



*Making Medicines Affordable*

EUROPEAN GENERIC MEDICINES ASSOCIATION

# Eastern Europe and the Balkans

Istanbul, 15<sup>th</sup> June 2007

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Chair EU Accession Committee EGA

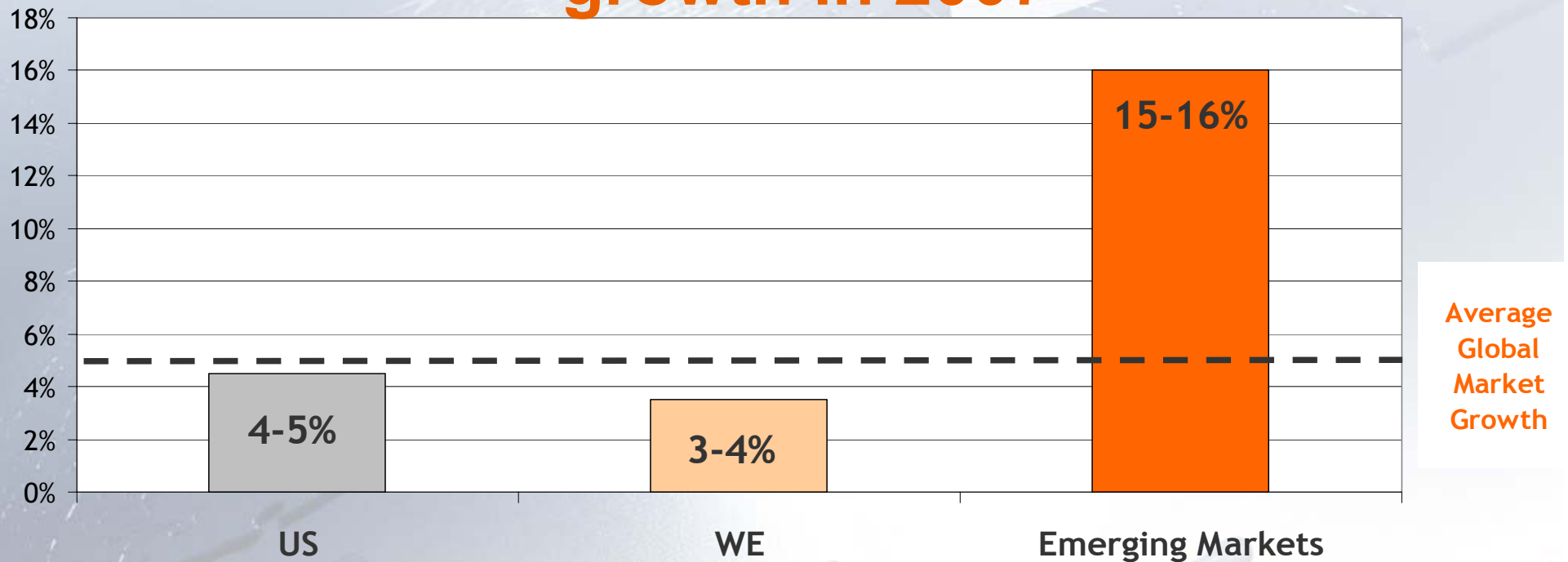
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# CEEA Opportunities 2007



## Global pharmaceutical market growth in 2007

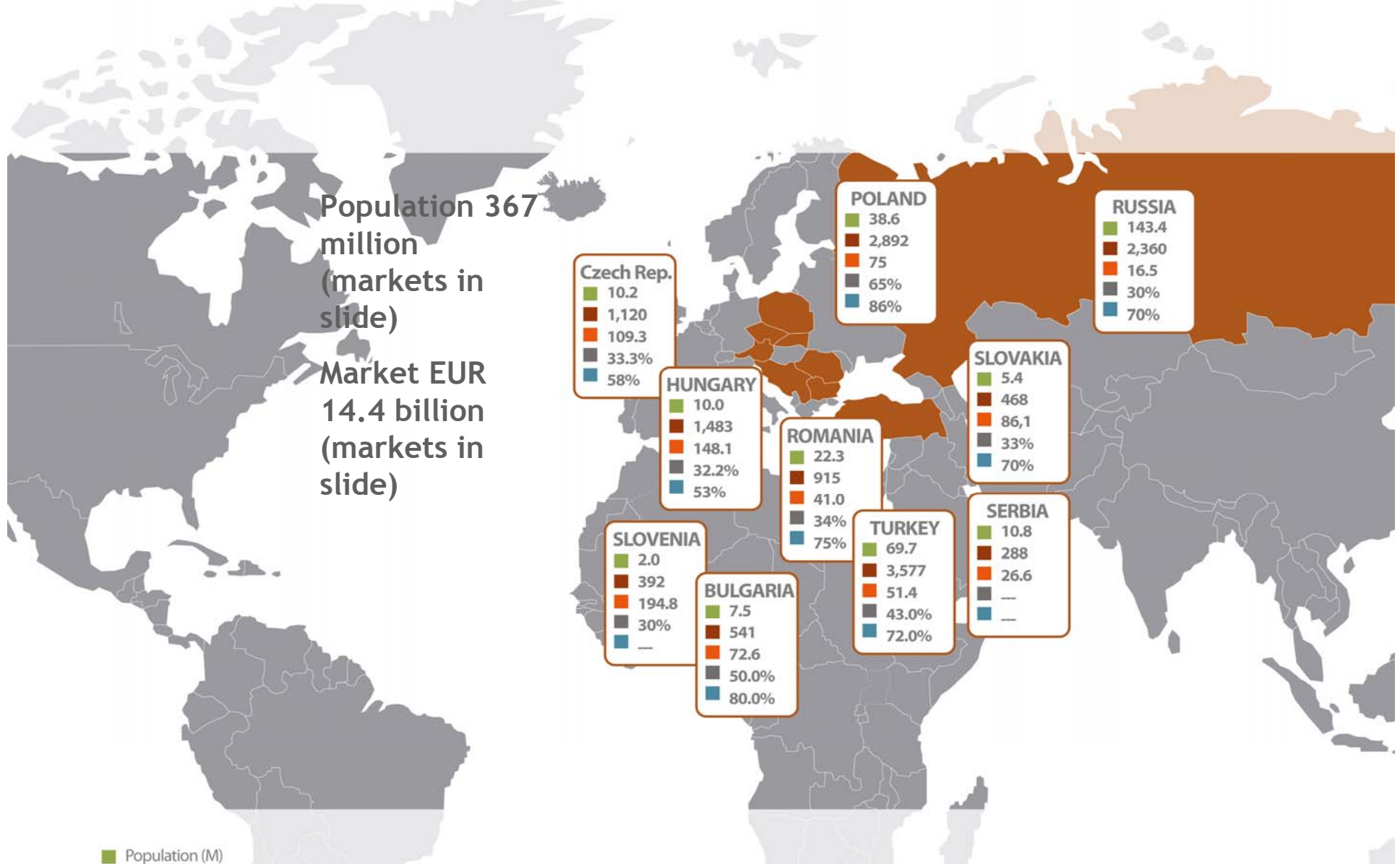


Source: IMS Health, Forecast of Global Pharmaceutical Market in 2007



# Market dynamics

## CEE



# CEE and the Balkans – diversity and high-growth perspectives

## Regulated Markets

### Romania, Bulgaria

- EU members since 1<sup>st</sup> Jan, 2007
- Consolidated local pharma industry. Well established direct foreign presence.

## Markets in transition

### Turkey, Croatia

- Applied for EU accession.
- Domestic industry in active stage of consolidation. Establishing of direct foreign investments.

## Developing markets

### Ukraine, Albania

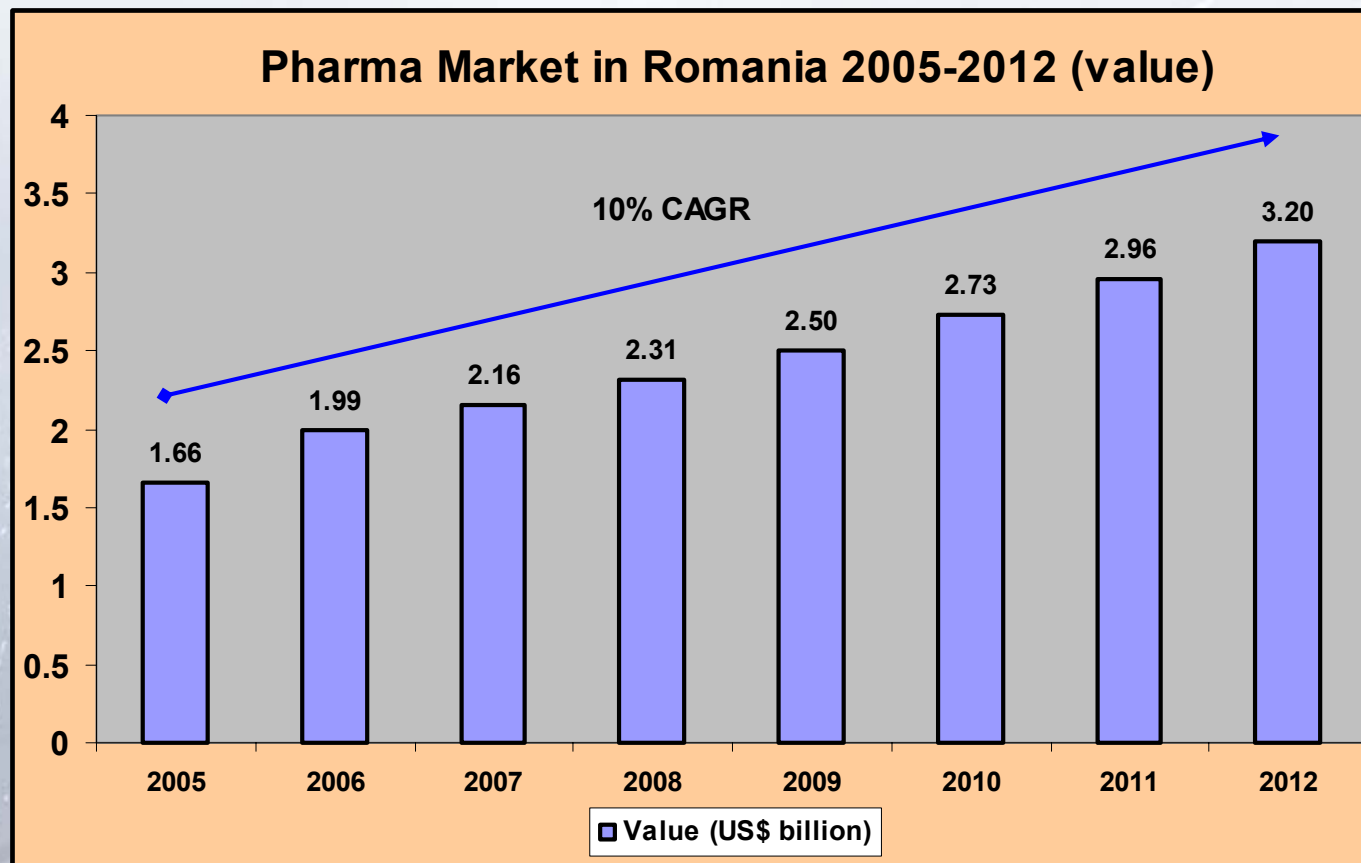
- Low degree of regulation. Highest growth expectations.
- Local industry in early stage of consolidation. Lack of direct foreign investments.

# Romania: key facts

- Population: 21.2 million (2006E)
  - 445 hospitals.
  - 44,500 medical doctors (2.1 doctors per '000 population).
  - Wholesale market fragmented (first 25 control four-fifths of the market).
  - 5500 pharmacies (privately – owned).
  - Products currently marketed in forms.
-



# Romania – pharma market (1)



- Romania placed at #1 spot on BMI's Q2'07 '*CEE Business Environment Ranking*'.
- Robust growth opportunities and competitive environment driven by key focus of big multinationals and direct generics presence.

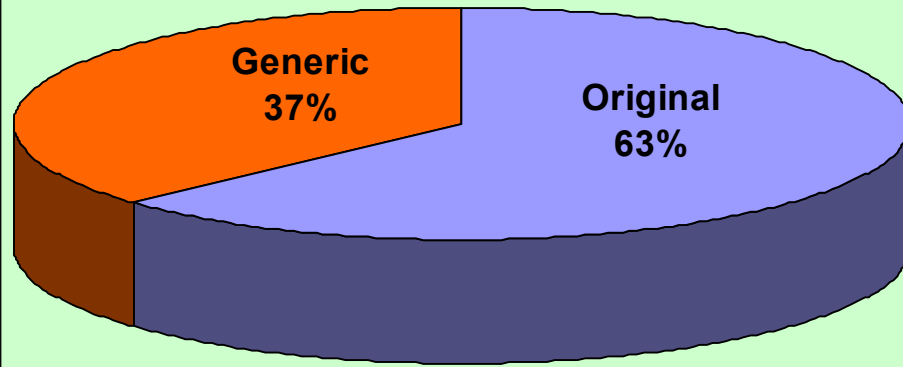


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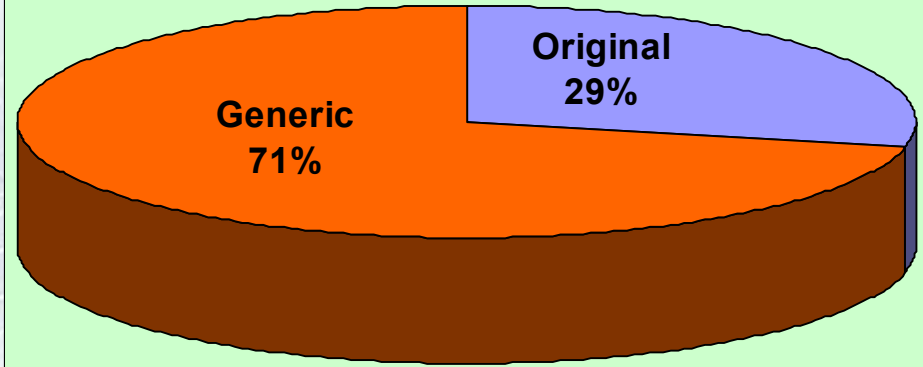
# Romania – pharma market (2)



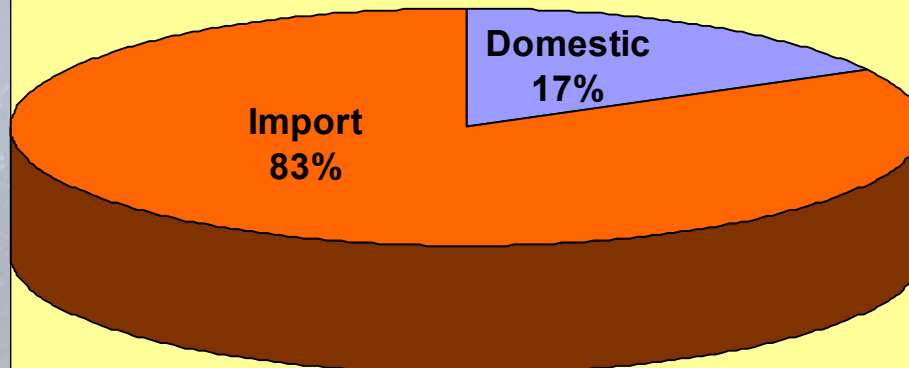
Generic penetration (value, 2006A)



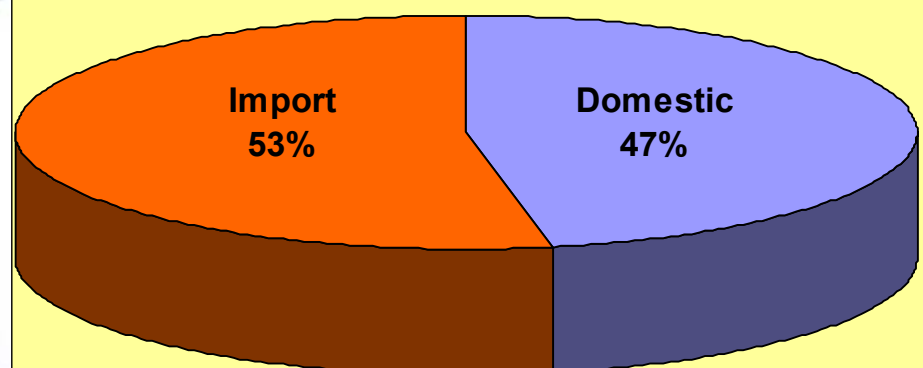
Generic penetration (volume, 2006A)



Share of domestic producers (value, 2006A)



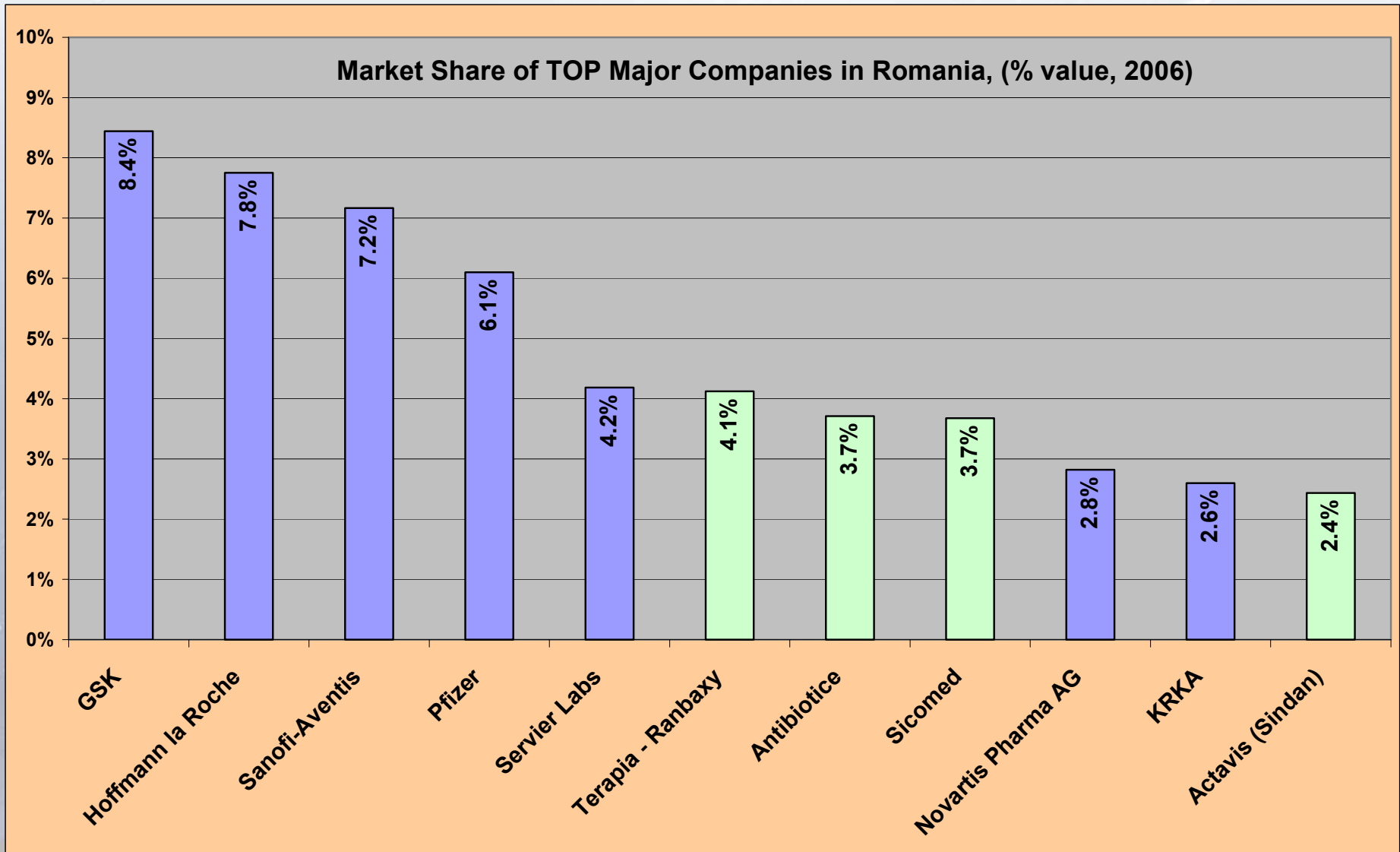
Share of domestic producers (volume, 2006A)







# Romania – leading companies



Source: IMS Health (Romania) (MIS)



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# Romania – top INNs



Rank*	TOP 10 INN (general)	Value MNF EUR 2006	Units 2006	Originator / Generic sales
1	Erythropoietinum	29,587,337	80,239	No generic sales
2	Insuline	21,833,009	1,046,760	No generic sales
3	Peginterferon alfa-2a	21,486,864	113,416	No generic sales
4 (1)	Simvastatin	20,343,334	3,178,446	Originator + generic
5 (2)	Amoxicillin + Clavulanic acid	16,744,465	2,655,669	Originator + generic
6	Olanzapin	16,088,828	194,593	No generic sales
7 (3)	Trimetazidin	16,068,818	3,078,497	Originator + generic
8 (4)	Indapamid	15,506,499	4,976,507	Originator + generic
9 (5)	Enalapril	15,036,490	11,324,733	Originator + generic
10 (6)	Metamizolum natricum	14,439,223	21,416,888	Originator + generic
11 (7)	Ginkgo biloba	14,313,203	3,598,478	Originator + generic
12 (8)	Omeprazol	13,884,137	4,251,335	Originator + generic
13 (9)	Ibuprofen	12,696,589	7,617,031	Originator + generic
14 (10)	Ketoprofen	12,322,143	5,129,330	Originator + generic

\* absolute rank / (INN going generics rank)

Source: IMS Health (Romania) (MIS)

# Romania – top 10 generic INNs

TOP 10 INN (generic sales only)	Value MNF EUR 2006	Units 2006
Simvastatin	19,690,490	3,138,790
Metamizol natriicum	14,439,223	21,416,888
Enalapril	14,334,773	11,127,841
Ampicillin	10,985,469	21,130,945
Amoxicillin	8,266,318	8,184,499
Ceftriaxon	8,245,916	2,045,051
Ketoprofen	8,182,381	3,970,884
Docetaxol	8,135,294	21,460
Ginkgo biloba	7,791,289	2,173,544
Omeprazol	7,250,858	2,690,303

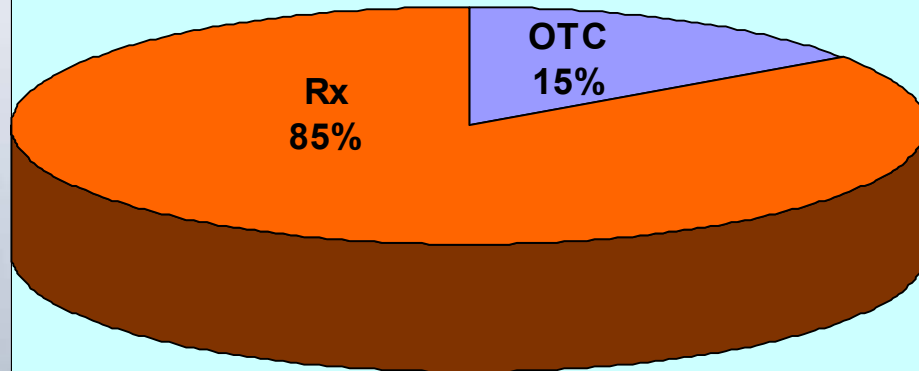


# Romania – pharma market

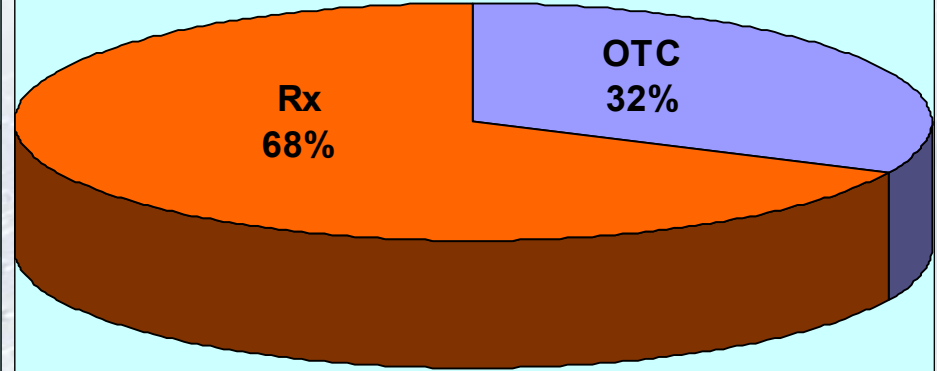


## (3)

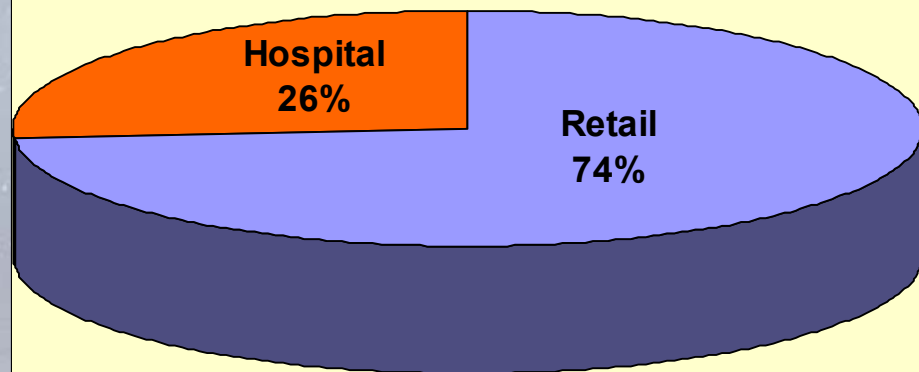
Rx vs. OTC (value, 2006A)



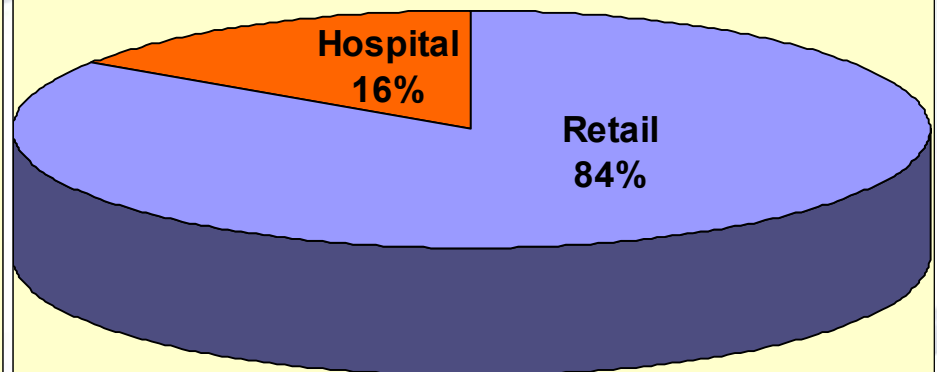
Rx vs. OTC (volume, 2006A)



Retail vs. Hospital market (value, 2006A)



Retail vs. Hospital market (volume, 2006A)





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# Romania – key growth drivers

- EU accession on 1<sup>st</sup> Jan, 2007 is the key factor for robust growth (as per BMI's forecast 7-8% annually in 2008-2012).
  - Stable business environment, boosting economy and rising real income.
  - EU common registration procedure to facilitate access of foreign companies.
  - Generic market growth further fostered by recent direct investments made by ACTAVIS (Sindan) and Ranbaxy (Terapia) – providing access to one of the world's largest generic industry portfolios (ACTAVIS) and supply of cheap pharmaceuticals coupled with expansionist growth strategy.
  - Possibility for increased parallel trade as part of the world's largest single market.
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# Romania – major hurdles

- Slow and erratic debt repayment
- Continued problems in financing state hospital drug purchasing
- Possible introduction of prescribing restrictions
- High costs associated with the modernization of the healthcare system



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# Romania – recent developments with a view to EU membership



- Medicine prices will further decrease in 2007 due to pressure from the MOH and the financial crisis in the insurance system
- Recent acquisitions will boost local production and rise the weight of the domestic products
- Simplified drug registry procedures will determine a surge in the number of new medicines



# Romania and Bulgaria – M&A perspectives (1)



**Romania** – industry consolidation and acquisitions of local players almost completed:

## I. Domestic manufacturers transactions overview:

- 51% of **Armedica S.A** acquired by Gedeon Richter in 1998 under state privatization. Acquisition completed in 2003 by taking it private as *Gedeon Richter Romania S.A.*
- 90% of **PharmaTech** acquired by Lek, Slovenia in 2001
- **Europarm** acquired by GSK in 2003 (full control)
- 51% stake in **Sicomed** acquired by ZENTIVA in Oct, 2005 (US\$ 102 mln). Increased share to 74.9% through a public buy-out offer in 2006.
- **Sindan** acquired by ACTAVIS in Mar, 2006 (EUR 147.5 mln)
- **Terapia** acquired by Ranbaxy in Mar, 2006
- **Antibiotice S.A** – the only major state-owned company left with ca. 3.7% MS. Privatization process delayed several times already, expected to complete 2H'2007/1Q'2008. Big interest from local and multinational generic players and fierce bidding war envisaged.

## II. Domestic wholesalers & retail sector transactions overview:

- 60% stake in **Farmexpert S.A.** (distributor) acquired by Andrae-Noris AG.
- **Bioplus-Pharma** (retailer) acquired by Gedeon Richter in Nov, 2006.
- **Dita Group** (3 domestic wholesaler companies) acquired by Gedeon Richter in Dec, 2006 – the deal followed the earlier acquisition of distributor **Sibofarm S.A.**
- **A&D Pharma Group** controlled by Sograno (consists of distributor **Mediplus** and pharmacy chain **Sensiblu**) is listed on the London Stock Exchange in 2006.
- **With highly fragmented distribution market and more than 50 active distributors, further consolidation is expected in the distribution/retail sector.**





# Romania and Bulgaria – M&A perspectives (2)



**Bulgaria** – industry consolidation and acquisitions of local players almost completed:

- Domestic manufacturers transactions overview:
  - Privatization of the state-owned manufacturing industry started in 1999 by selling the 3 biggest pharma plants **Balkanpharma-Dupnitsa**, **Balkanpharma-Troyan** and **Balkanpharma-Razgrad** to **Actavis Group**.
  - **Unipharma AD** merged with **Sopharma EAD** and later with **Pharmachim EAD** and **NIHFI** (local horizontal merger).
- Domestic wholesalers transactions overview:
  - **Higia AD** (major local distributor) acquired by **ACTAVIS Group** in 2005.
  - **Libra AD** (2<sup>nd</sup> biggest distributor) acquired by **Phoenix** in 2005.
  - **Sanita** and **Kaliman** (distributors) acquired by **Sopharma** in 2005.
- Several smaller independent local manufacturers and distributors are still operating independently on the Bulgarian market.
- **Further consolidation is expected in the distribution/retail sector in Bulgaria.**

# Bulgaria: key facts

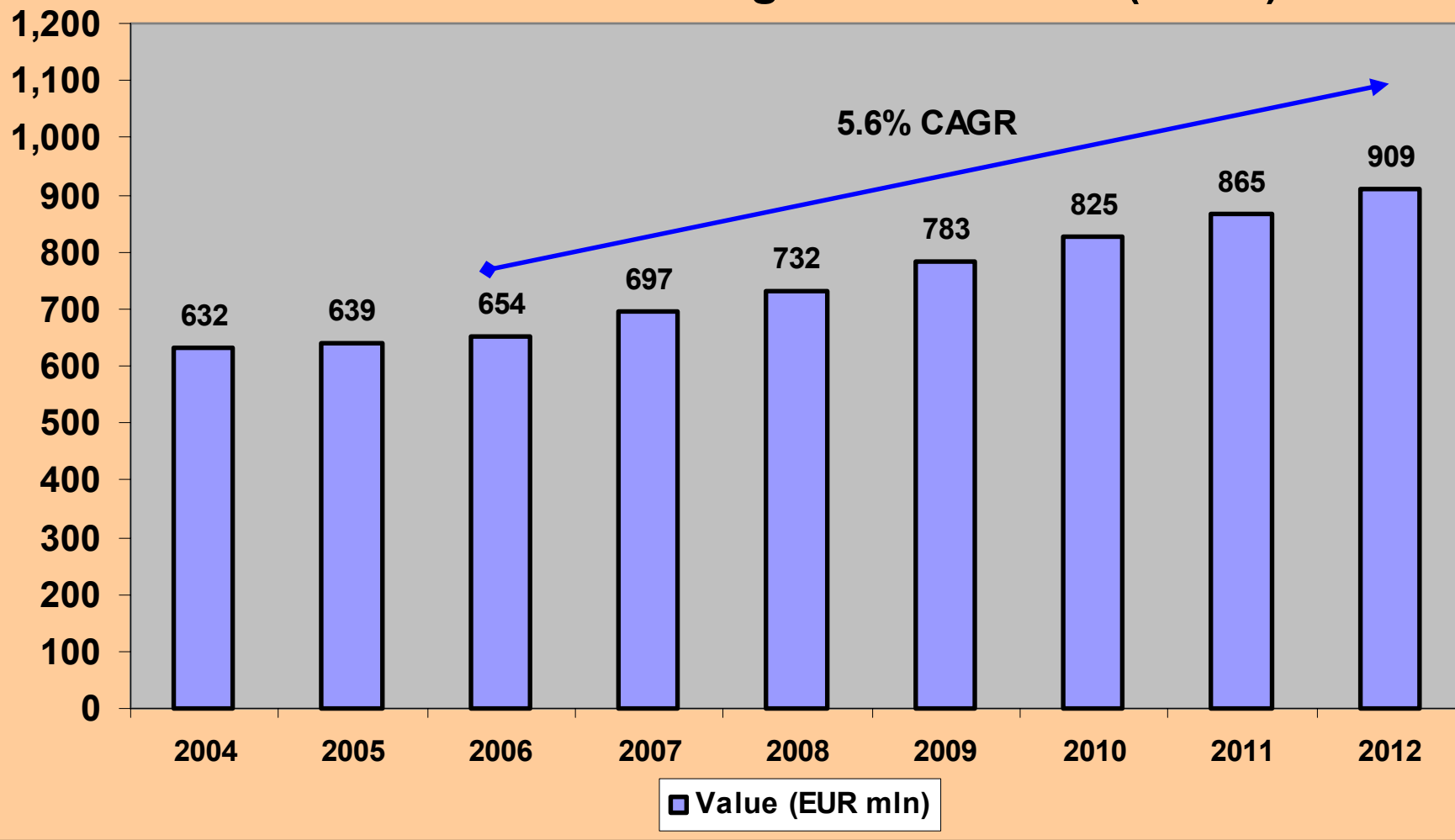
- Population: 7.7 million (2006E)
  - 290 hospitals
  - Ca. 44,000 medical doctors (5.2 doctors per '000 population).
  - 300 registered distributors (10 major).
  - 4,446 pharmacies (3 large chains, 90 small).
  - 3 major local producers and few other small
  - 23 foreign producers with >1% market share
  - 1,710 INNs marketed under 3,422 brands and 7,067 different forms
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# Bulgaria – pharma market (1)



## Pharma Market in Bulgaria 2004-2012 (value)



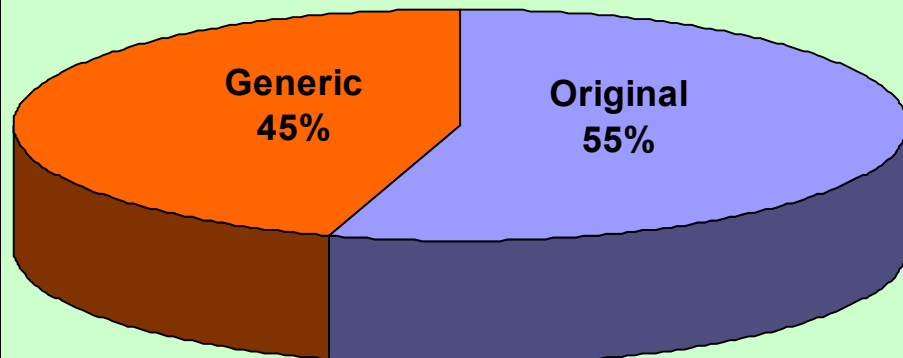
Source: IMS Health (Bulgaria), BMI forecast and Actavis estimates



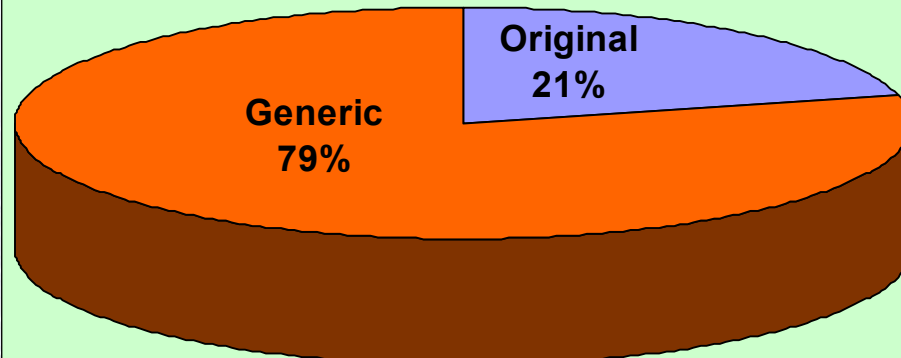
# Bulgaria – pharma market (2)



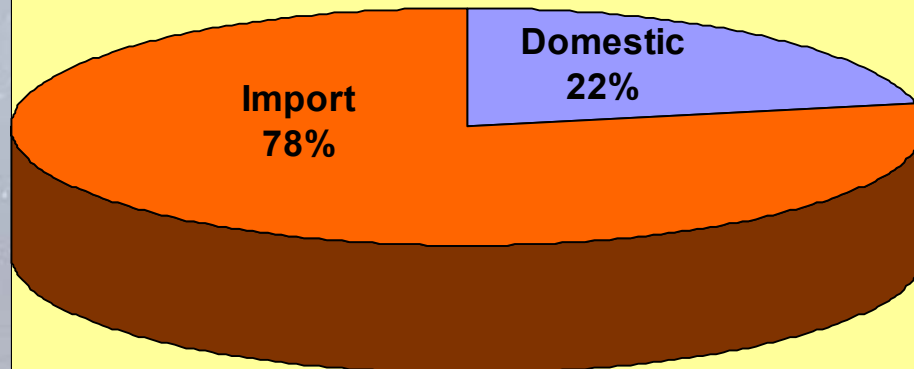
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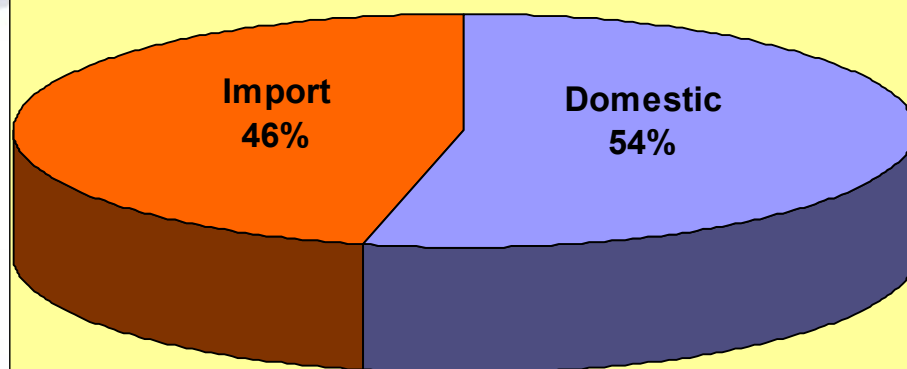
Generic penetration (volume, 2006A)



Share of domestic producers (value, 2006A)

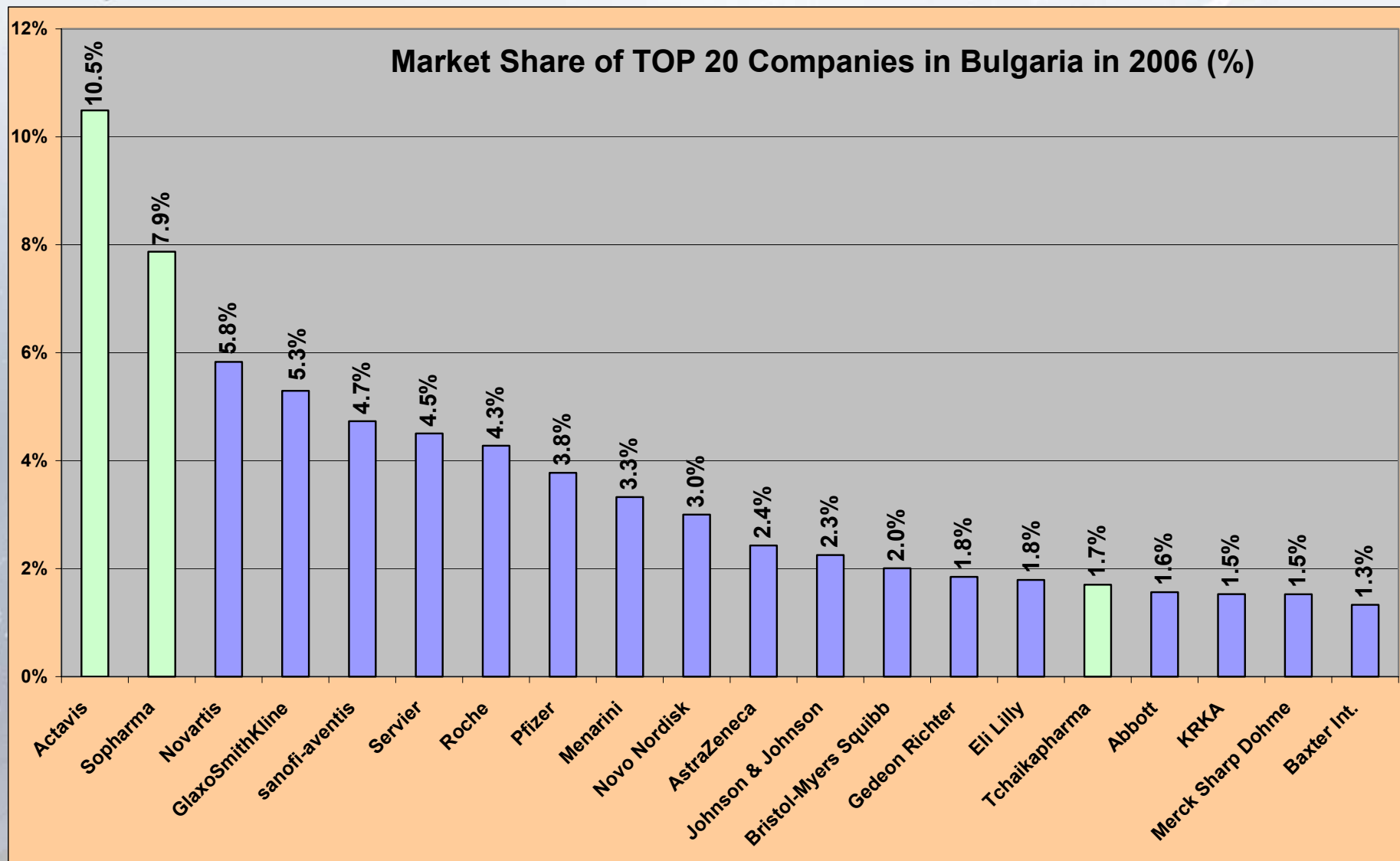


Share of domestic producers (volume, 2006A)





# Bulgaria – top 20 companies



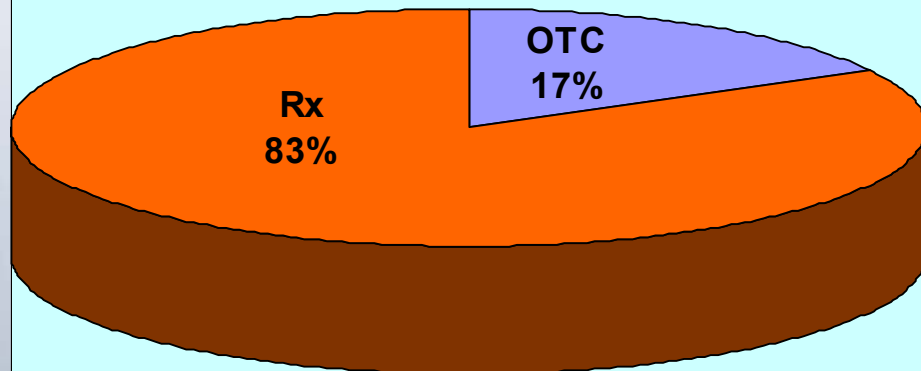
Source: IMS Health (Bulgaria)



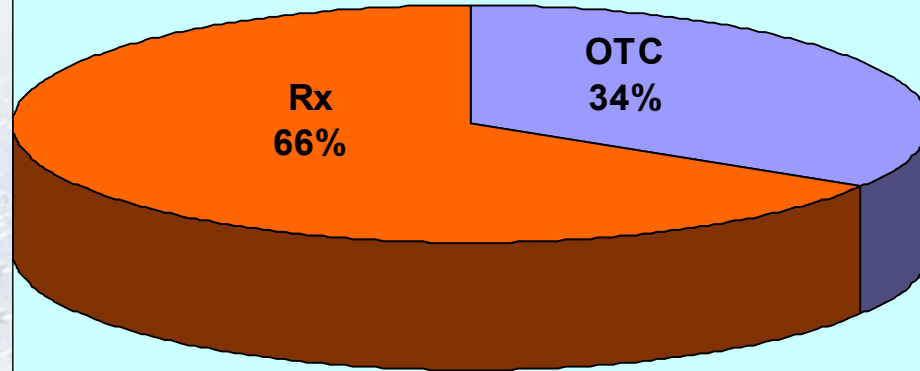
# Bulgaria – pharma market (3)



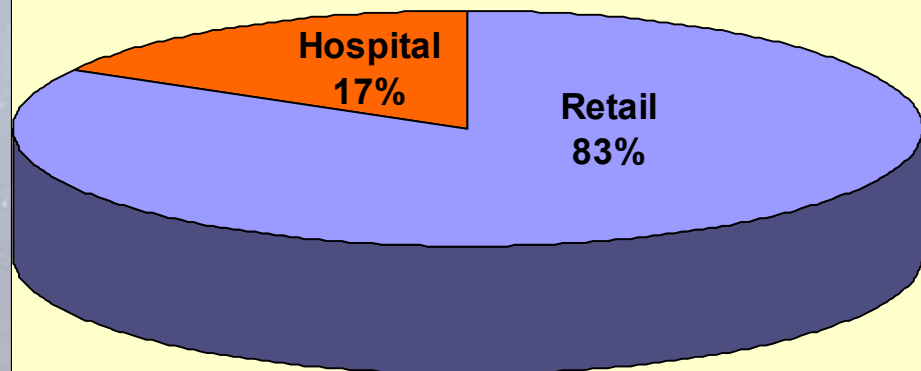
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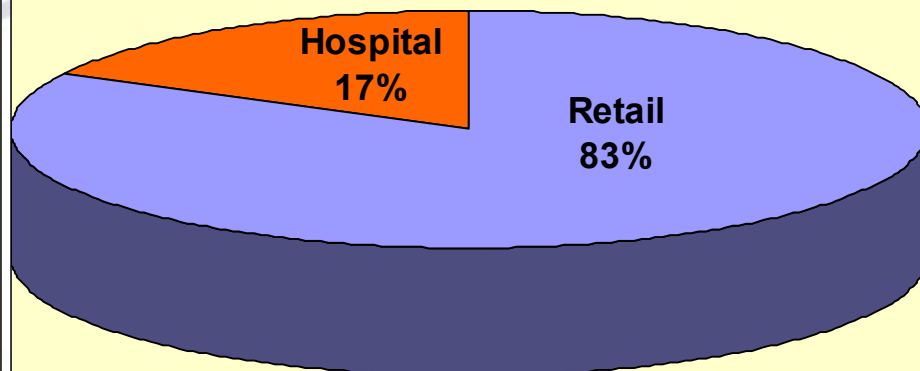
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**Retail vs. Hospital market (value, 2006A)**



**Retail vs. Hospital market (volume, 2006A)**





# Bulgaria – key growth drivers

- EU accession on 1<sup>st</sup> Jan, 2007 is the key factor for robust growth
  - Stable business environment, boosting economy and rising real income.
  - Favorable local taxation increasing investment's growth.
  - Political stability
  - EU common registration procedure to facilitate access of foreign companies.
  - Developed distribution system
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# Bulgaria – major hurdles



- Economically active population – only 3,45 mln (44,8%)
  - 2,7 mln pensioners combined with ineffective reimbursement system
  - Low income/high emigration
  - Continued trend of price erosion
  - Life expectancy – only 64,4 years
  - Low budget expenses for health care and medicines (4,5% of GDP)
-





# Bulgaria – recent developments



- In 2007 Bulgaria was removed from the USTR Report 'Special 301' listing countries that constantly violated IP rights.

# Romania and Bulgaria – M&A perspectives (1)

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# Croatia: key facts

- Population: 4.5 mln (2006E)
  - Stable GDP growth at 4% y-o-y.
  - Drug expenditure per capita: EUR 100 in 2006
  - 91 hospitals
  - Ca. 9,000 medical doctors (2.0 doctors per '000 population).
  - 130 pharmaceutical companies active on the market
  - 2 domestic companies – Pliva and Belupo hold ca. 1/3 of the market.
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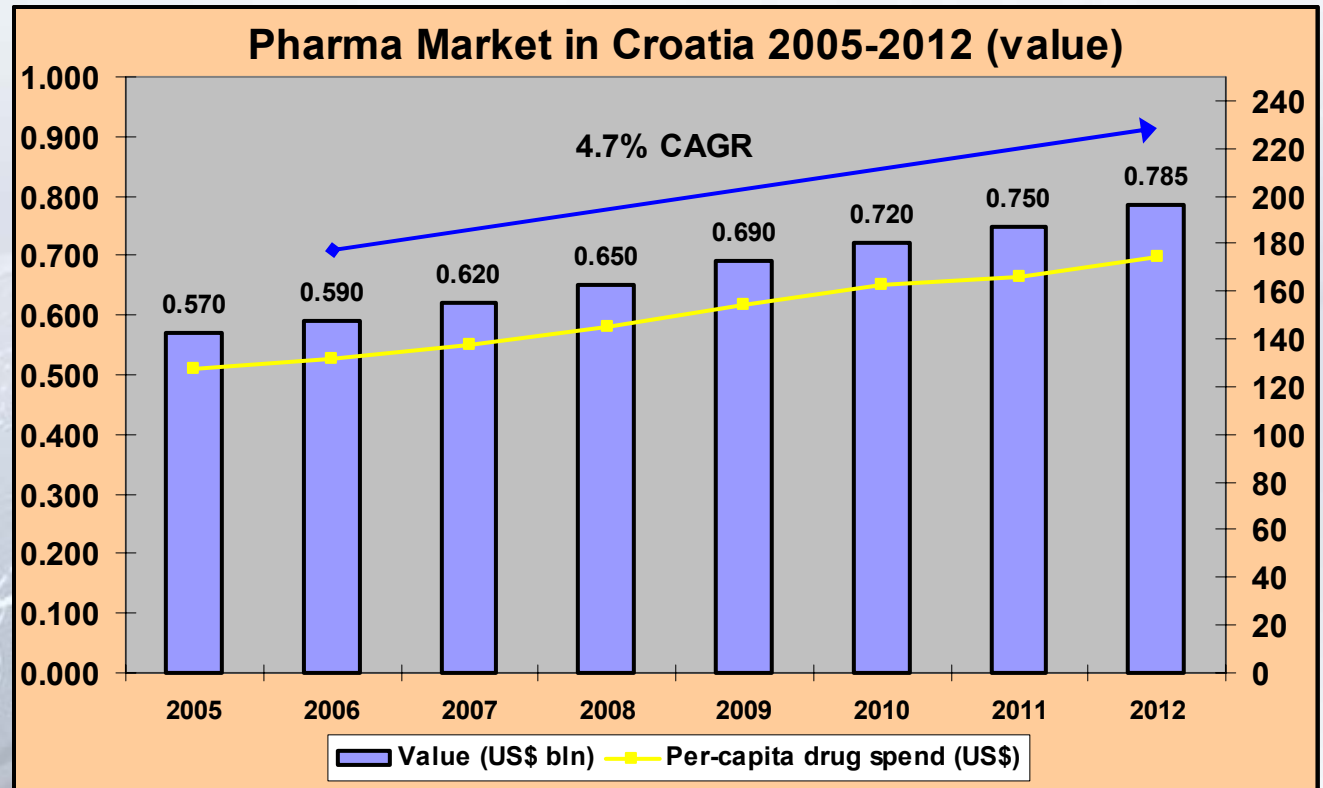
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# Croatia – pharma market (1)



- Moderate market growth expectations at 4-5% CAGR.

- High-growth period in 1998-2003 is over (market grew at 10-15% y-o-y).



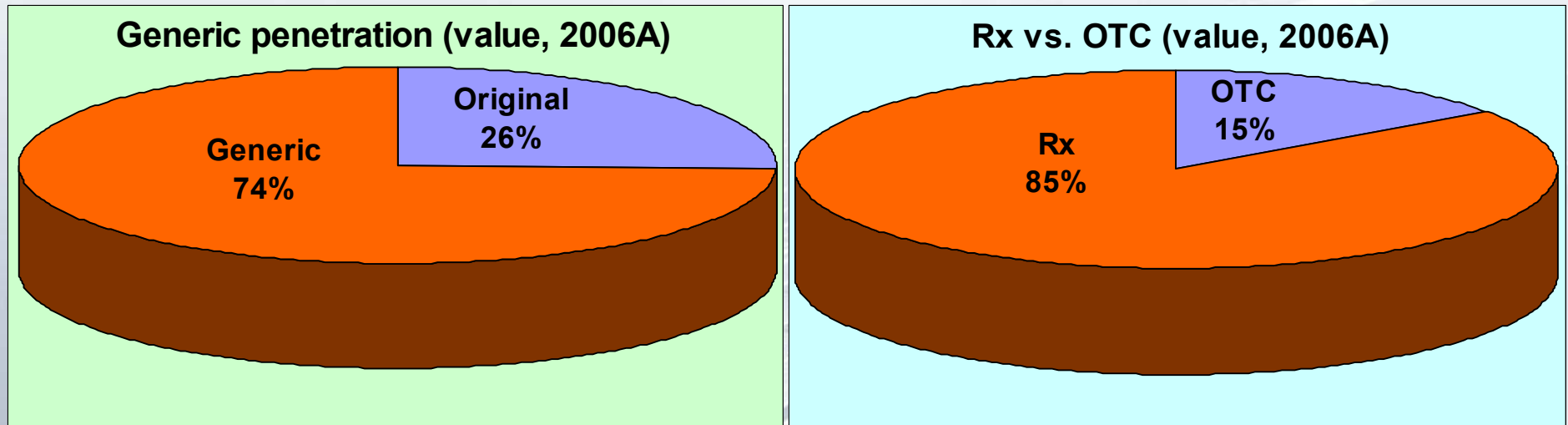
- Shrinking market share of domestic leader Pliva – dominating the market with MS of 50% several years ago to MS of just 20% in 2006. Reasons: competition by new market entrants and strategic orientation of Pliva towards export markets.

- Still limited presence of big multinationals due to historically unfavourable regulatory regimen and IP deficiencies.



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## Croatia – pharma market (2)



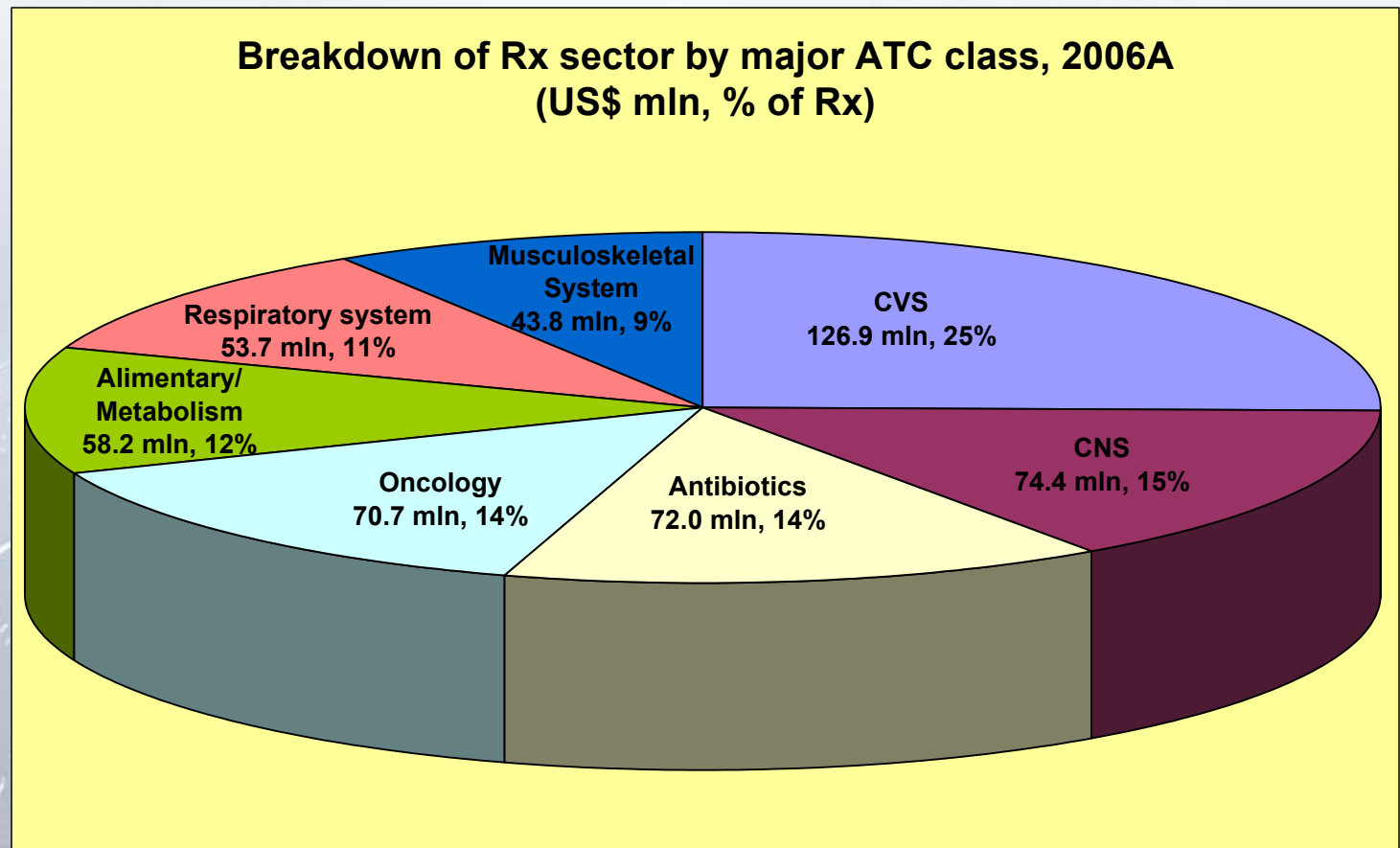
**Extraordinary high generic penetration (comparable to Russia and Ukraine only), due to:**

- **Strong local manufacturing industry combined with government protection of the sector**
- **IP deficiencies forcing big multinationals to protect their innovative drugs by not launching in Croatia.**

**Average prices of generics are only 5% cheaper than original drugs!**



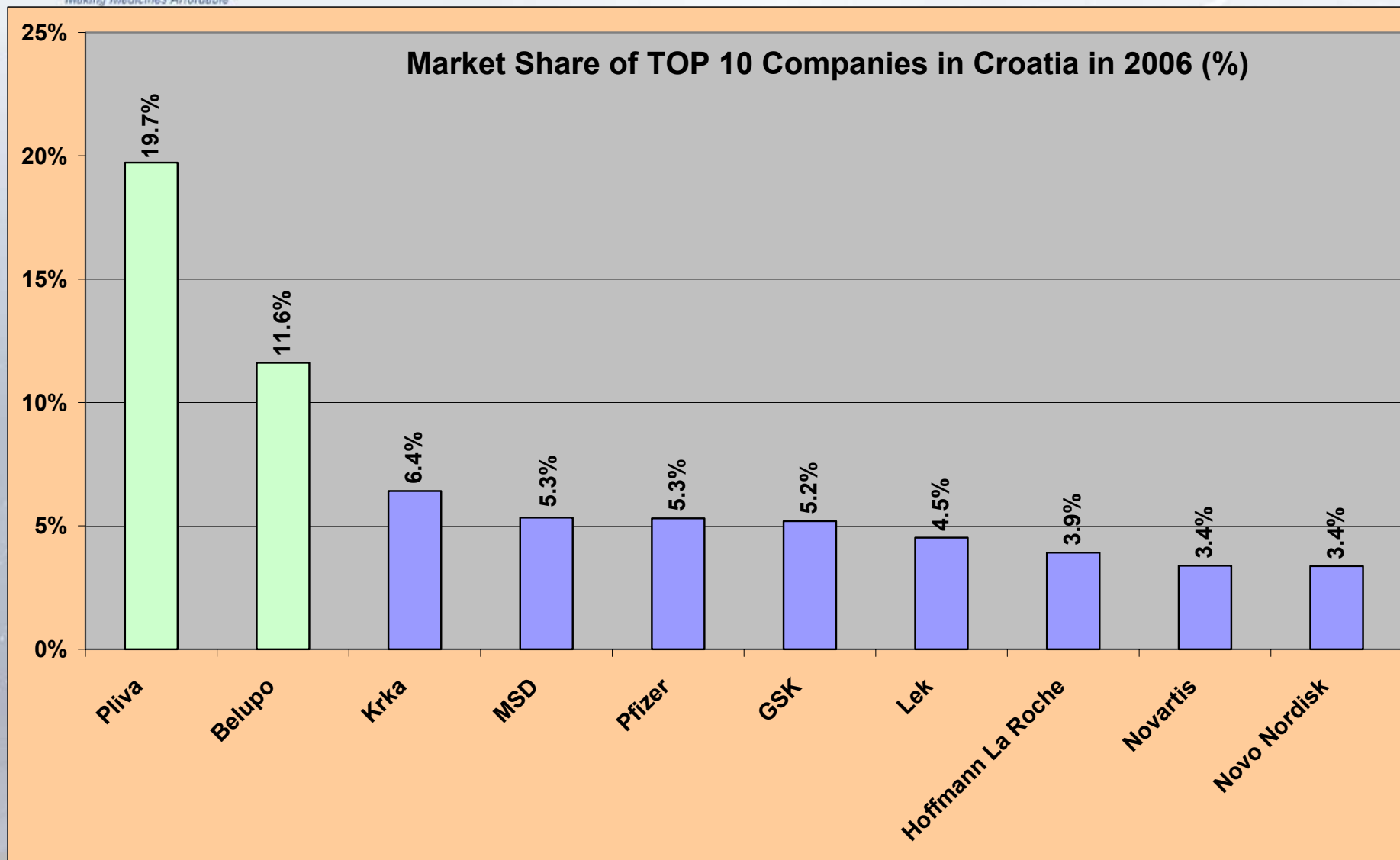
# Croatia – pharma market (3)



- Drug market profile of a mature market, dominated by CVS and CNS.
- CVS account for  $\frac{1}{4}$  of Rx market, reflecting the country's health profile.
- Further growth driven by constant update of the reimbursement lists, including innovative expensive drugs and modern treatments. *Source: BMI Report*



# Croatia – top 10 companies



Source: IMS Health (Croatia)





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# Croatia – top 10 INNs dynamics



Rank	INN	2005 Sales (EUR)*	2006 Sales (EUR)*	% change
1	Amlodipin	14,846,179	15,311,871	+3%
2	Atorvastatin	12,911,969	15,078,441	+17%
3	Simvastatin	16,229,451	14,011,543	(14%)
4	Lizinopril + hidrochlortiazid	14,191,941	13,457,305	(5%)
5	Salmeterol + Flutikazone	7,592,988	9,626,015	+27%
6	Alendronic acid	9,751,176	9,448,370	(3%)
7	Pantoprazole	7,319,135	9,316,041	+27%
8	Amoxicillin + clavulanic acid	11,091,572	8,954,382	(19%)
9	Olanzapine	6,630,891	8,031,446	+21%
10	Diclofenac	8,147,045	7,565,693	(7%)

Source: IMS Health (Croatia)



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# Croatia– key growth drivers



- Well developed local industry, stable business environment (*sustainable real GDP growth, low inflation and stable exchange rate*), rising real income.
  - Largely ‘western’ type demographic and decease profile, and drug use typical for a developed market.
  - Health reform measures aimed at creating a base for sustainable long—term market growth.
  - Strong and relatively low-cost production base and a skilled workforce in the sector.
  - EU candidate status stimulating a rapid improvement in the regulatory environment.
  - Sustainable high share of generics sector fostered by government attempts to reduce healthcare debts and patent expirations.
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# Croatia – major hurdles



- Government drug pricing and reimbursement policy focused on cutting prices and spending.
  - Still strong government protection of domestic industry.
  - Implementation of import tariffs on drugs in 2005.
  - Inadequate enforcement of intellectual property rights.
  - Data exclusivity period still at six years.
  - Price cuts and growing distortion in the supply chain as payment continue to be delayed.
  - Severe healthcare debt due to extensive reimbursement lists (with expensive modern drugs present) and inadequate hospital spending.
-



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# Croatia – recent developments



- Active steps towards harmonization with EU regulations in healthcare.
  - In 2007 Croatia was removed from the USTR Report 'Special 301' listing countries that constantly violated IP rights.
  - Domestic market-leader Pliva taken-over by Barr in 2006.
  - GSK acquired Pliva's R&D center in Zagreb.
  - New reimbursement and price policy aimed at cutting costs.
  - Active government actions aimed at decreasing healthcare debt – a '*control committee*' created to audit hospital spending and tighten management.
  - As Croatia continues to prepare for the EU accession (2010), IP and regulatory regimes gradually streamlined, providing new incentives for big multinational players.
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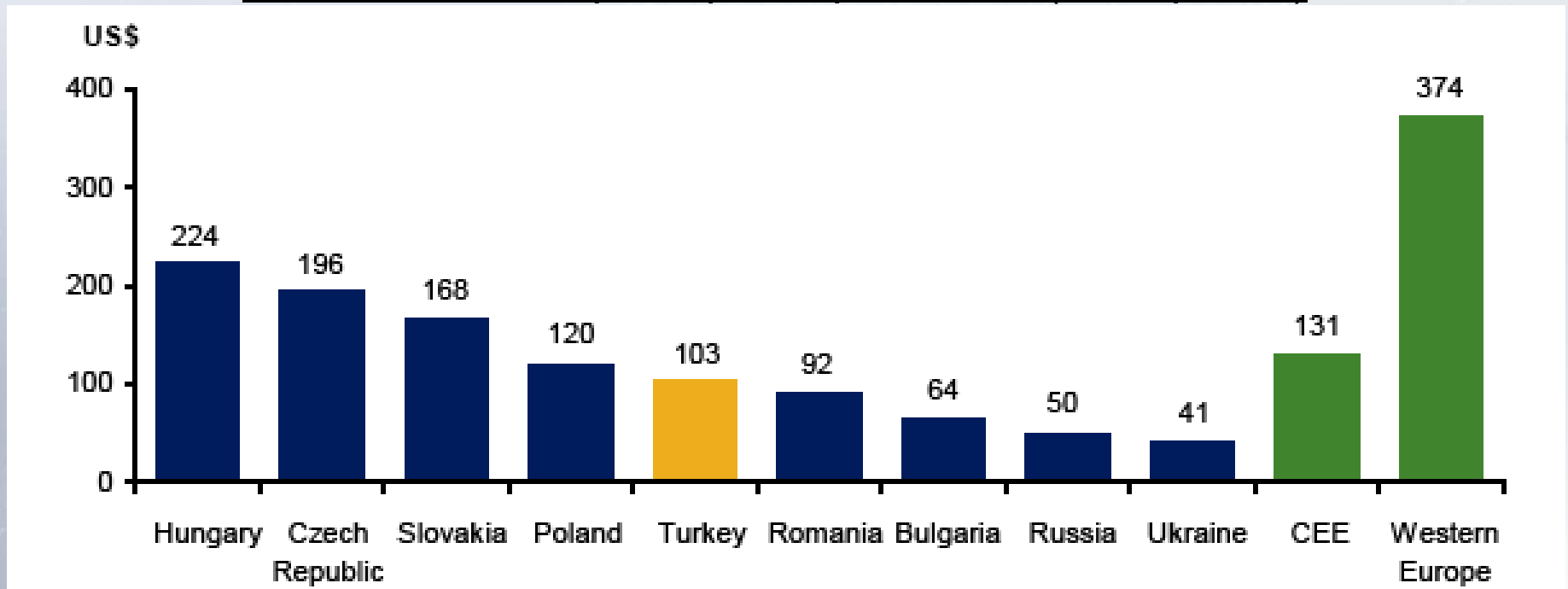
# Turkey: key facts



- **Population: 74 mln**
- **Ca. 12,000 village health stations, 6,000 district health centres and 1,250 hospitals, most of which are concentrated in urban areas.**
- **95,000 medical doctors, of which about half are GPs.**
- **Two dominant wholesalers – *Hedef Alliance* and *Selçuk Ecza*, accounting for over 70% of the market.**
- **21,400 retail pharmacies in Turkey. Each pharmacist may own only a single pharmacy, resulting in the absence of pharmacy chains.**

# Turkey - pharmaceutical spend per capita

Pharmaceutical spend per capita, 2006 (MNF prices)

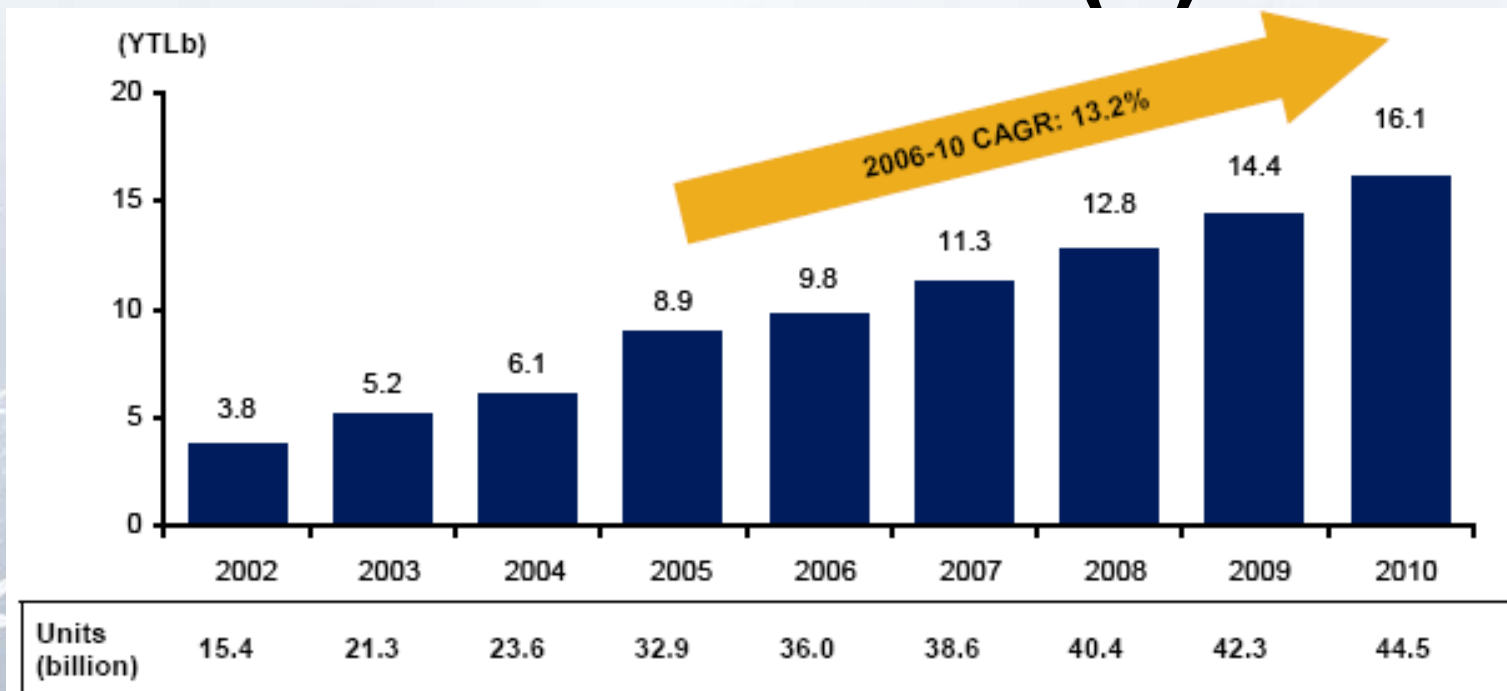


- **Pharmaceutical spend per capita in Turkey was 78% of CEE average and only 28% of Western European average in 2006.**
- **The difference is expected to decline based on economic and demographic factors.**

# Turkey – pharma market



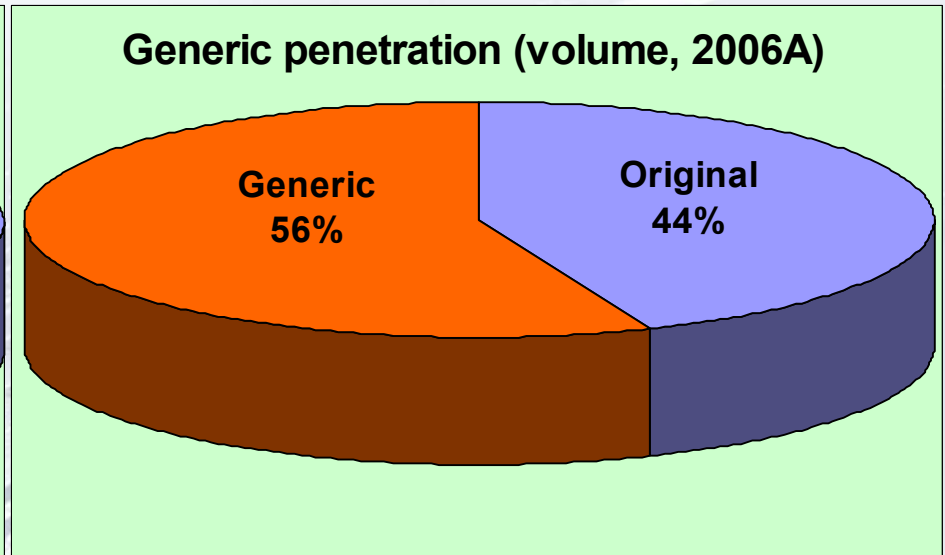
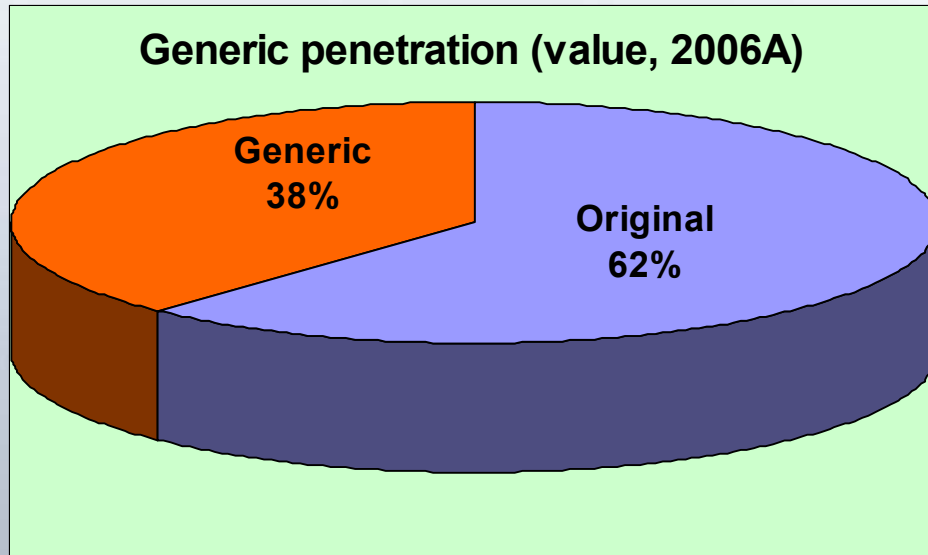
## (1)



- Between 2002 and 2006, Turkey was among the fastest growing pharmaceutical markets in the region, achieving 22% annual growth.
- The high growth is coupled with a large market opportunity represented by a population of approximately 74 million people, making Turkey one of the largest and most important pharmaceutical markets in the region.
- IMS Health forecasts the retail pharmaceutical sector to grow at 13.2% on an annual basis between 2006 and 2010.



# Generics market in Turkey



## Turkey is a branded generics market.

- Generics sales are supported by strong promotional activities and priced at lower discounts to the originator drugs than in a classical generic market.
- The generics segment is largely dominated by local companies.
- Growth of the generic market is expected, due to the ongoing reforms and the commitment of the Government to the efficient use of the healthcare budget.





# Turkey – prescribing and reimbursement



- Doctors are restricted to prescribing no more than four drugs at any one time (a reduction from five since February 2005).
  - A specialist-only prescription reimbursement list (to be used by the GHIS) enacted in Dec, 2005 and includes drugs such as *ceftriaxone*, *citalopram* and *mirtazepine*. Currently, about a quarter of all prescriptions are written by specialists.
  - Prescribing done by brand name and not by INN. The only exception is unbranded generic oncology drugs (have a 40% INN prescription rate).
  - Pharmacists are able to substitute a prescribed product with an equivalent generic product, provided that the generic is reimbursed and is less expensive than the prescribed product. However, there are no encouragements or incentives for physicians to prescribe generic drugs. The patient has to be informed of the substitution and has the right to decline. Currently, substitution rate is approximately 10%-15%.
  - The MoH is expected to consider making INN prescribing a mandatory requirement.
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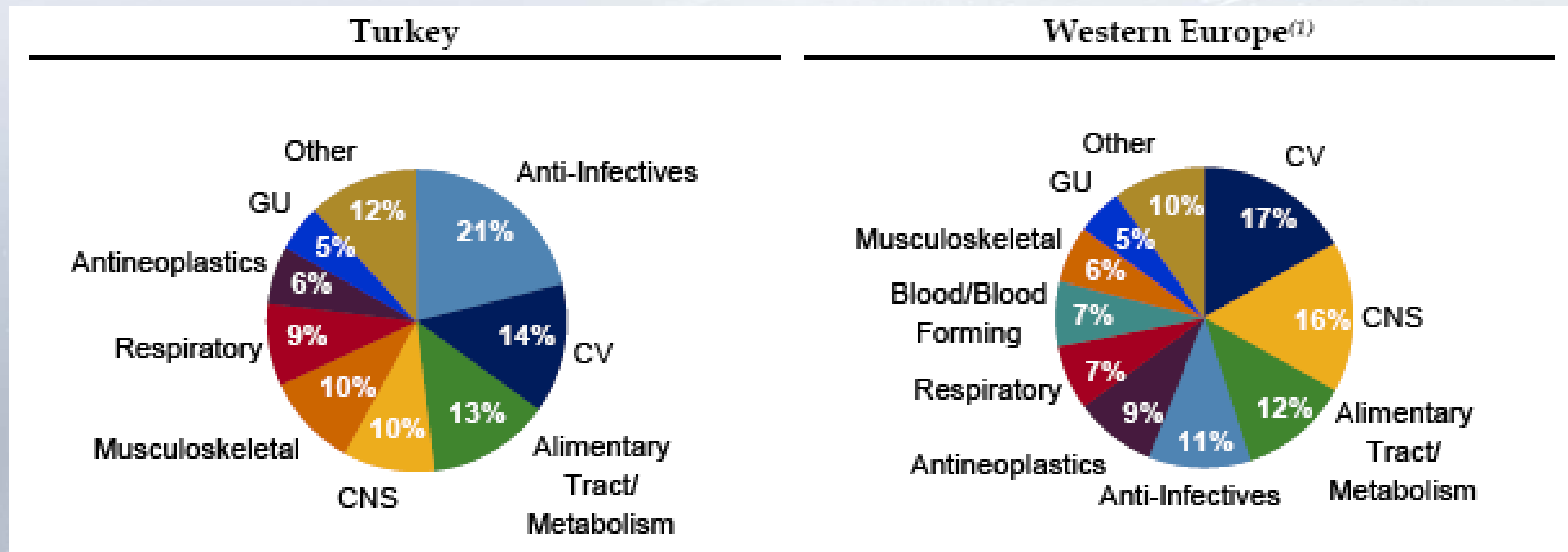


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# Turkey – market structure by ATC class



## Market structure by therapeutic group Turkey vs. Western Europe



- Strong prevalence of antibiotics, reflecting a relatively high incidence of infectious diseases (developing market pattern)
- As the Turkish market develops, other therapeutic categories that are more commonly prescribed in EU and the US, such as CV, CNS and oncology are expected to grow at above-market growth rates.

**Source:** (1) IMS Global Analyzer. Western European average figure based on Austria, Belgium, Denmark, Finland. France. Greece. Italv. Portuual. Spain. Sweden. Switzerland. United Kinadom.



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# Turkey – key growth drivers



- Strong GDP growth and increasing consumer purchasing power.
  - Continuing growth and increasing life expectancy of the population.
  - Ongoing urbanisation of the country.
  - Growth in the prevalence of private health insurance.
  - Ongoing reforms in the Turkish healthcare sector
  - Wider introduction of modern treatments.
-



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# Turkey – regulatory developments



- In 1993, Turkey became an active member of the European Pharmacopoeia, and pharmaceutical regulation has been increasingly aligned with EU laws.
  - Directives covering Good Clinical Practice (“GCP”), Good Laboratory Practice (“GLP”), Good Manufacturing Practice (“GMP”) and pharmaceutical advertising have been transposed into local regulations in 1993, 2002, 2003 and 2004, respectively.
  - 6-year data exclusivity period introduced in 2005.
  - Since 2004, the Turkish patent law has included a Bolar exemption, enabling pharmaceutical manufacturers to perform research and development on patent protected drugs without infringing that patent.
  - There is currently no framework for patent extension using Supplementary Protection Certificates under Turkish law.
  - All applications have to be in CTD format since Jan, 2006.
-



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# price mechanism developments

(1)

- **Price reductions (Jan, 2002)**
- **New reimbursement rules (Feb, 2002)**
- **New measures to reduce healthcare spending (Mar, 2003)**
- **VAT reduction on pharmaceuticals (Feb, 2004)**
- **Introduction of reference price mechanism (Feb, 2004)**  
*Benchmark are the prices in 5 EU countries (Greece, Spain, Italy, Portugal and France). Based on this system, the prices of the original and generic products are capped at 100% and 80% of the reference price, respectively. 20-year old drugs (i.e. for which the registration was made over 20 years ago) are currently not included in the reference price mechanism.*
- **Single budget for state social security systems (Feb, 2005)**
- **Transfer of all SSI Hospitals to the MoH (May, 2005)**  
*Social security members are entitled to purchase Rx pharmaceuticals from independent pharmacies (not only SSK pharmacies). Positive effect on independent pharmacy sales.*



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# price mechanism developments

## (2)

- **Data exclusivity (Jan, 2005)**

*Introduced in the ongoing EU alignment and harmonization process. The data exclusivity period is 6 years as follows:*

- *original products registered in any Customs Union country for the first time between 1 Jan 2001 and 1 Jan 2005 and for which no generic manufacturer had previously applied to register in Turkey*
- *original products registered after Jan, 2005 in any Customs Union country*

- **Mandatory discounts (Feb, 2005).**

Producers are required to provide a mandatory discount on pharmaceutical products - 11% on generics and originals older than 6 years, 4% on other originals.

- **Introduction of band system (Feb, 2005).**

Provides a ceiling price for which the MoF will make reimbursements.

- The MoF set the payment band at 30% in Feb, 2005.
- Effective from May, 2006 the band is reduced to 22%.





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# Turkey – market developments

- Ongoing reforms in the healthcare sector, such as the introduction of a family physician as a gatekeeper to specialist services, thus reducing hospital expenditures.
- Merger of the three main state-administered health insurance schemes into a single system, which will increase efficiency and improve access to healthcare.



# Croatia and Turkey – M&A perspectives



- **Countries in active stage of industry consolidation.**  
**The two major acquisitions made in the generics industry during 2006-2007:**
  - Pliva d.d., Croatia acquired by Barr Pharmaceuticals, Inc. for US\$ 2.5 billion.
  - 75% of Eczacibasi generics acquired by Zentiva in Mar, 2007 for EUR 460 mln.
- High growth opportunities in Turkey – estimated to emerge as one of the world's TOP 10 pharma markets by 2010.
- Further consolidation expected in both countries.





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# Ukraine: key facts

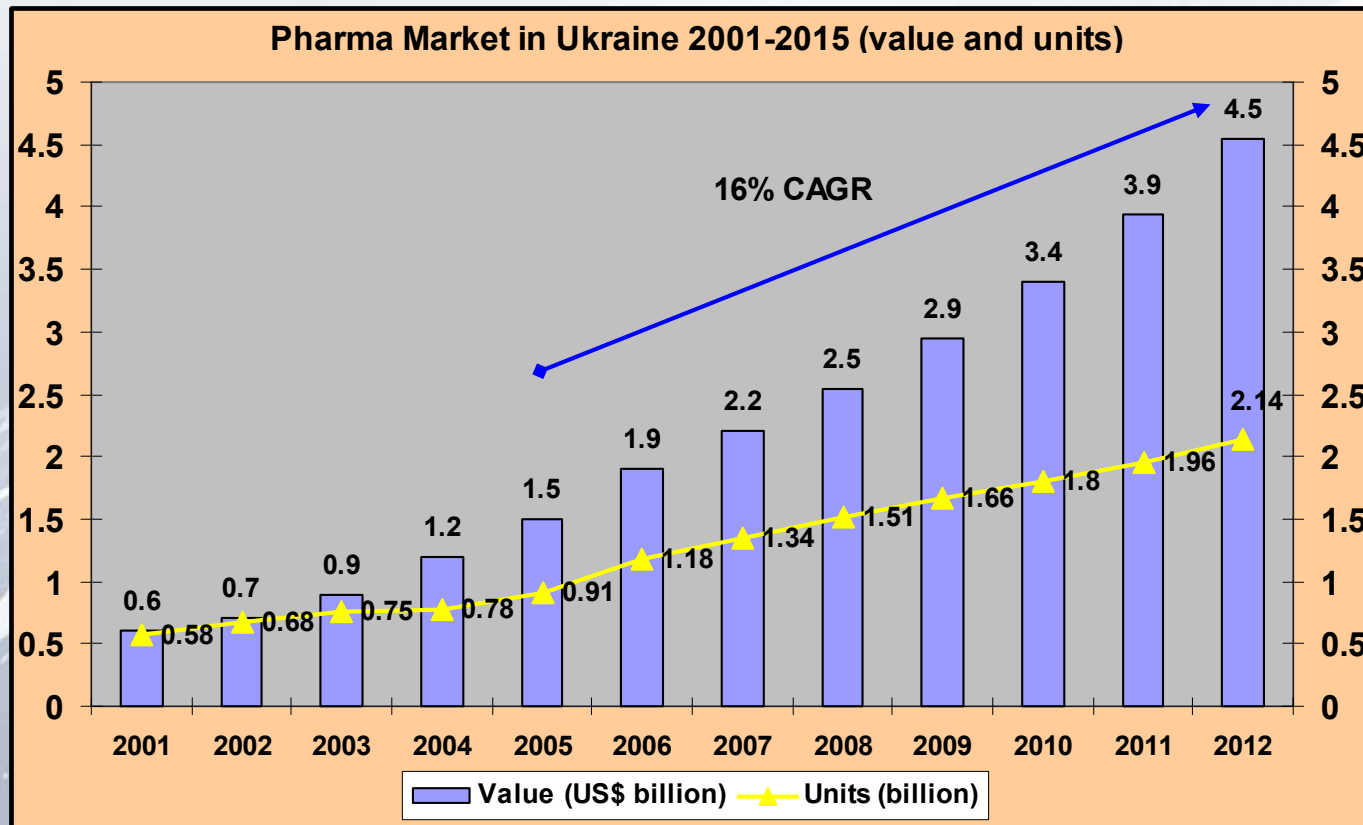
- Population: 48 mln (2<sup>nd</sup> largest European market by population).
- 3,000 hospitals.
- 20,000 medical doctors.
- 3,000 registered distributors (9 major).
- Ca. 20,000 pharmacies (40% state-owned).
- 7,000 products currently marketed in 13,000 forms.
- **Highest generic penetration among CEE countries – 80% by value in 2006A**



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# Ukraine – pharma market (1)



- Among the fastest growing pharma markets in the CEE. Exhibited 26% yoy growth in 1H2006.
- Sustainable growth to persist up to 2012 according to industry analysts (pessimistic forecast for ca.10% CAGR vs. optimistic forecast of 15-20% CAGR for 2008-2012).

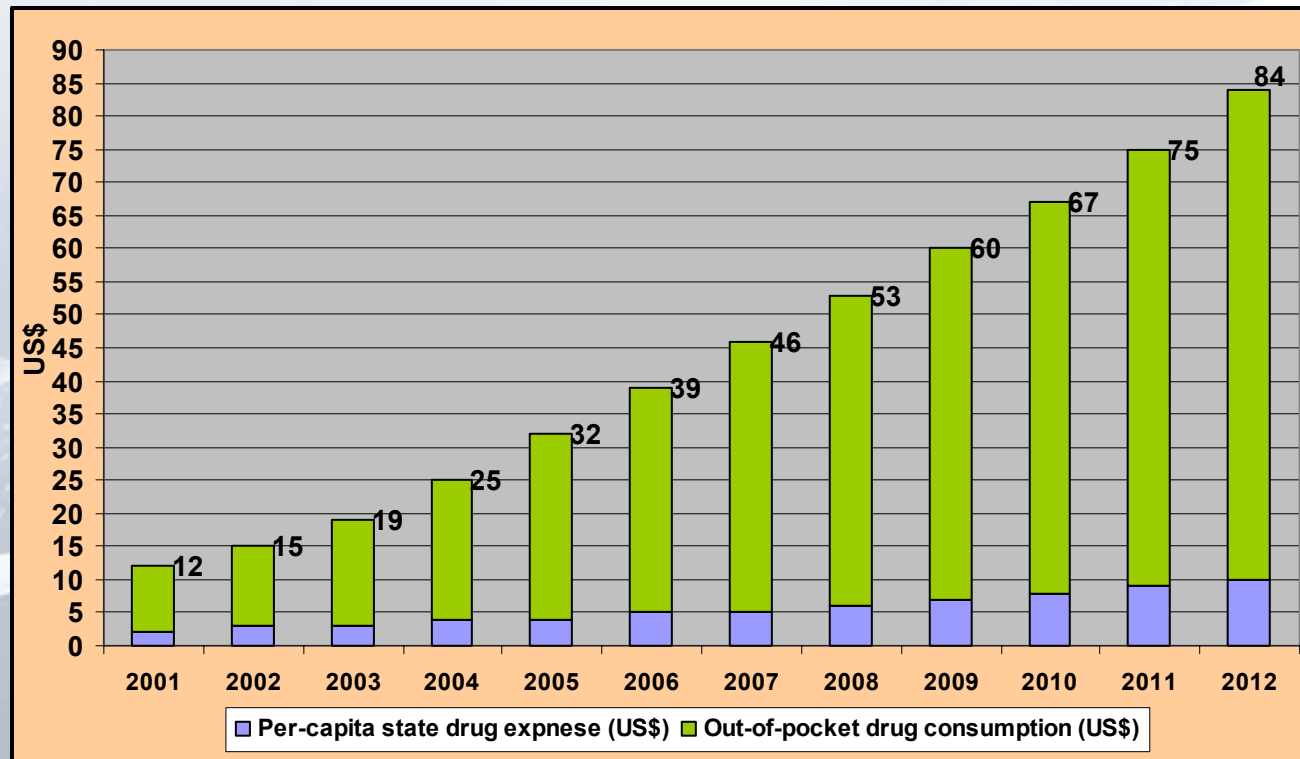
Source: BMI forecast, RMBC data and Actavis company estimates



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# Ukraine – pharma market (2)



- Growing per capita real income and economic stability is driving consumer out-of-pocket spending on medicines in line with more advanced CEE peers.
- No government reimbursement system currently in effect.

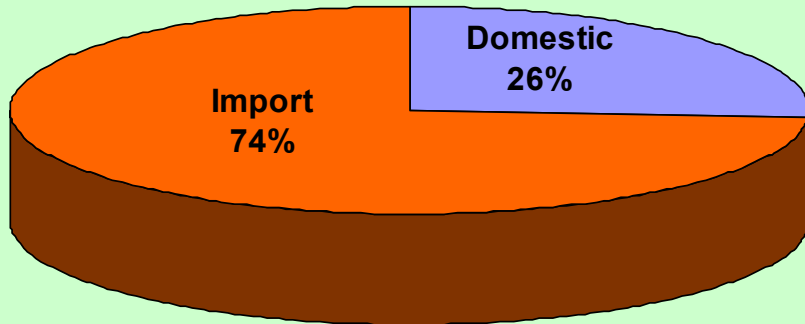
Source: BMI forecast and Actavis company estimates



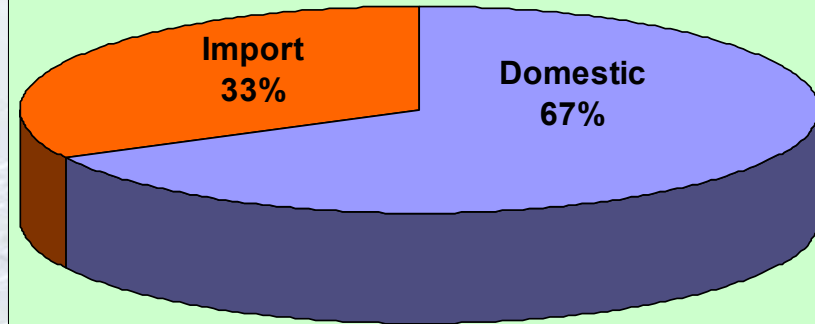
# Ukraine – pharma market (3)



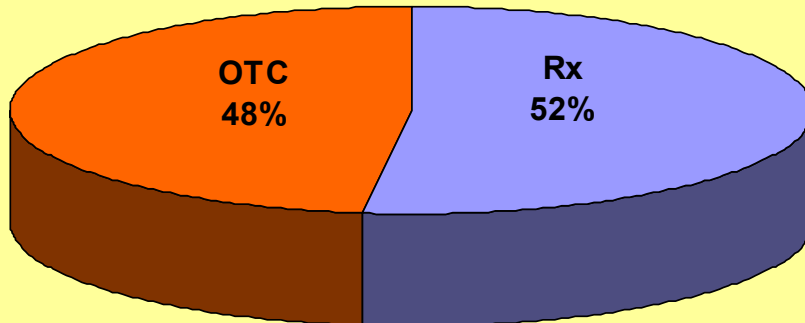
Domestic producers by value 2006A



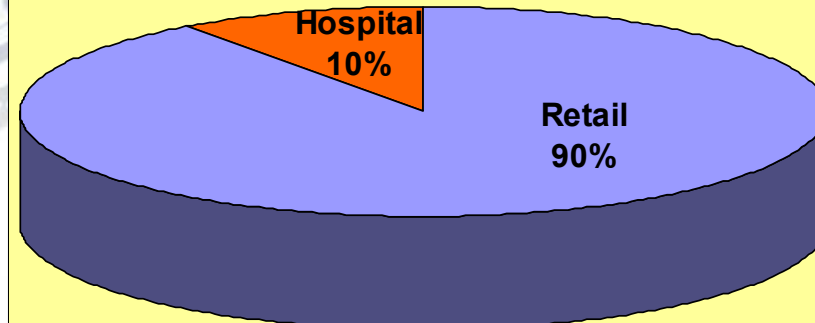
Domestic producers by volume 2006A



Rx vs. OTC by value, 2006



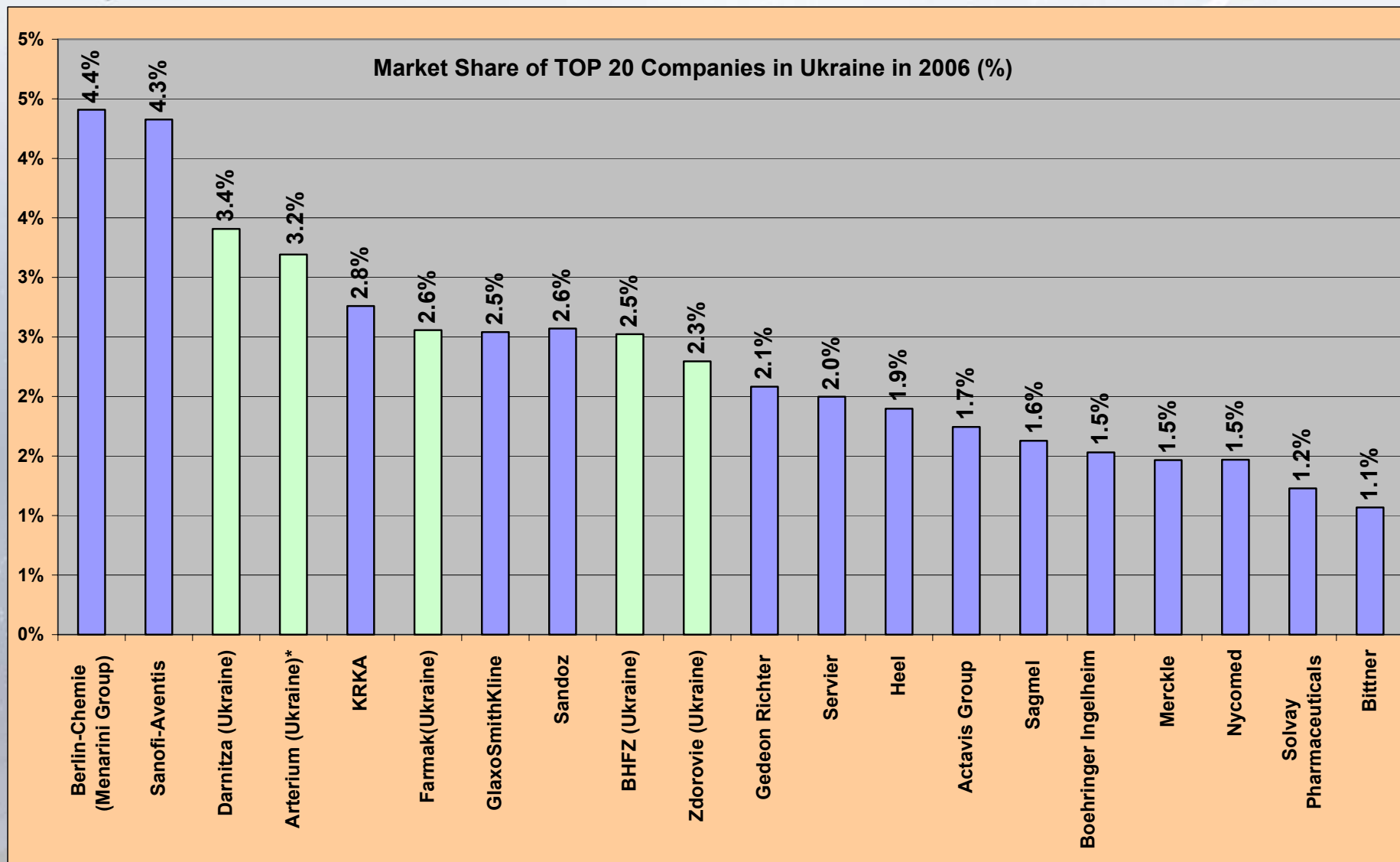
Retail vs. Hospital by value, 2006



**Ukraine is a typical branded generic market with ca. 80% generic sales by value.**



# Ukraine – top 20 companies

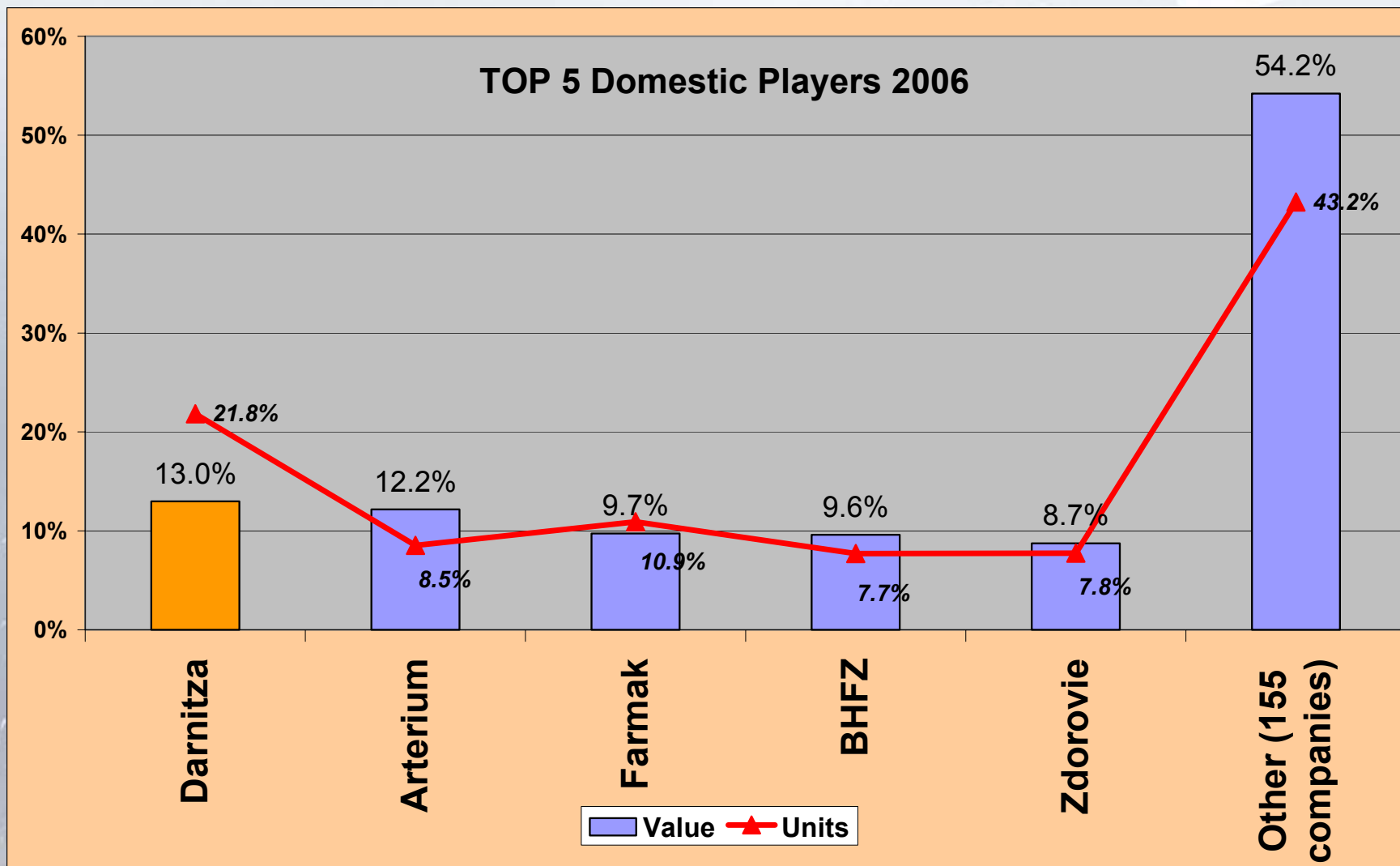


Source: IMS data



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# Ukraine – top 5 domestic players



Source: IMS data

# Ukraine – key growth drivers

- 48 mln population!!!
  - Real increase in income is driving out-of-pocket drug expenditure in line with more advanced CEE peers.
  - Very high share of generic market (ca. 80%) and generic prescribing culture.
  - High unmet demand for modern treatment and low penetration of the market create good launch opportunities for multinational generic players.
-



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# Ukraine – major hurdles

- Recent political instability increasing overall country risk and causes delays in reforms.
  - Complex regulatory system and specific entry barriers, lack of transparency of rules in terms of government funded programs and hospital tenders.
  - No reimbursement system introduced so far. Chaotic prescription practices (100% payment by the patients and decision making at pharmacy level).
  - Low average market prices (each 5 out of 6 packs sold has avg. net price <\$1).
-



# Ukraine – recent developments

- End of political crisis – consensus reached for new parliamentary elections in September.
- Harmonization of the pharmaceutical system with EU (registration is already in line with current EU practices).  
Mandatory EU GMP compliance as per Jan, 2009.

# ALBANIA: key facts

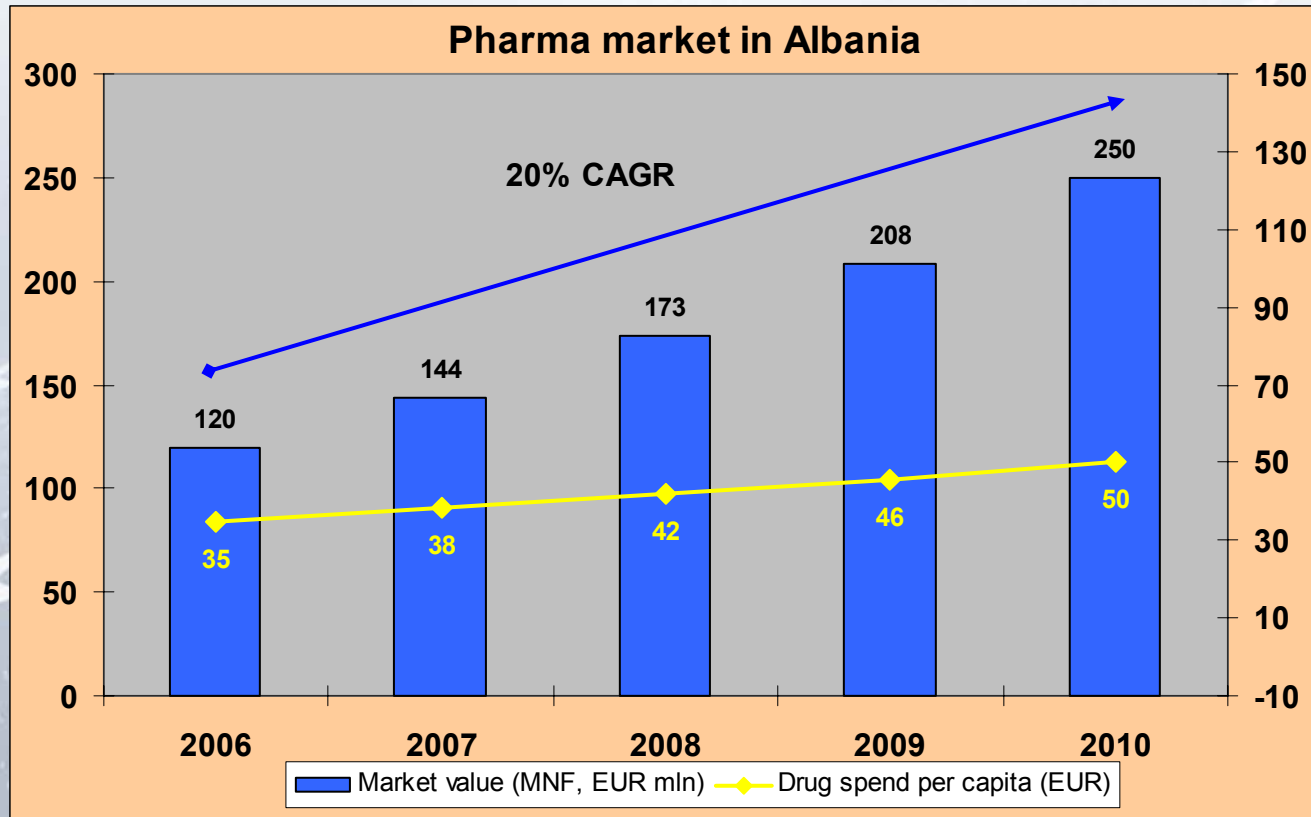
- Population: 3.5 mln
  - Ca. 45-50 hospitals (35-40 big + 10 small)
  - 2,150 general practitioners
  - 1,050 specialists
  - 89 registered distributors (15 big)
  - 900 pharmacies
  - Ca. 3,600 registered pharma products
-



# ALBANIA – pharma market



## (1)



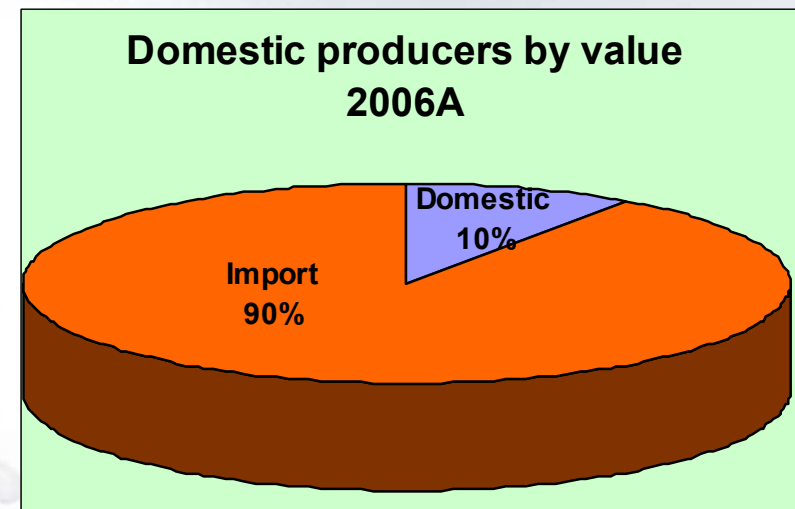
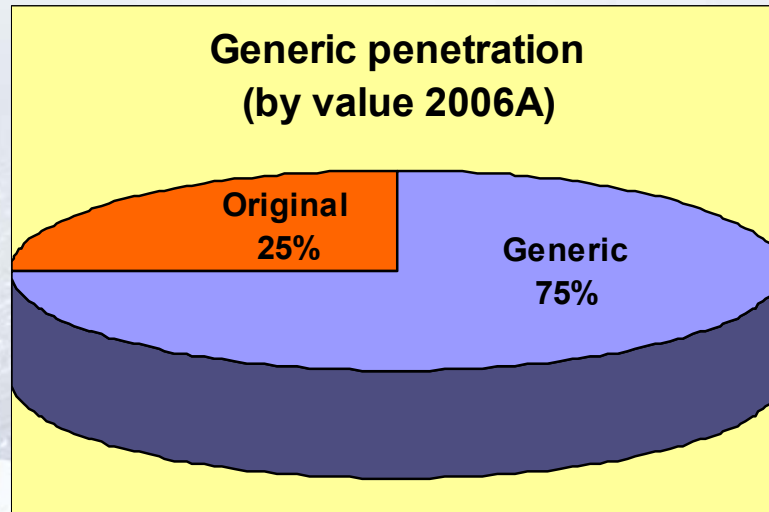
- **High-growth expectations: y-o-y growth to exceed 20%.**
- **Pharma market to double its value by 2010 – from 120 mln EUR in 2006 to 250 mln EUR in 2010.**
- **Drug spent per capita growth at ca. 10%.**



# ALBANIA – pharma market (2)



Albania TOP companies
<b>DOMESTIC</b> (Profarma & Prodentalpharma +Eurofarma)
Berlin-Chemie
GSK
KRKA
BAYER-SCHERING
NOVARTIS
LEK-SANDOZ
ROCHE
SANOFI-AVENTIS
ALKALOID
CHIESI
YAMANOUCHI
CHEMOFARMA-STADA
ACTAVIS
MEDOCHEMIE
NOBEL-ILAC



## key growth drivers

- Stable GDP Growth (exceeding 6% y-o-y)
- Increased y-o-y drug spent per capita
- Macroeconomic stability
- Stable currency (the only CEE currency revalued vs. EUR in the recent years)
- Stable increase in budget for government health reimbursement fund (EUR 39 mln in 2006 or 33% of pharma market)
- Consolidation in the distribution sector



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# ALBANIA – major hurdles



- Lack of transparency in the registration procedures
  - Government reimbursement budget still not sufficient (33% of drug spent) and significant patient participation
  - List of reimbursed products updated only once per year
  - Government protection of domestic industry.
  - Bureaucracy hurdles at every import deal.
-



# ALBANIA – recent developments



- Beginning of harmonization with EU regulations in healthcare.
- Adopting of effective governmental policy against counterfeiting.
- Mandatory requirement for packages of all products to be in Albanian language soon to be implemented.



# Ukraine and Albania – M&A perspectives (1)



- Industry consolidation is in early stage of development
  - **Ukraine**: first reported transaction in Mar, 2005 b/w Kyivmedpreparat (KMP) and Halychpharm to create Arterium Group.
  - **Albania**: only 2 domestic companies - Profarma & Prodentalfarma and Eurofarma.
- Direct foreign investments in the pharma sector:
  - **Ukraine**: absence of large scale investments Exceptions: **Gedeon Richter's** US\$ 6 mm investment in small packaging facility in Kiev in 2005/2006 and **Bioton (Poland)** investment in local insulin maker Indar.
  - **Albania**: complete absence of direct investments.

**Major reason: country risk and investor's preferences towards the larger and comparatively more stable market in Russia.**





# Ukraine and Albania – M&A perspectives (2)



## **Strong opportunities to capitalize on:**

- Good perception of home made drugs.
  - State support of local manufacturers (despite of ownership) in terms of government programs and tenders.
  - Taking advantage of high-growth domestic market expectations.
  - Early stage of consolidation of the local pharma industry and lack of direct foreign investments.
  - Consolidation to be driven by enforcement of mandatory EU GMP standards requiring significant capital outlays.
-



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**THANK YOU!**

EUROPEAN GENERIC MEDICINES ASSOCIATION