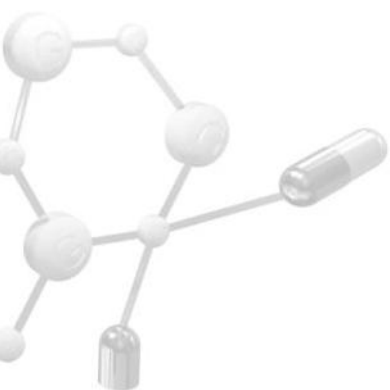
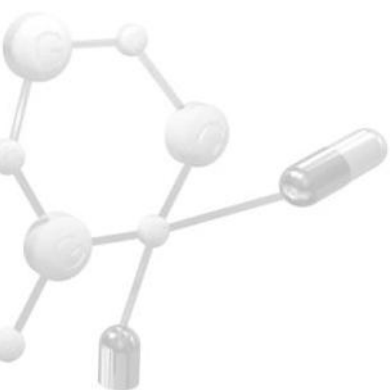


The Romanian generic medicine industry – between regional development and survival on the local market

Laurentiu Mihai
Executive Director



About APMGR & generic medicines



Members of the association



RANBAXY

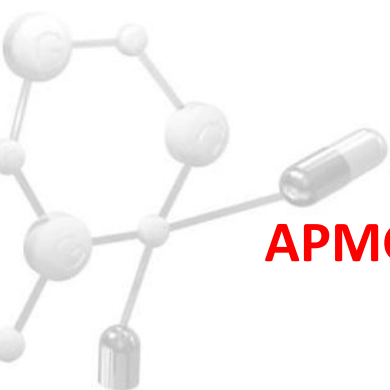


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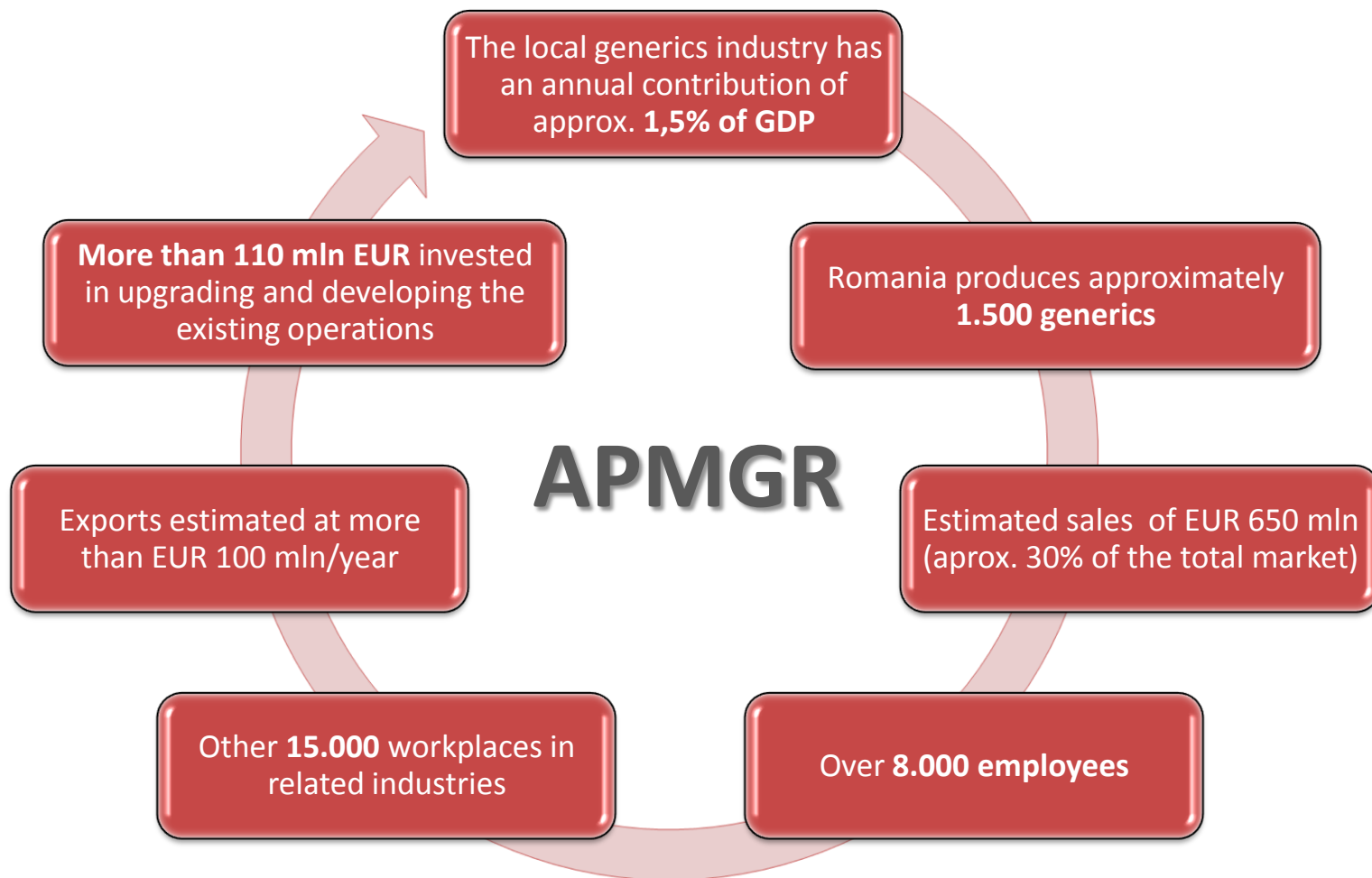


GEDEON RICHTER





APMGR member companies contribute to the Romanian economy





About generics

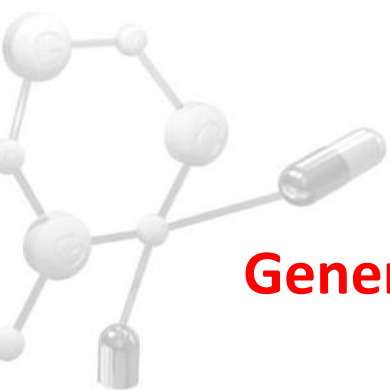
A generic medicine contains the same active substance as the reference medicine, being equivalent in terms of dosage, concentration, administration, safety, efficacy and therapeutic guidelines.

Generic medicines are therapeutic equivalents of the originator pharmaceutical products whose patents have expired.

In Romania, through Order 15/2009 of the Ministry of Health, the price of a generic medicine cannot exceed 65% of the corresponding originator product.

Generic manufacturing sites are audited and certified according to the Good Manufacturing Practices (GMP) norms issued by the National Agency for Medicines and Medical Devices (ANMDM), as well as similar agencies throughout Europe, the US, Japan and Australia.



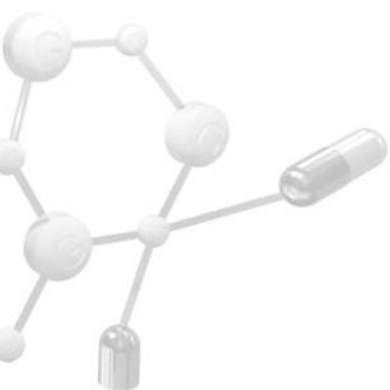


Generics – treatment areas

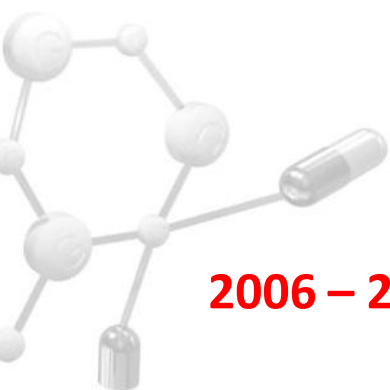
Key Treatments Areas treated with affordable generic medicines

Cancer	Asthma	Parkinson's Disease
Diabetes	Osteoporosis	Epilepsy
Depression	Gastro-intestinal Disorders	Rheumatism
High Cholesterol	Viral Infections	Pain Relief
High Blood Pressure	Bacterial Infections	Inflammation
Allergies	Migraine	Skin Diseases
Alzheimer Disease	HIV/AIDS	Contraceptives

Source: European Generic Medicines Association



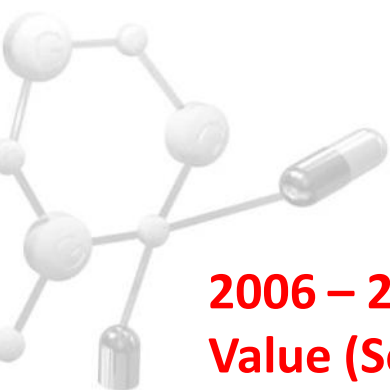
The pharmaceutical market -Romania-



2006 – 2011: Medicines consumption trends in Romania

Product	Value 2007 RON	Value 2008 RON	Value 2009 RON	Value 2010 RON	Estimate 2011 RON	Average increase 2011/2007
Total	5,341,543,532	6,619,920,886	7,513,603,149	8,827,357,828	9,647,472,201	15.93%
Brand	3,023,442,773	4,106,215,426	4,942,186,797	5,942,716,440	6,346,029,159	20.36%
Generic	1,531,662,506	1,628,194,883	1,652,961,235	1,874,241,621	2,139,006,835	8.71%
OTC	786,438,253	885,510,577	918,455,116	1,010,399,766	1,162,436,209	10.26%

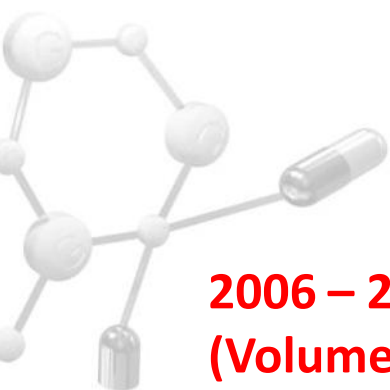
Product	Units 2007	Units 2008	Units 2009	Units 2010	Estimate 2011 Units	Average increase 2011/2007
Total	518,007,334	506,189,650	460,004,995	459,071,321	471,225,964	-2.34%
Brand	86,692,563	100,235,890	105,298,503	115,709,321	119,946,760	8.46%
Generic	258,076,730	241,898,451	214,863,143	207,203,669	208,399,212	-5.20%
OTC	173,238,041	164,055,309	139,843,349	136,158,331	142,879,992	-4.70%



2006 – 2011: Manufactured in Romania vs. Imported drugs Value (Source: Cegedim)

Market	MS% Value 2006	MS% Value 2007	MS% Value 2008	MS% Value 2009	MS% Value 2010
Import %	76.38%	78.79%	82.74%	84.61%	86.15%
Made in Ro %	23.62%	21.21%	17.26%	15.39%	13.85%

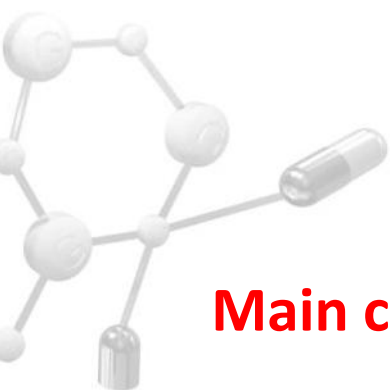
Market	Growth Value 2006	Growth Value 2007	Growth Value 2008	Growth Value 2009	Growth Value 2010
Increase	19.90%	13.59%	23.93%	13.50%	17.49%
Import %	22.41%	17.18%	30.15%	16.07%	19.62%
Made in RO %	12.45%	2.00%	0.83%	1.19%	5.73%



2006 – 2011: Manufactured in Romania vs. Imported drugs (Volumes. Source: Cegedim)

Market	MS% Units 2006	MS% Units 2007	MS% Units 2008	MS% Units 2009	MS% Units 2010
Import %	38.12%	44.38%	49.76%	53.25%	58.58%
Made in Ro%	61.88%	55.62%	50.24%	46.75%	41.42%

Market	Growth Units 2006	Growth Units 2007	Growth Units 2008	Growth Units 2009	Growth Units 2010
<i>Increase</i>	<i>5.50%</i>	<i>1.92%</i>	<i>-2.28%</i>	<i>-9.12%</i>	<i>-0.20%</i>
Import %	17.09%	18.65%	9.59%	-2.75%	9.77%
Made in Ro%	-0.56%	-8.39%	-11.75%	-15.43%	-11.57%



Main causes leading to these developments

1. Anti-trust practices

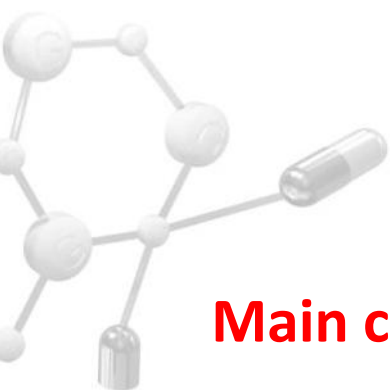
- Distribution margins for imported medicines vs. distribution margins for medicines manufactured in Romania.
- Generic price benchmark of 65% from the innovator's price.

2. Price methodology

- The minimum price benchmark from 12 EU countries, applied retroactively, to already extremely low prices
- Non-comparable basis in setting the price (i.e.: catalogue of price distribution; catalogue of price-volume negotiations; prices resulting from tenders; prices negotiated between private operators etc.).
- Lack of incentives for the technological transfer (medicines manufactured in Romania is given a lower price than the same imported medicine).

3. Administrative blockages

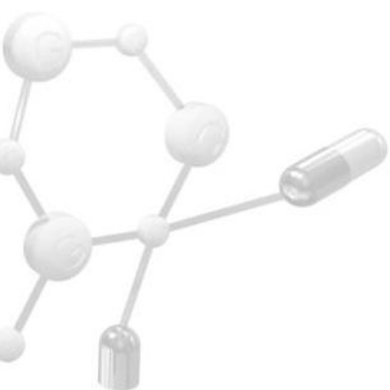
- Alternating the prescription four times between the commercial name and ICN: generics producers cannot inform the medical doctor about the presence of the generic option.
- *National Agency of Medicine and Medical Devices*: Changing the operation status from stand-alone institution to state institution and cutting resources obstructed the activity of most departments.



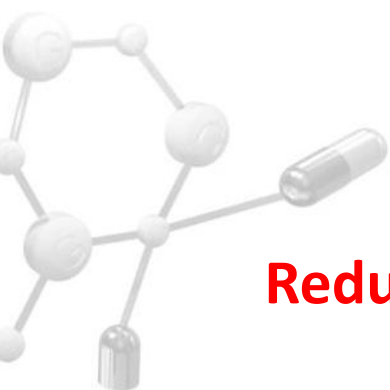
Main causes leading to these developments

5. Burdensome fiscal framework : Claw back tax

- The tax is applied only to medicine producers but its calculation base is the shelf price, which includes the distributor's margin, the pharmacy margin and the VAT.
- Medicine producers are required to pay the tax irrespective of each company's contribution to the overall increase of medicine sales (individual market growth)
- The tax is paid four times per year while the reimbursement is made at over 300 days, thus creating important cash flow problems for companies.
- The tax is calculated based on erroneous data provided by the National Health Insurance House (CNAS) including medicines that have not been marketed in Romania



The pharmaceutical market -EU-

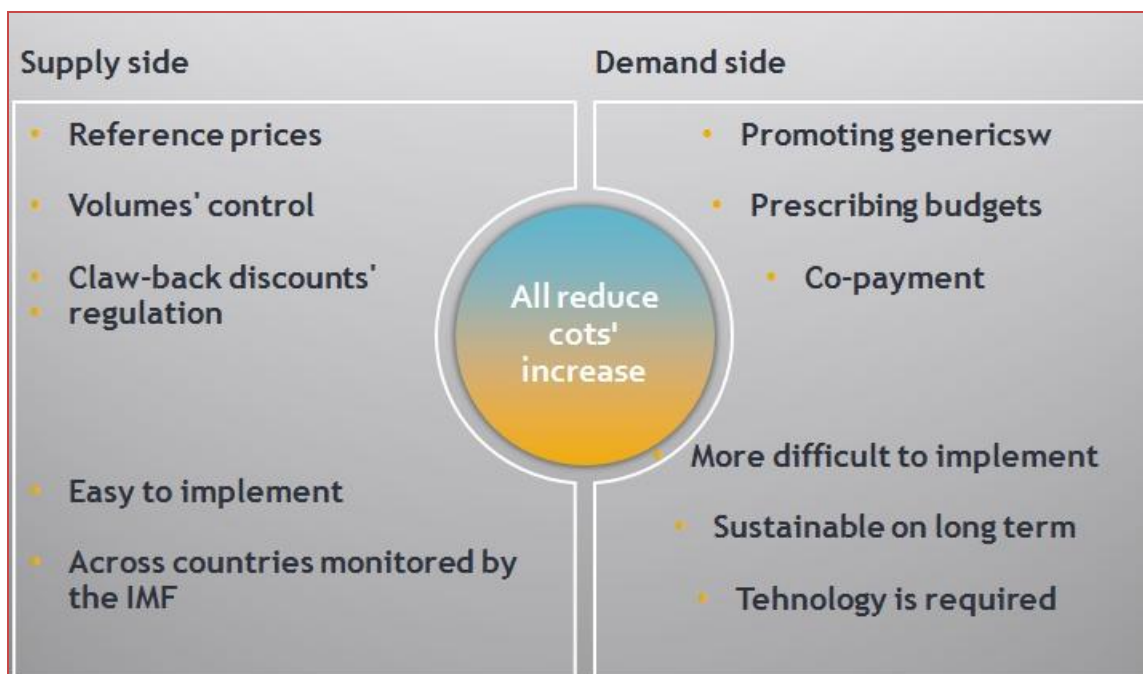


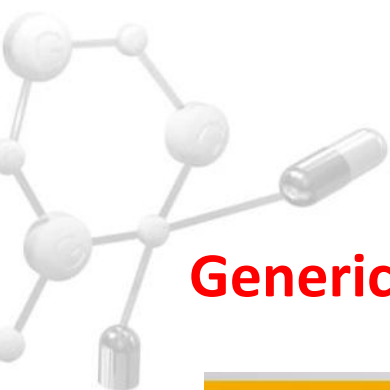
Reducing costs in the EU – public policy

To maximize savings, coherent policies are needed to create the right environment for generics both on the supply and the demand sides

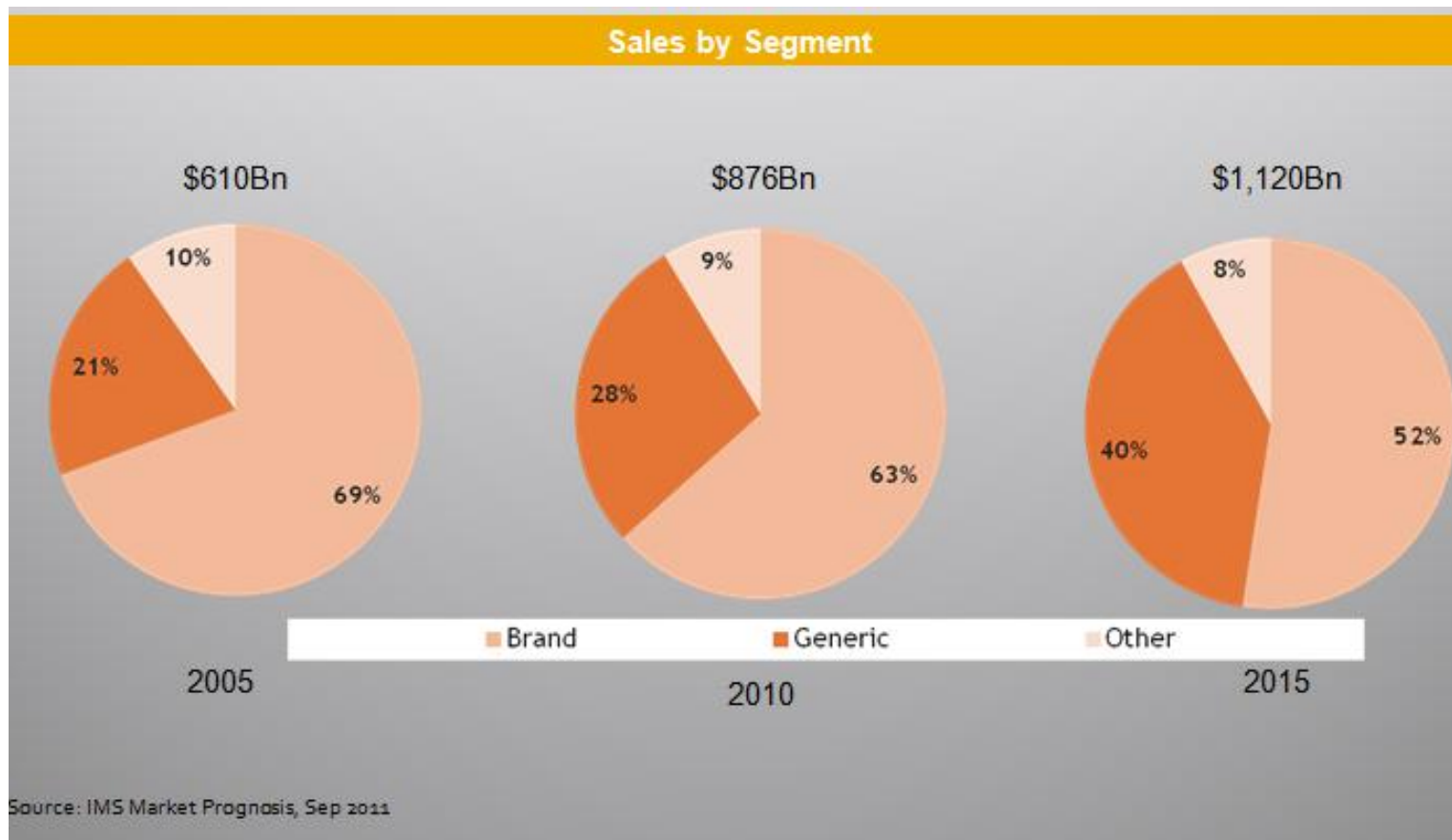
Generics have a major contribution to the sustainability of healthcare systems:

- generate savings to the state budgets
- increase access to pharmaceutical treatment, at affordable costs



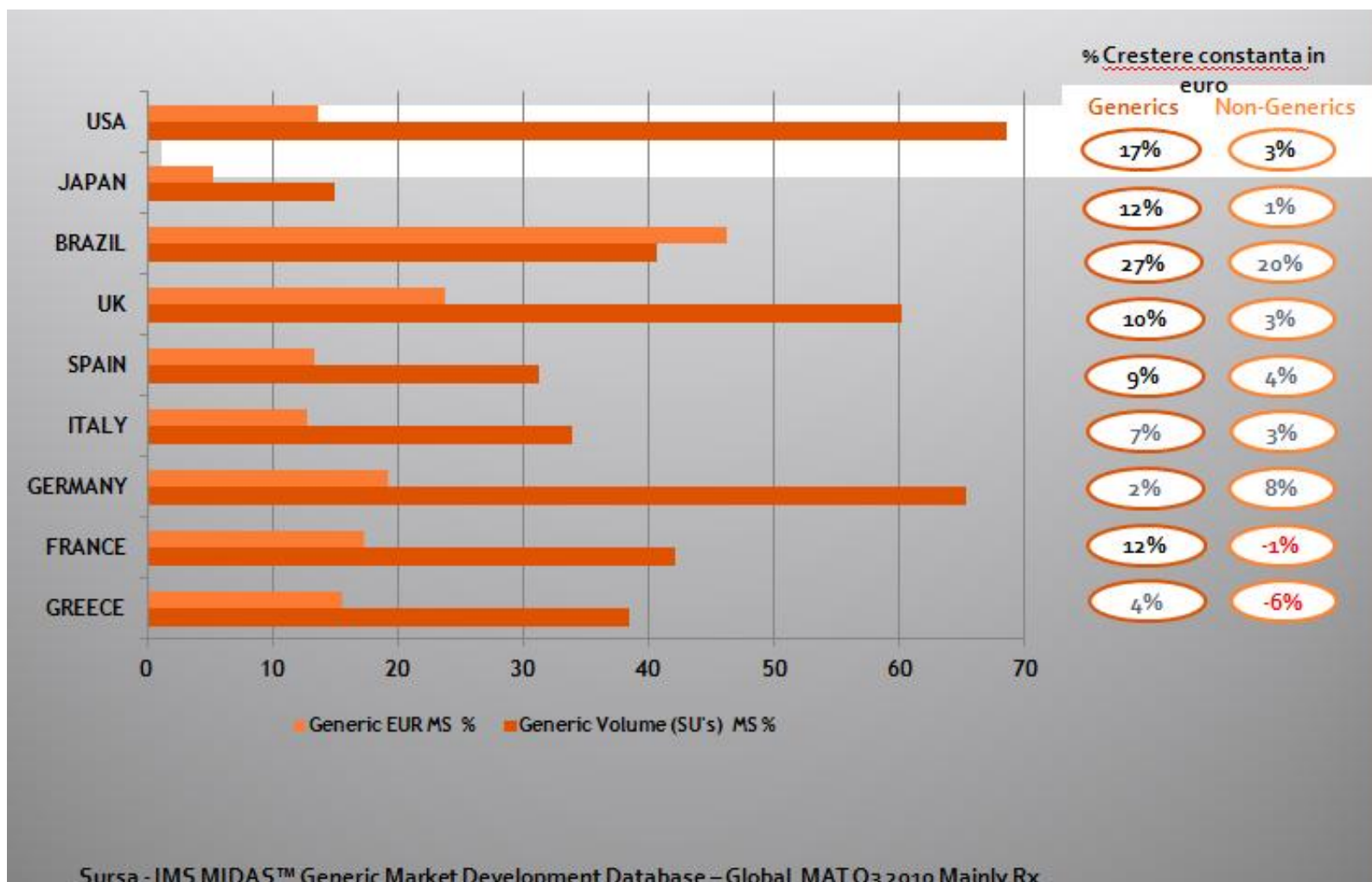


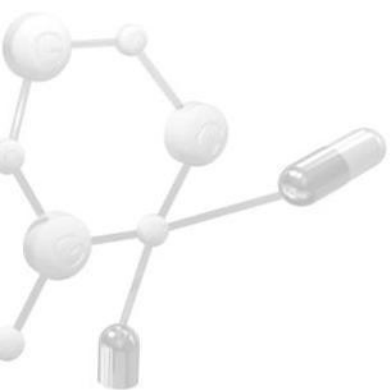
Generic vs. Brand : Generic penetration will continue to grow





Generic vs. Brand: current status





APMGR – solutions for a sustainable healthcare system

Reducing losses in the healthcare system

Increasing access to pharmaceutical treatment, at affordable costs



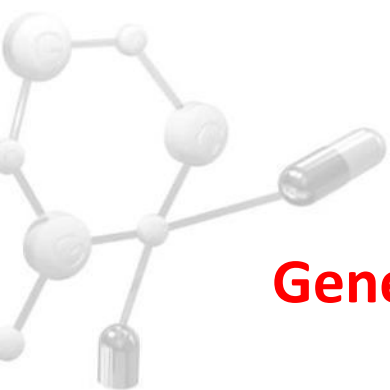
Urgent measures for correcting the claw-back system

Sustainability

- Using claw-back for the control of unbalanced medicine sales' increase and not for covering the budgetary deficit
- Exclusion from taxation of medicine under 30 Ron per commercial unit (producer price)
 - Have the highest risk of being eliminated from the market
 - Represent only 30% of the National Health Insurance House reimbursement budget and 85% of the volumes of medicines marketed in Romania (according to Cegedim data)

Predictability

- Calculation base: manufacturing selling price (MSP)
- Reference amount in the formula: real consumption of previous year
- Liaising payment deadlines with reimbursement (maximum 60 days)



Generics - encouraging the consumption

Increasing access to pharmaceutical treatment

- Regulate prescriptions using commercial names, depending on the medical needs
- Introduce norms that encourage drugs substitution in pharmacies
- Effectively implement provisions of Directive 7/2011 on combating payment arrears in the public sector
- Include provisions on “generic incentives” for MDs and/or pharmacists