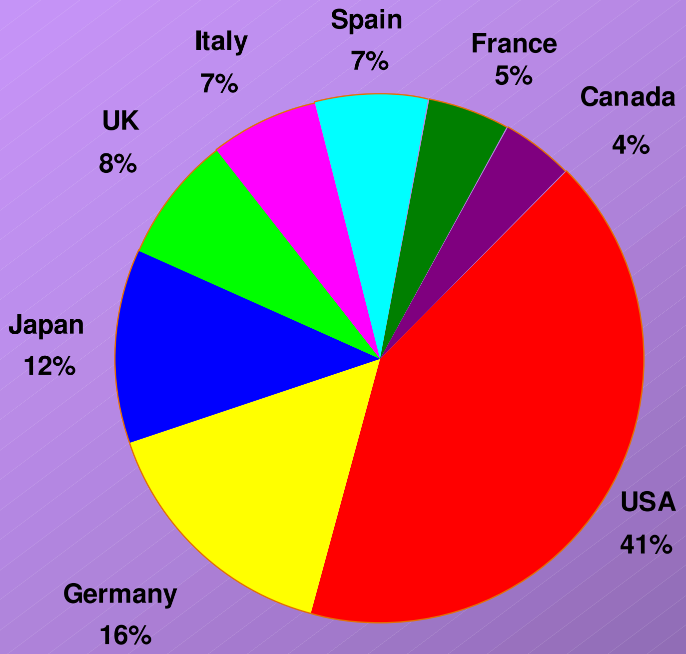
- "A product, which is a copy of an original product whose patent has expired, and may be marketed either as a brand or using the generic name."

Geographic Overview

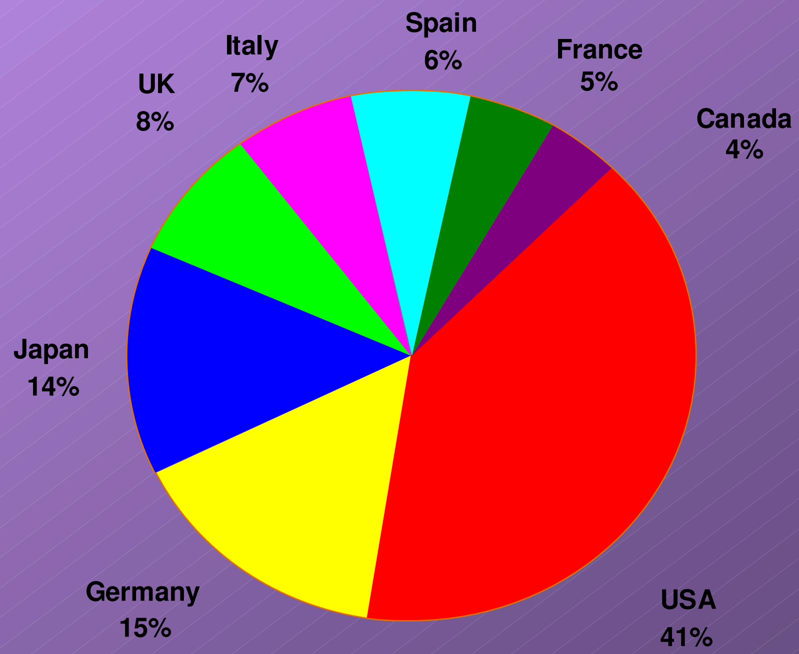


Retail Growth For Major Generics Markets 1998 & 1999

1998 - US$ 15.9 bn



1999 - US$ 17.2 bn



Retail Generics Growth 1999/1998 = 8.2%
Total Retail Growth 1999/1998= 12.4%

Key trends US

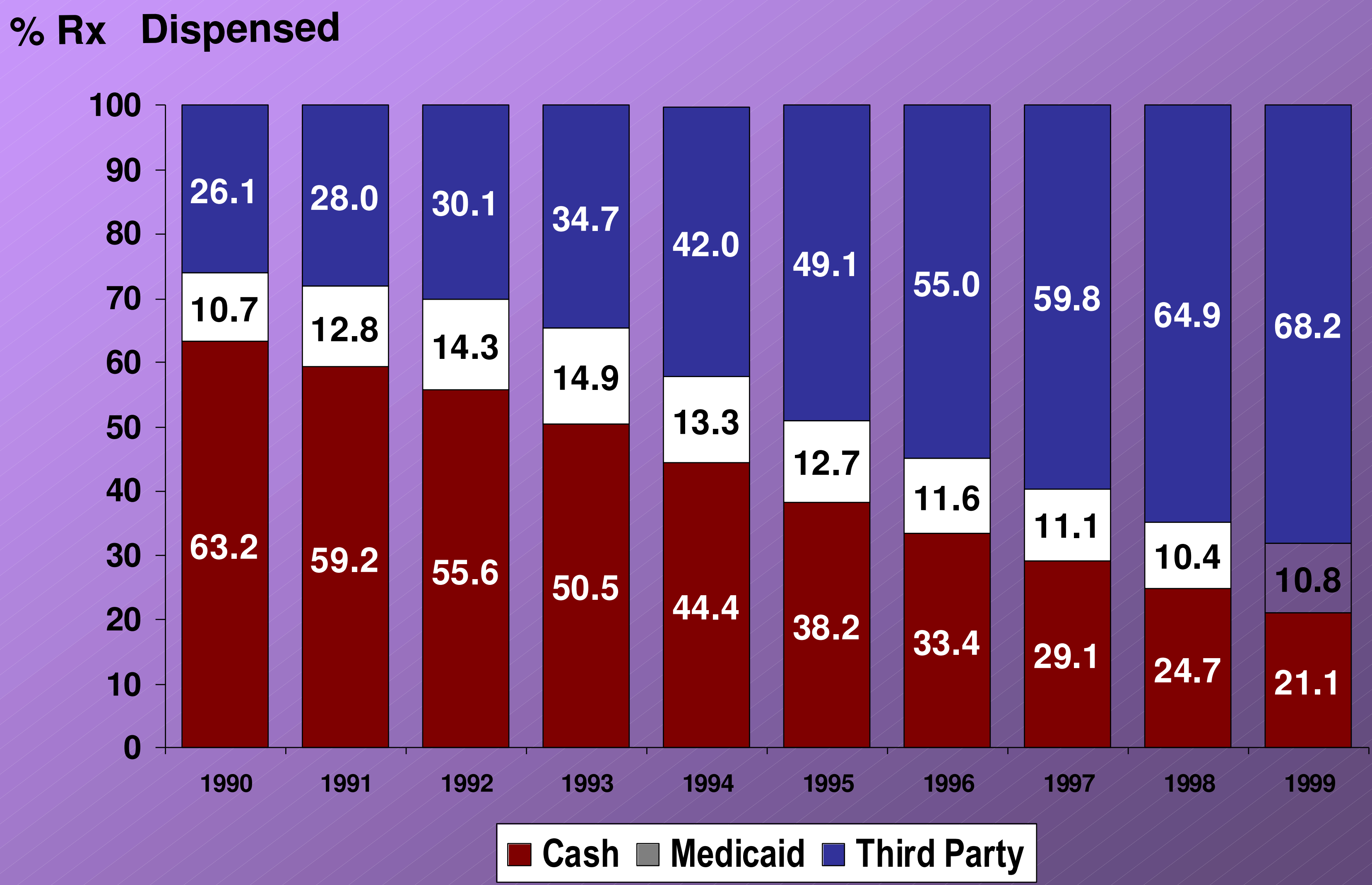
Assumptions

- Election unlikely to drastically impact Medicare
- GDP growing 3-3.5% p.a.
- Price increase 1-2% + inflation, generic price increases
- Open for innovation - pharmacos fully leveraging opportunity
- Consumerism continued to increase in health care

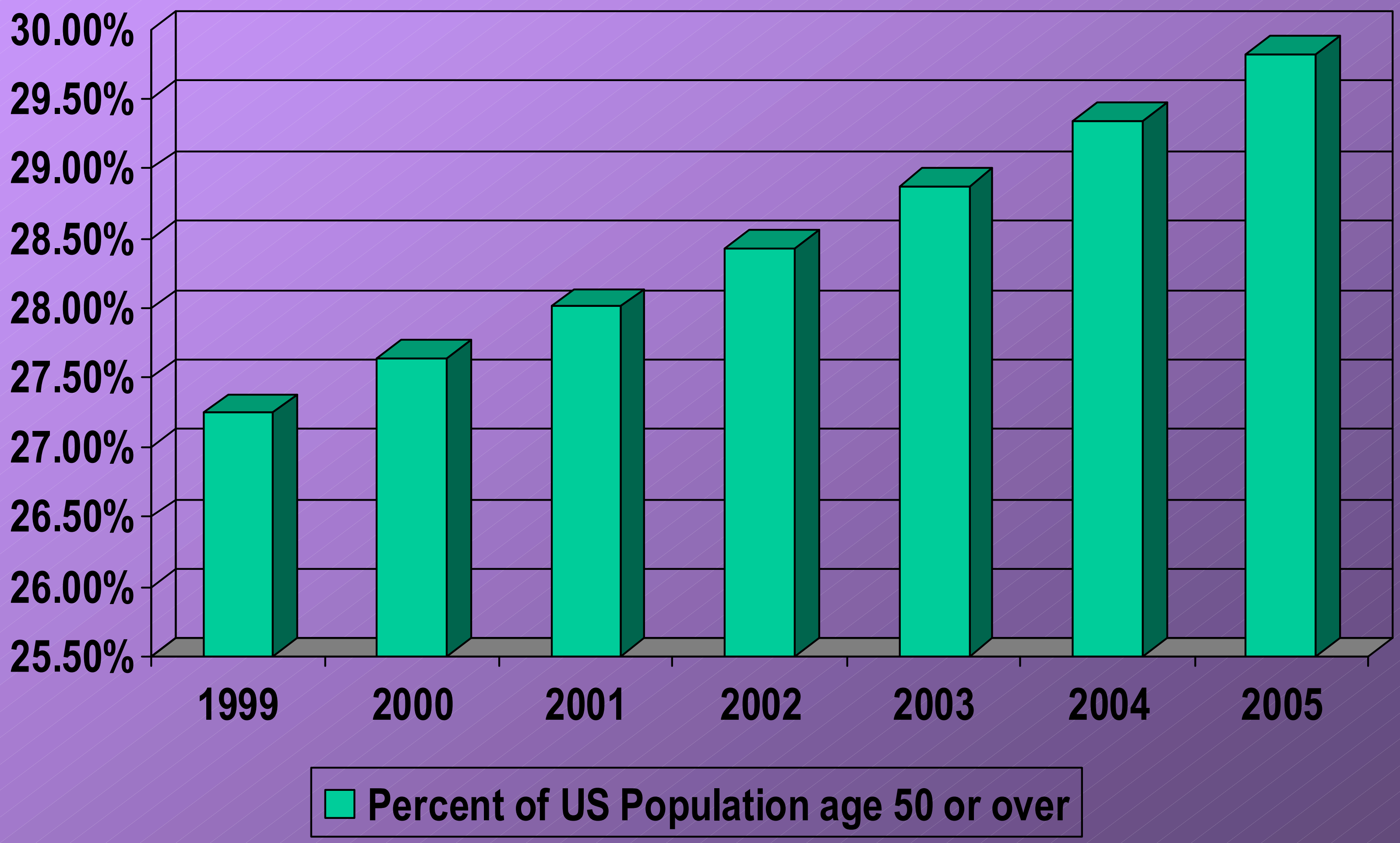
	1999	2000	2001	2002	2003	2004
$ billions	132	151	167	185	203	224
%growth	16.7	13.8	11.2	10.2	10.1	10.4

But even more significantly - 59 % of products launched after 1995 are sold in US!

Managed Care Pays for 68.2% of all Prescriptions Dispensed



By the Year 2005, Nearly 30% of the U.S. Population will be 50 Years or Older

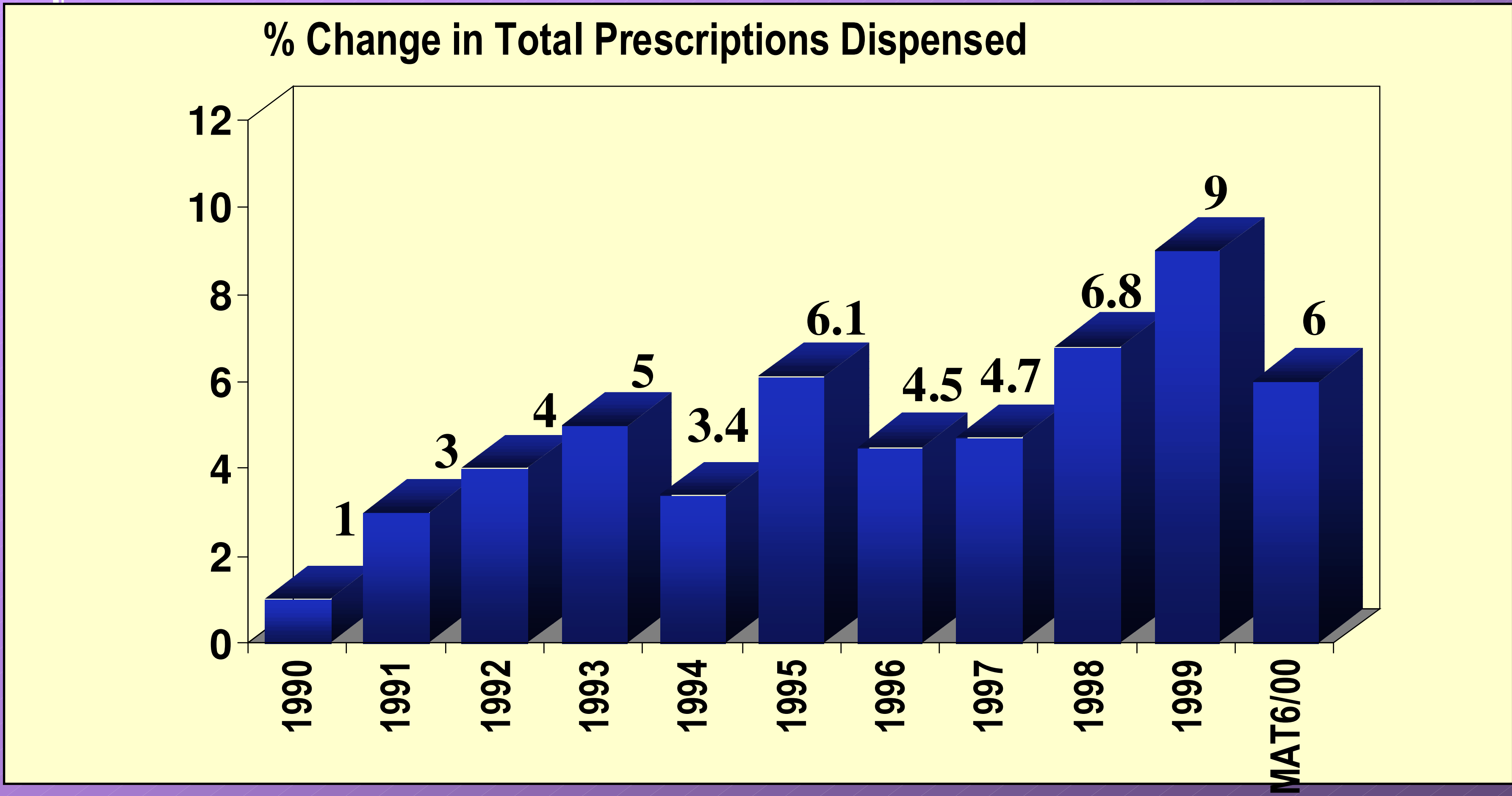


The Most Common Illnesses in the 50+ Age Group Require Chronic Care

Diagnosis	Visits* (M)
Essential Hypertension Unspec	52.9
Diabetes Mell without Complic	24.5
Lipid Disorders	19.8
Osteoarthritis	11.1
Menopause	7.2
Cataracts	7.2
Chronic Obstructive Airways Disease	7.1
Depression	6.3
Esophagitis	6.1
Hypothyroidism	6.1

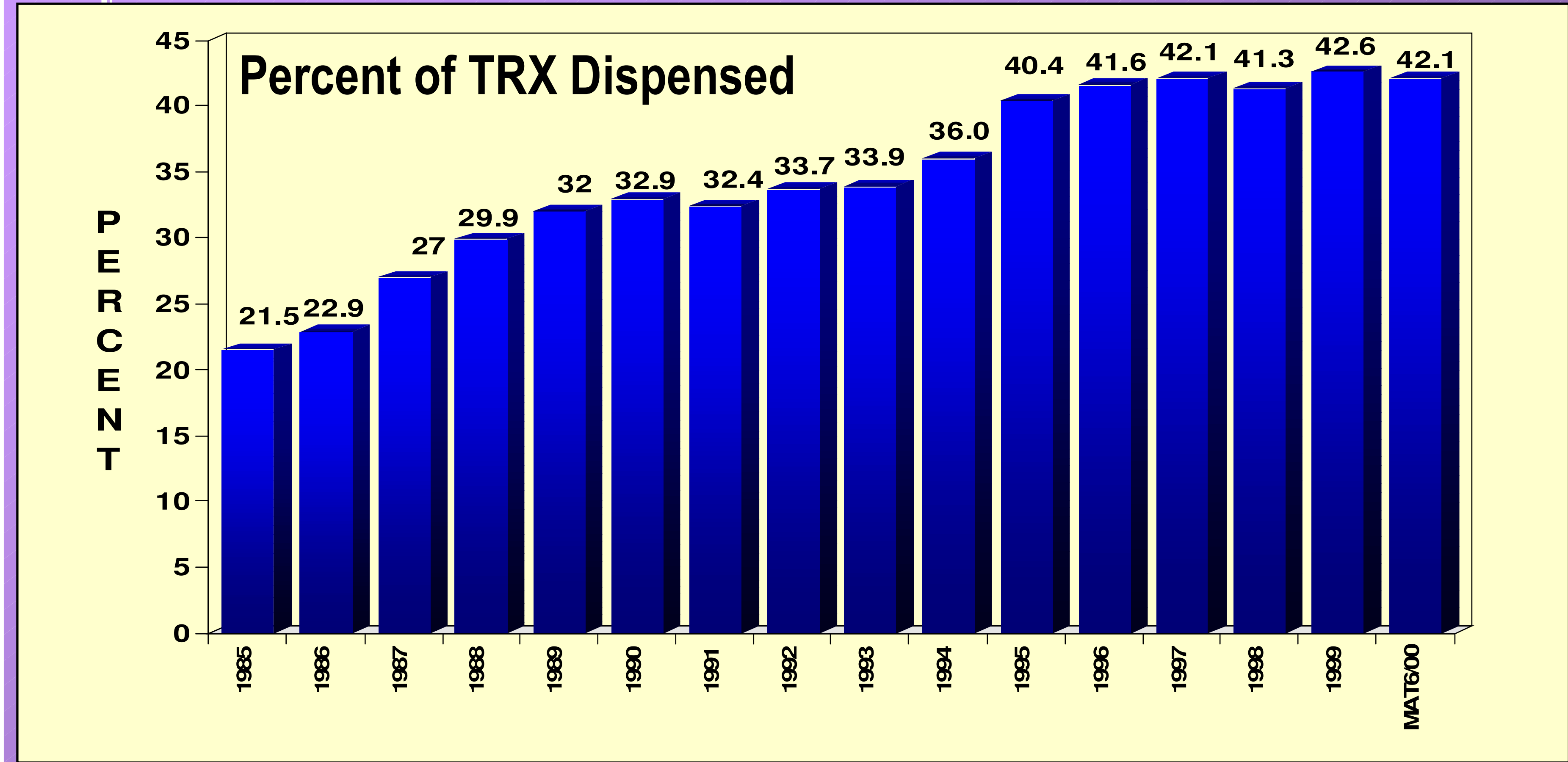
Note: Excludes all post-operative visits and routine wellness exams.
Source: IMS HEALTH National Disease and Therapeutic Index June 2000
* Represents, in millions, projected number of patient visits specific to the diagnoses for which they are being treated by office-based physicians in the U.S.

Prescription Volume Remains Elevated



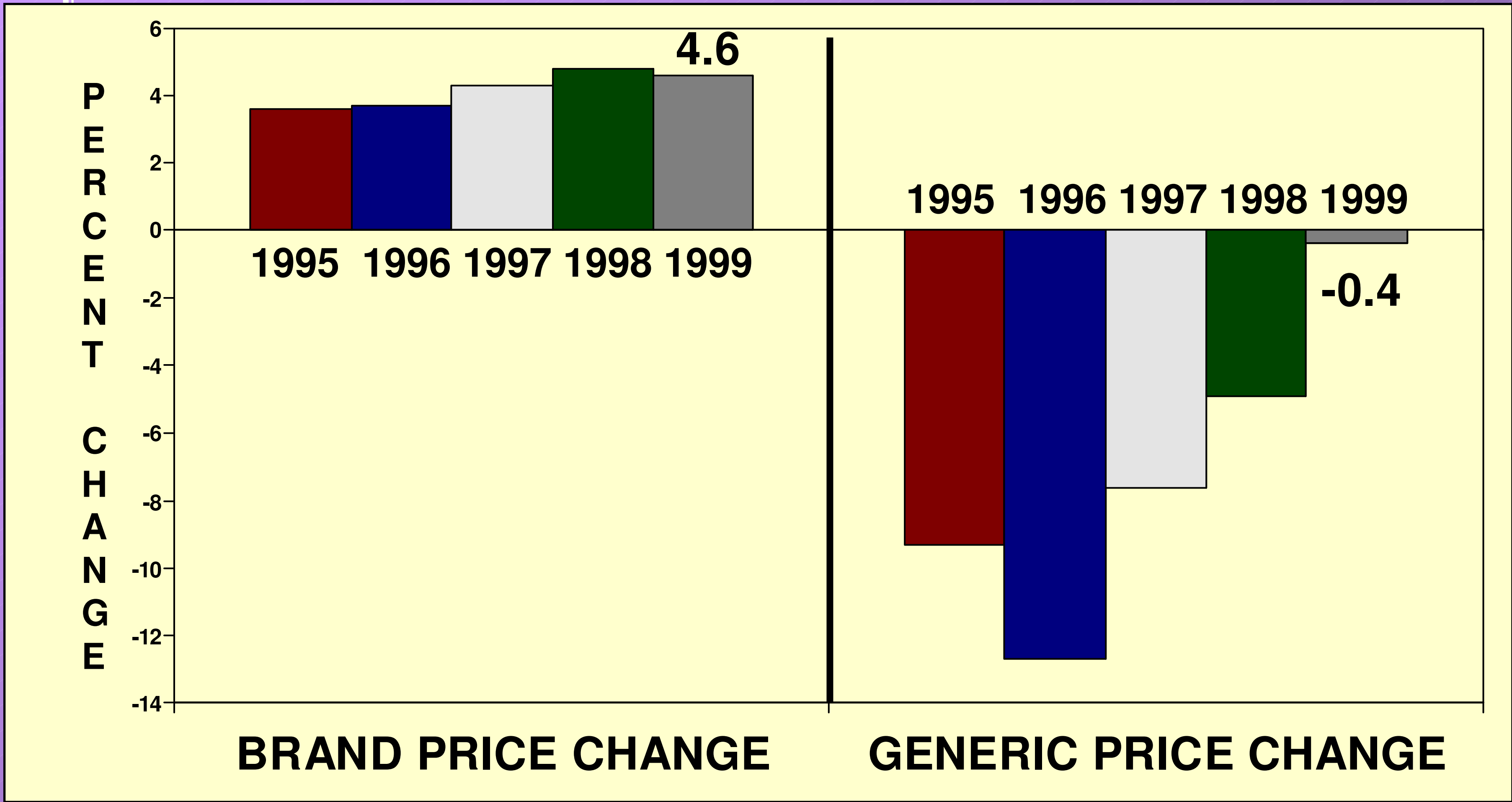
Source: *National Prescription Audit Plus*[TM]

Generic Share Has Hit a Plateau Despite Managed Care and Differential Co-pays



Source: ***Pharmaceutical Pricing Index UPDATE***

Brand Price Increases are Above CPI, Generic Prices Shrink Less



Source: ***Pharmaceutical Pricing Index UPDATE***

Many Significant Products will Lose Patent Protection by 2003

Selected Key Patent Expiries: 2000-2003

2000	2001	2002	2003
BuSpar	Accupril	Augmentin	Cipro
Cytotec	Accutane	Axid	Detrol
Glucophage	Allegra	Claritin	Flonase
Hismanal	Feldene	Duracef	Flovent
Hytrin	Mevacor	Evista	Floxin
Proscar/Propecia	Nasonex	Intron A	Lotensin
Sporanox	Pepcid	Nolvadex	Plavix
Vasotec	Pravachol	Omnicef	Serzone
	Prilosec	Proleukin	Sonata
	Prinivil	Relafen	Valtrex
	Prozac	Sandostatin	
	Zestril	Suprax	
		Xanax	

Source: Patents International and Strategic Business Planning Analysis 05/00
NOTE: Patent Expiry does not necessarily result in genericization

Key trends Europe

Assumptions

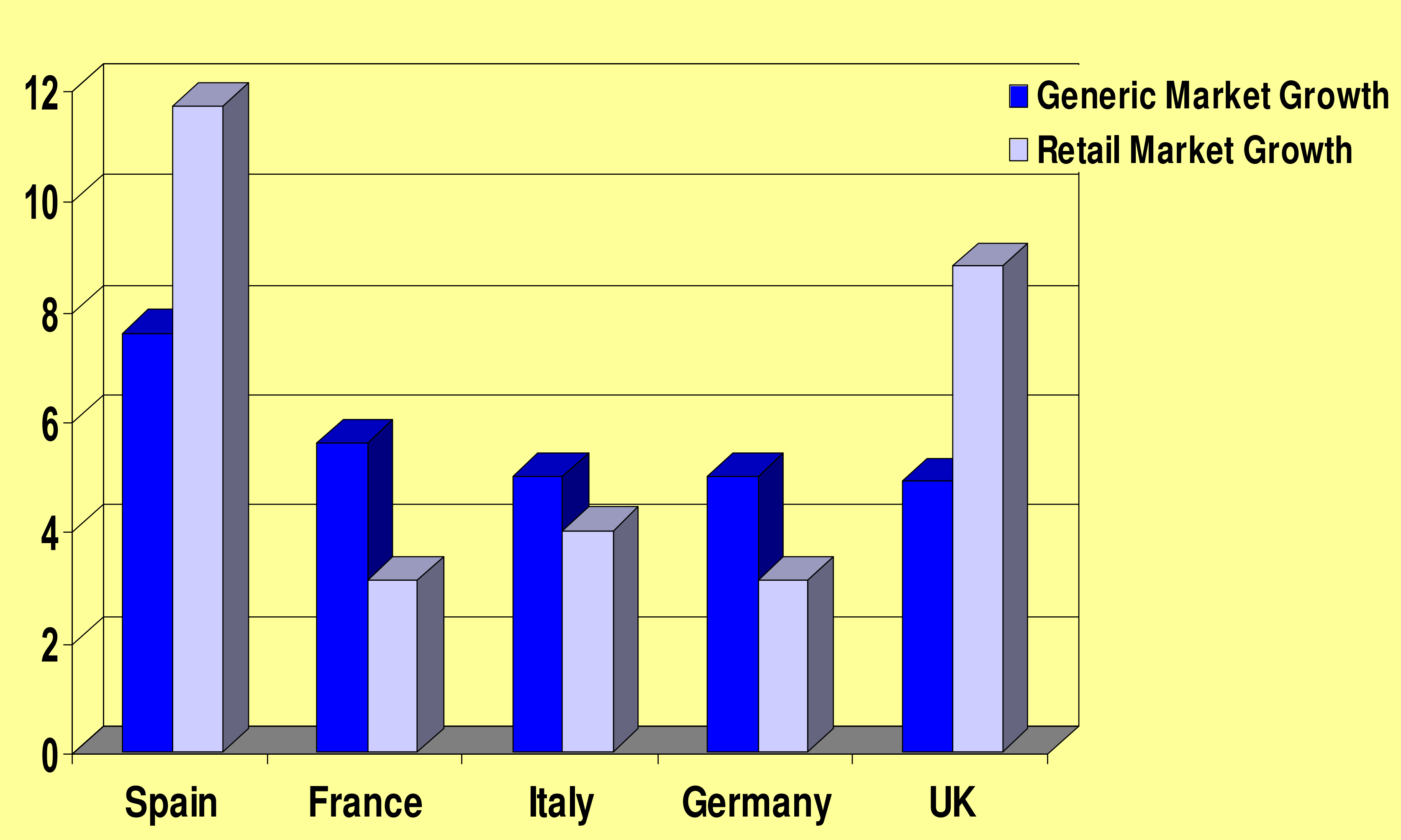
- Slow changes towards “market driven” health care
- Increasing GDP growth but low inflation
- Price effected by regulation, generics and parallel trade
- Consumerism in health care more limited
- Continued market integration - Speeding-up of launches

	1999	2004	CAGR% 1999-2004
	$ billions		
France	17.8	23.7	6.0
Germany	19.4	25.0	5.2
Italy	10.7	14.9	6.8
Spain	6.7	10.4	9.2
UK	11.1	17.4	9.6
Total EU	79.9	110.6	6.7

Source: Pharma Prognosis International
IMS HEALTH, 1999

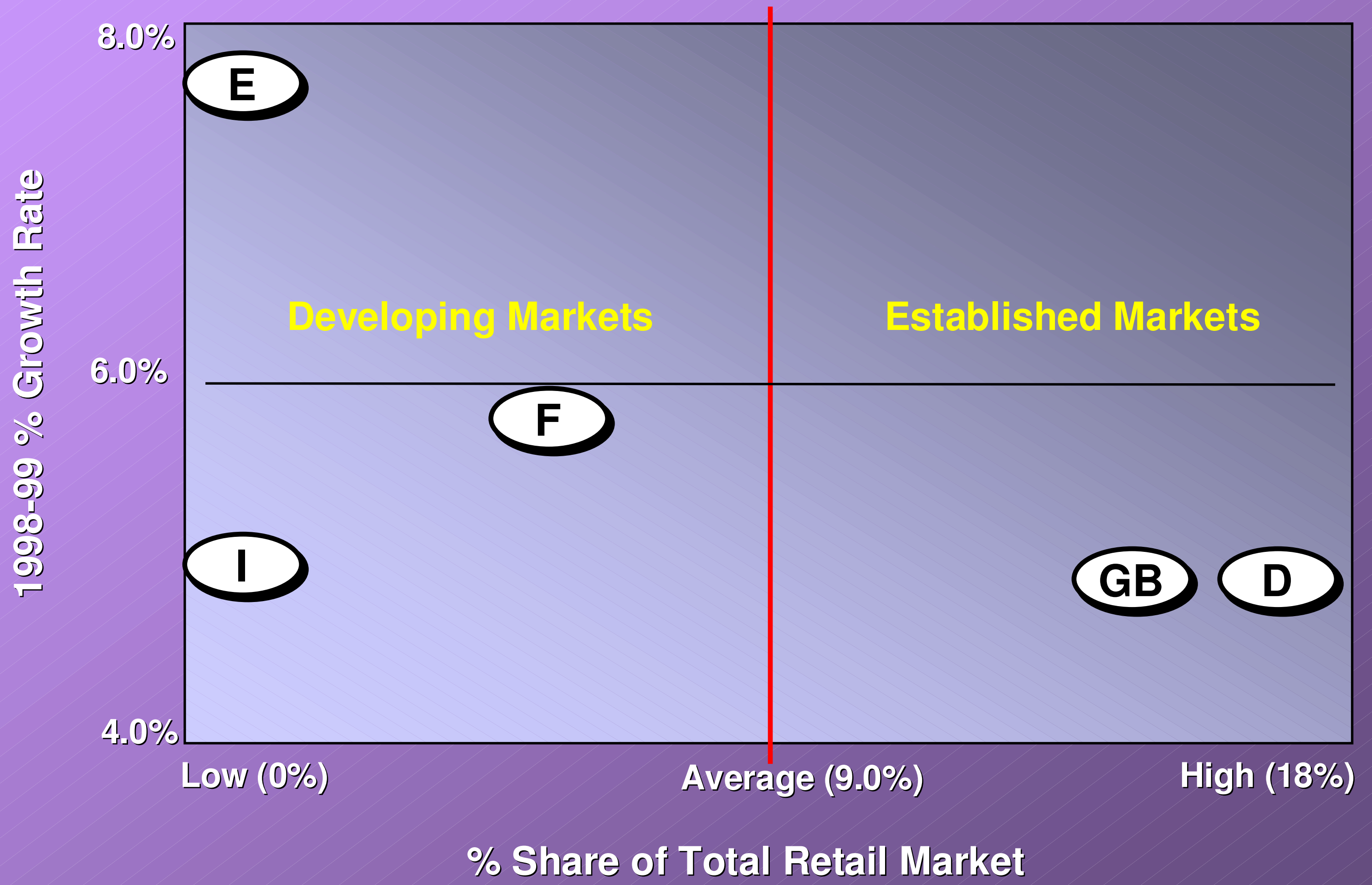
5 Leading European Markets Sales Growth

1998-99 (% USD)



Generics Growth And Size Of 5 Leading European Markets:

9199* % SHARE (USD) - 1998*-1999* % GROWTH (USD)



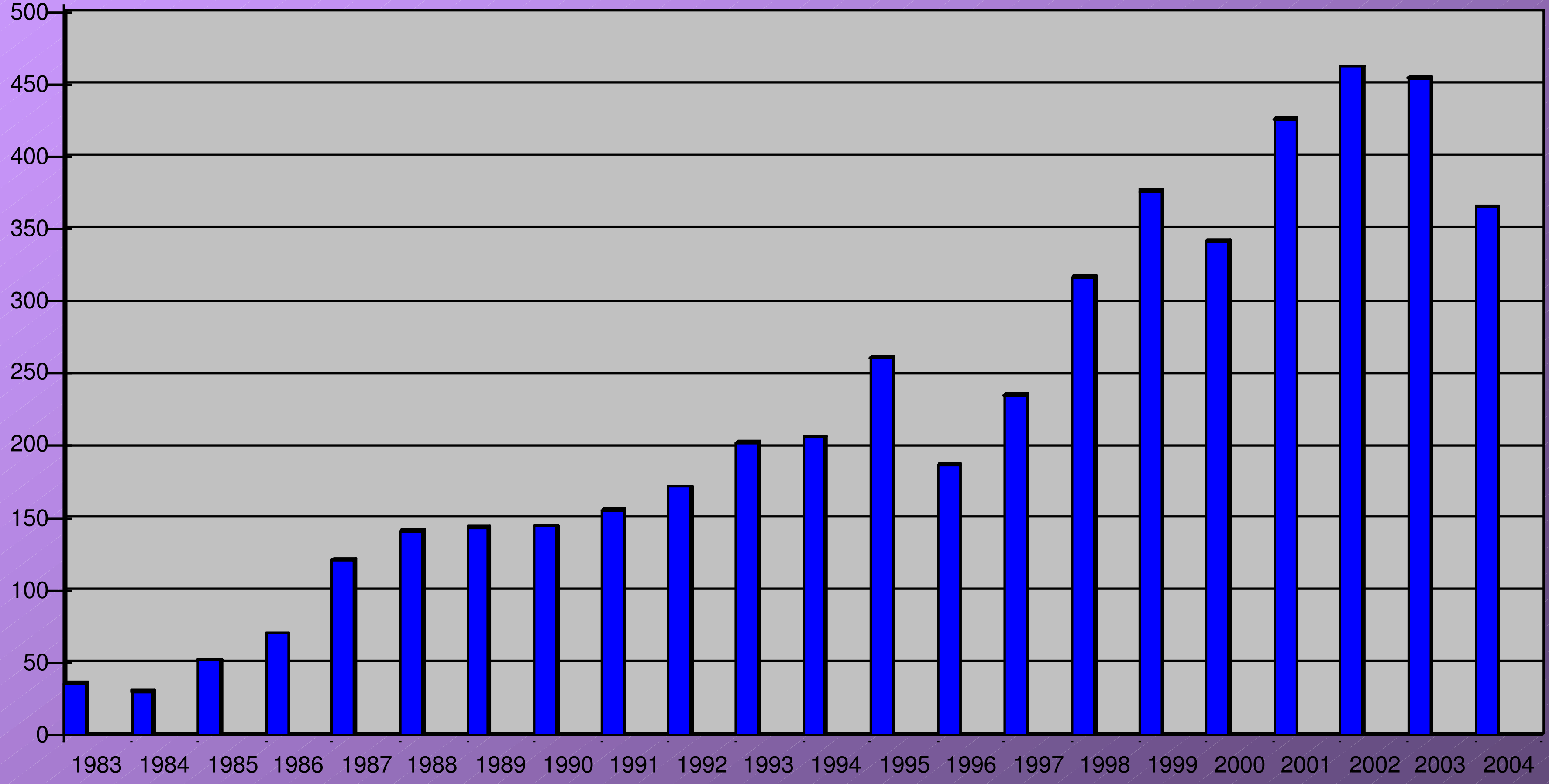
Penetration Rates And Price Differential - National Averages

	Penetration on average after 4 years	Differential between reference price and generic after 4 years
➢ UK	50-60%	80%
➢ Germany	40-50%	30%
➢ France ➢ Italy ➢ Spain	5-15%	20-30%

Generic Forecasts

- $30.5 billions by 2004 - CAGR = 12%
- 1/3 of top 35 molecules lose patent protection by 2004
- Total exposure for top 21 companies 44.6 billion
  - 61% with top 8

Number Of Patent Expires In The 5 Leading European Markets



Leading Molecules Coming Off Patent

	UK	GERMANY	SPAIN	USA
1999	Paroxetine Lisinopril	Omeprazole	Ranitidine	
2000	Fluoxetine	Lovastatin		Simvastatin Pravastatin
2001	Simvastatin	Simvastatin Ciprofloxacin	Enalapril	Omeprazole/ Fluoxetine/Loratadine
2002	Omeprazole	Cetirizine	Sertraline	
2003			Ciprofloxacin	
2004			Aceclofenac	

The Future for Euro Generics

Retail market share in 2004

	%
UK	17.4
France	8.3
Germany	18.5
Italy	0.8
Spain	1.5

Regulatory And Legal "Attitude" Towards Generics

Country	Patent Situation	Registration	Pricing
France	↑	↑	↓
Germany	↑	↑	↑
Italy	↓	↓	↓
Spain	↓	↓	↓
UK	↑	↑	↑

↑= Positive attitude; ↓ = Negative attitude; ↔ = Indifferent

Attitudes To Generics In The Supply Chain And Their Impact On The Market

Country	Wholesalers	Prescribers	Dispensers	Patients
France	↔	↑	↑	↔
Germany	↔	↑	↔	↑
Italy	↔	↔	↓	↓
Spain	↔	↓	↓	↓
UK	↔	↑	↑	↔

↑= Positive attitude; ↓ = Negative attitude; ↔ = Indifferent

Latest Developments Spain And France

- **France**
  - Substitution
  - Margins
  - Discount up to 10.74%
  - Abbreviated registration if price 30% below original brand
- **Spain**
  - Medicine Agency set up working group for generic registration
  - Generic substitution
  - Reference pricing

Four Categories Of Generic Competitors In Germany

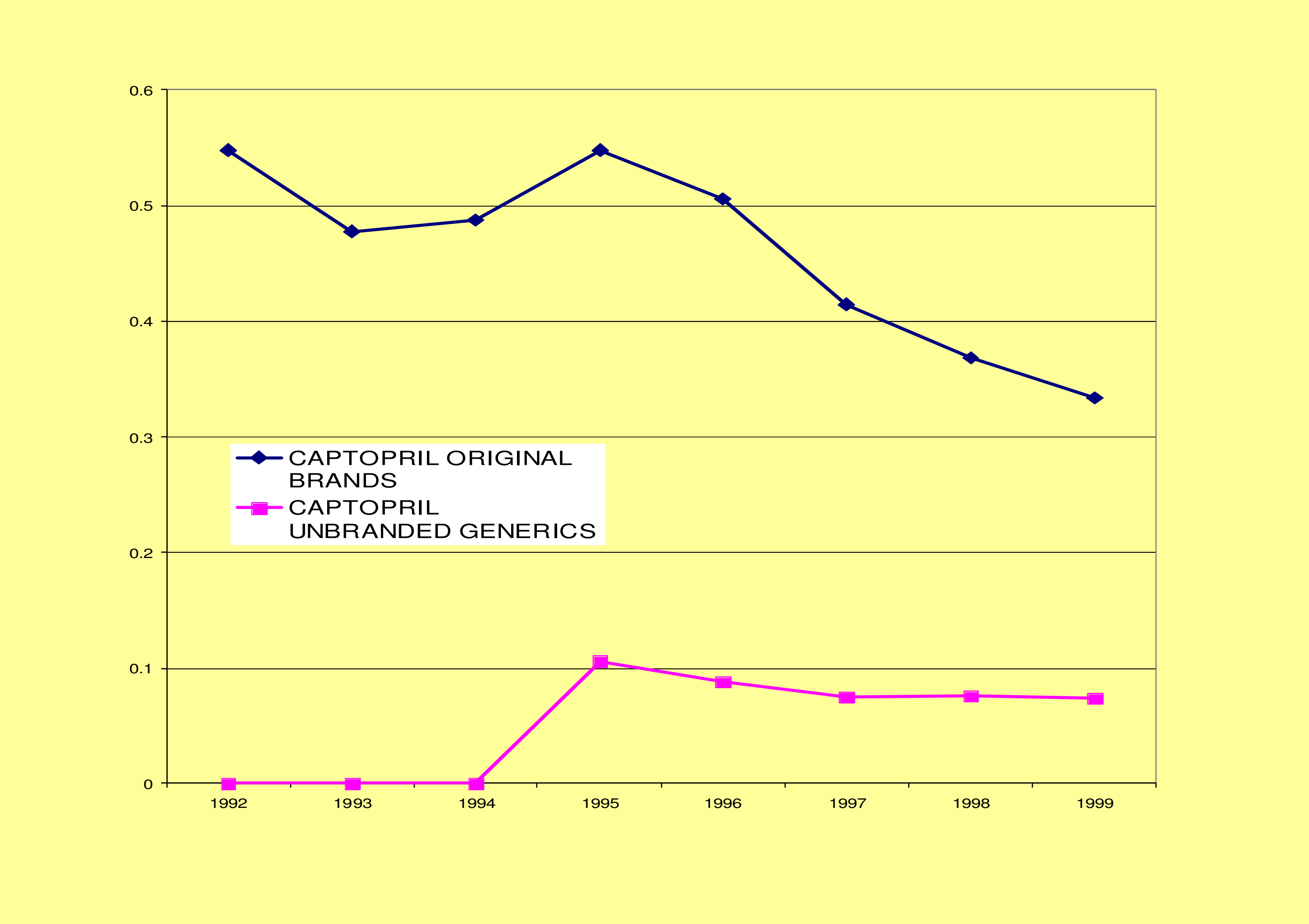
- Full range suppliers
- Companies specialising in specific indication groups
- R&D-based manufacturers offering generics as line extension
- Low-priced generic operators which offer the lowest prices by saving on sales and service cost

Examples Ofgeneric Entrants In Germany

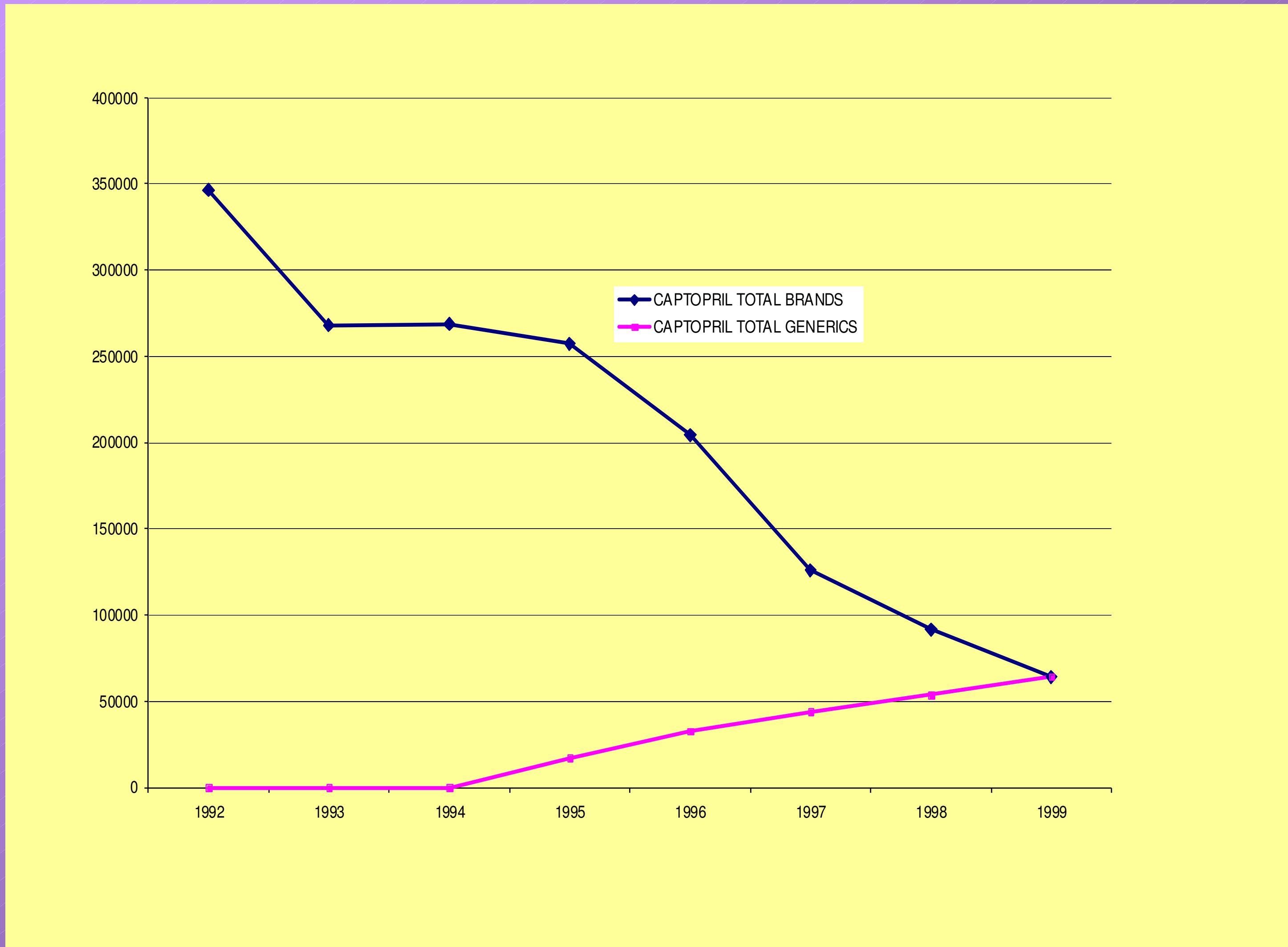
Number of generic for Metoprolol launched by year (exp. 03/1989)	
1990	2
1991	7
1992	3
1993	5
1994	3
1995	5
1996	4
1997	1
1998	1
1999	1
Total 9 years	32

Number of generic for Atenol launched by year (exp.02/1988)	
1987	1
1988	2
1989	12
1990	3
1991	2
1992	1
1993	3
Total 6 years	25

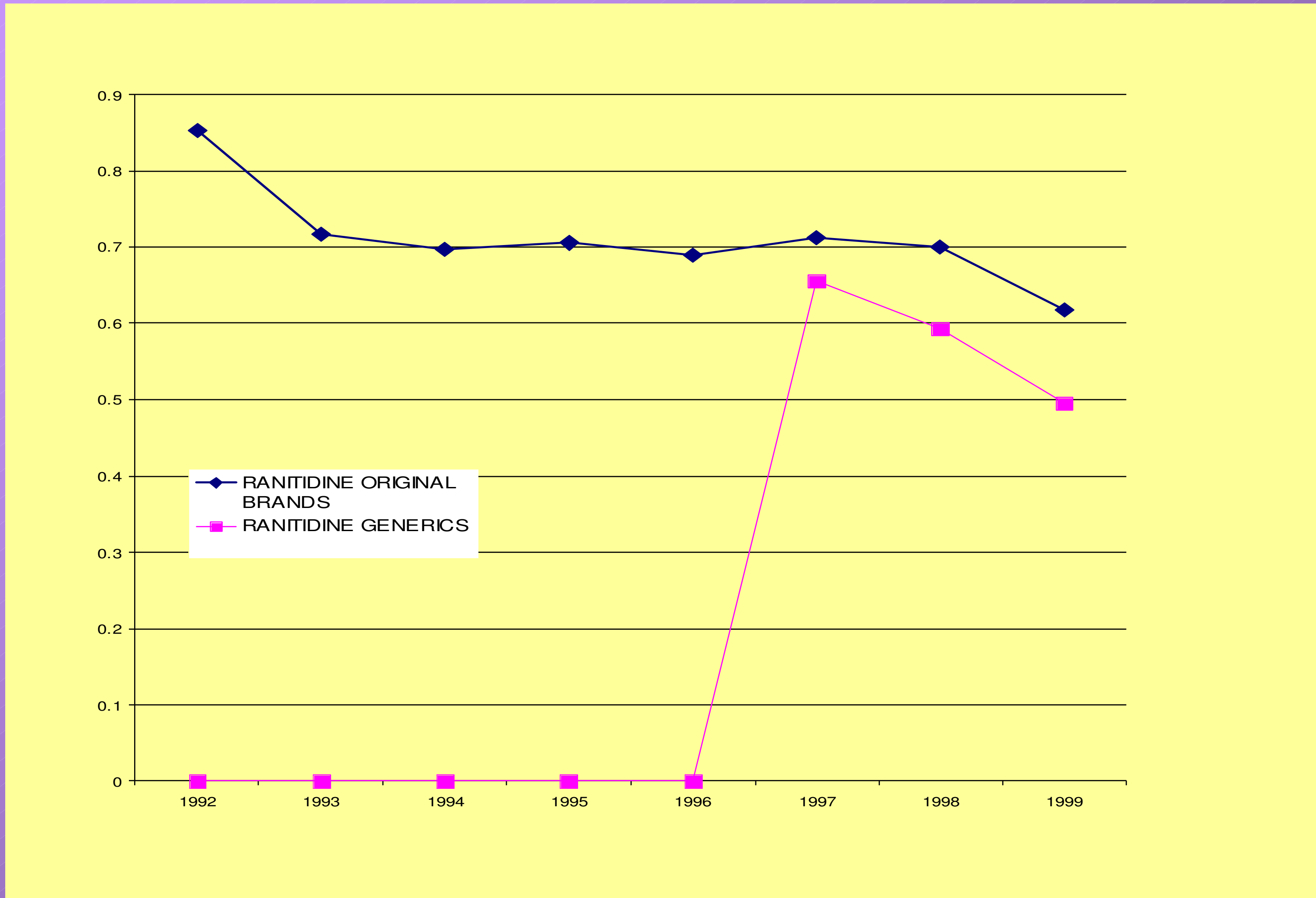
Example Of Price Erosion: Captopril In Germany 1992- 1999 (Price Per Su) Usd



Example Of Revenue Erosion: Captopril In Germany 1992-1999 Usd (000)

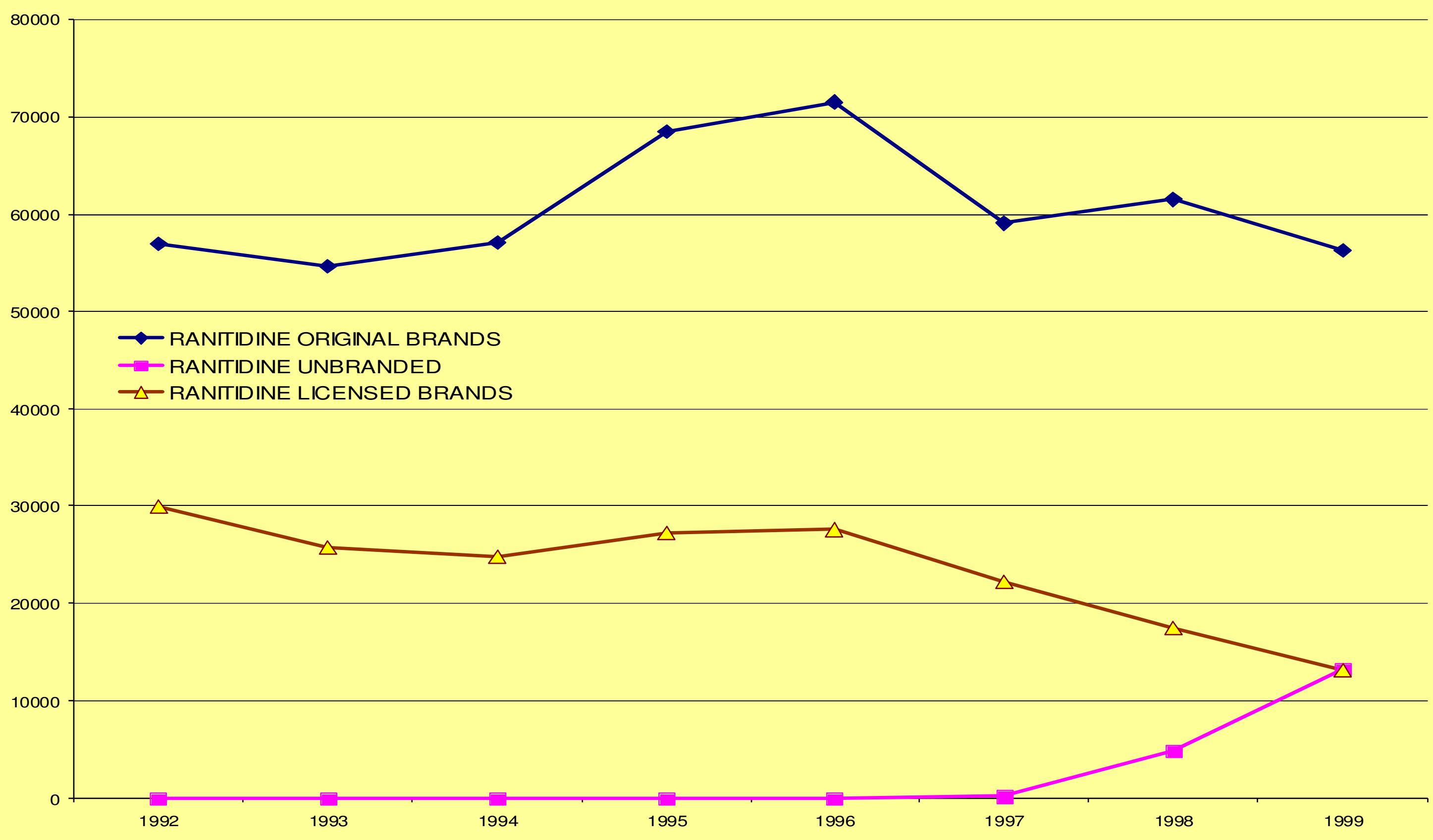


Example Of Price Erosion: Ranitidine In The UK 1992-1999 (Price Per Su) USD



Example Of Volume Erosion: Ranitidine In The UK 1992-1999 SU (000)

Example Of Revenue Erosion: Ranitidine In Spain 1992-1999 USD (000)



Reference Pricing

- There are two types of reference pricing operating in EU countries:
  - Internal
  - External
- Nine EU countries focus on price comparisons

Reference Pricing

…The Theory

Focuses on drug interchangeability

Fixes maximum limits on reimbursed prices

Patients can decide whether to pay

Companies can compete on price

Doctors focus on prescribing not on price

Fair prices and equal access

Reference Pricing and Generics

COUNTRY	REF PRICE	GENERICS
France		✓
UK		✓✓
Germany	✓(89)	✓✓ established
Netherlands	✓	✓✓ established
Italy	✓(96)	✓
Spain	✓(99)	✓
Denmark	✓(93)	✓✓ established
Sweden	✓(93)	✓
Belgium		✓

✓ *small mkt share*
✓✓ *large mkt share*

Complexity of Reference Pricing

Spain - ‘Bioequivalent generic competitor’
Ref price 10 - 15% lower than most expensive product
annual revisions
1st year launch within 2 months of market approval to trigger ref mechanism
Average of cluster or reimbursement. Level fixed at or closest

Netherlands - Cluster system (brand & generics)
a) similar therapeutic activity;
b) similar range of indications;
c) no clinically relevant differences e.g. side effects;
d) administered by same route;
e) same age group
Reviewed each time a new product enters

Denmark - Only Synonymous products
Reimbursement level calculated as % of the mean of the two lowest priced products on a DDD basis within ATC

Complexity of Reference Pricing

Germany- Off patent products

a) identical active ingredients
b) pharmacologically & therapeutically comparable ingredients
c) comparable therapeutic effects

Reviewed every year

Italy - Same active ingredients - cheapest reimbursed

Sweden - 'Identical' products off-patent, therapeutically equivalent generics

Cheapest equivalent product available four times a year

Impact of Reference Pricing

- **Brand name products are generally forced to reduce prices to the reimbursement level**

- **Generic products lower maximum reimbursement level**

Impact Of Reference Pricing In Spain

- Brand name products are generally forced to reduce rices to the reimbursement level
- Generic products lower maximum reimbursement level
- Patients can decide whether to pay
- Doctors focus on prescribing not on price
- Drug Interchangeability

Central & Eastern Europe

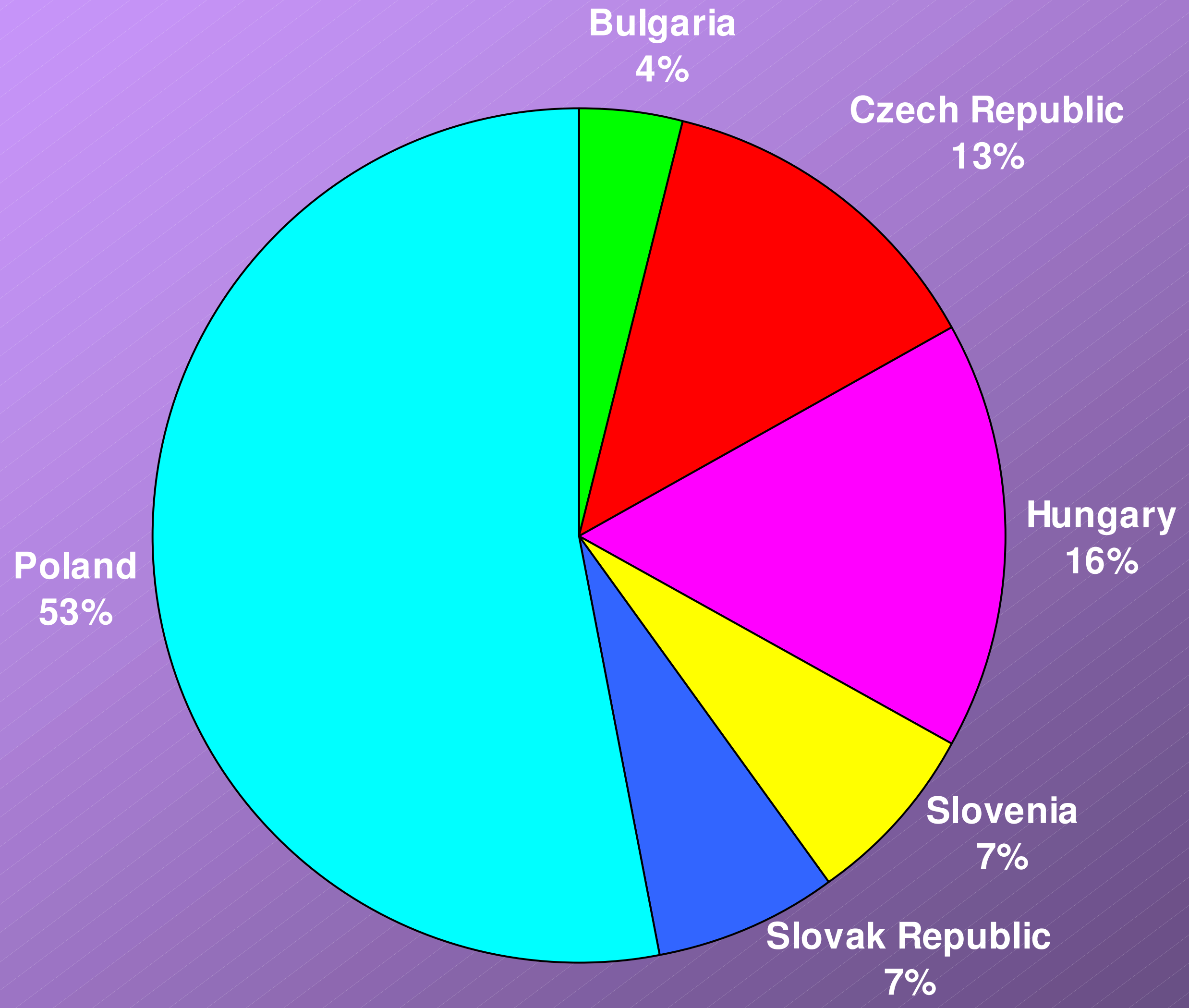
CAGR: 1999 - 2004

7.2% (US$ terms)

Central Europe

	Generic Market Share in Combined CEE Countries		
	MAT Qtr III 97	MAT Qtr III 98	MAT Qtr III 99
Total Retail Market	100.0%	100.0%	100.0%
Unbranded	6.6%	6.2%	5.9%
Other Brand	35.2%	37.6%	38.9%
Licensed + Original Brand	50.0%	52.0%	52.4%
Products not yet classified	8.2%	4.2%	2.8%

Forecast Breakdown of the CEE Total Market Sales at Actual Price (US$) in 2004



East European Pharmaceutical Market (2000-2004) US$ Billion

Country	2000	2004	CAGR 1999-2004
Poland	2.74	4.83	14.8%
Hungary	0.96	1.46	12.6%
Czech Republic	0.85	1.15	8.2%
Romania	0.50	0.67	7.8%
Slovak Republic	0.41	0.67	15.3%
Slovenia	0.38	0.61	13.4%
Bulgaria	0.24	0.40	16.4%
Croatia	0.18	0.25	8.5%
Yugoslavia	0.14	0.15	0.9%
Macedonia	0.11	0.11	0.1%
Total Market Size	6.54	10.33	12.4%

CIS Pharmaceutical Market (2000-2004) US$ Billion

Country	2000	2004	CAGR 1999-2004
Russian Federation	1.10	1.43	6.7%
Ukraine	0.18	0.20	2.5%
Lithuania	0.10	0.12	4.2%
Latvia	0.09	0.10	4.1%
Estonia	0.05	0.05	3.6%
Kazakhstan	0.03	0.03	2.7%
Belorussia	0.03	0.03	1.6%
Uzbekistan	0.02	0.02	1.2%
Georgia	0.02	0.02	4.0%
Azerbaidzhan	0.01	0.01	1.6%

Central & Eastern Europe Healthcare Environment

- Healthcare spend remains well below EU/OECD average except in Czech, Hungary/Slovenia
- Pharmaceuticals account for over 20% of healthcare spend
- Govts committed to healthcare reform with Poland most advanced and Bulgaria furthest behind
- Markets dependent on health insurance funds & direct govt subsidies for funding but health insurance collection remains problematic as is management of funds
- Pricing & reimbursement systems are over-complex, bureaucratic and lack transparency
- No retroactive product patent protection

Per Capita Sales (US$)

Country	1999	2004	CAGR 1999-2004
Bulgaria	22.3	49.2	+17.1%
Czech Republic	75.3	112.5	+8.4%
Hungary	80.2	148.1	+13.1%
Poland	62.5	124.1	+14.7%
Slovak Republic	60.9	123.3	+15.1%
Slovenia	161.9	306.1	+13.6%

Central & Eastern Europe
Key Events Impacting Future Growth

- Reimbursement listing policies
- Price controls
- Increasing copayments
- Stricter hospital budgets
- Prescribing controls such as guidelines, treatment protocols

Generics - Future Situation

- Volume sales will increase significantly driven by:
  - Govt policies such as substitution and prescribing guidelines
  - Patent Expiries

- Growth in value terms will be constrained due to:
  - Price competition
  - Govt pricing initiatives such as reference pricing
  - New competitors in the most attractive markets, eg Canada and the UK and low-priced competitors from India and South East Asia

Generics - Future Situation

- **Retail growth for major generics markets (1999-2004) is forecast to grow at 12% CAGR to US$ 30.5 bn in 2004**
- **Of the leading 35 molecules world-wide in US$ terms, 13 will lose their patent protection over the next five years**
- **Major patent expiries during the period in all major therapy classes:**
  - Central Nervous System (Anti Depressants - SSRIs)
  - Cardiovascular System (Ace Inhibitors)
  - Alimentary Tract (Proton Pump Inhibitors)
  - Respiratory System (Antihistamines)

IMS HEALTH

Thank you!

Graham Lewis

Vice President

Strategic Consulting

email:
glewis@uk.imshealth.com
phone: +44 (0)20 7393 5208
Fax:
+44 (0)20 7393 5266