



*Making Medicines Affordable*

EUROPEAN GENERIC MEDICINES ASSOCIATION



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# **Developing Markets Belgium - France**

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

**Elke Grooten**

Senior Manager EU Pharmaceutical Policy

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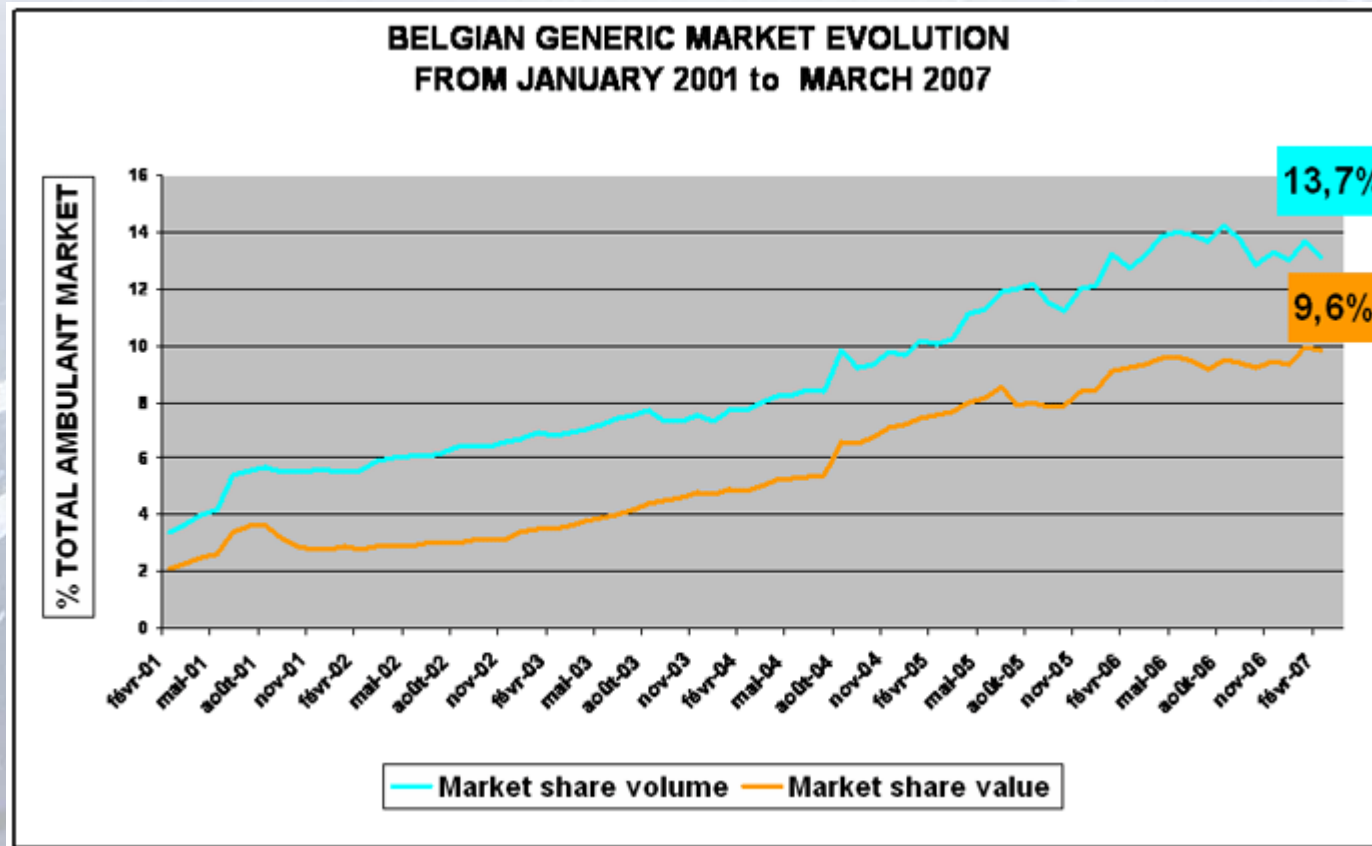


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# Belgium



# Belgium – current Market share



Source: FeBelGen 05/2007



# Belgium – Generic market in value by molecule/TOP 5



<b>TOTAL MARKET</b>	<b>250.995.680</b>
OMEPRAZOLE	40.185.800
SIMVASTATIN	26.608.683
LORMETAZEPAM	8.757.824
CITALOPRAM	7.593.642
BISOPROLOL	7.174.827

Source : IMS Selling out Year 2006



# Belgium – Generic market in units by molecule/TOP 5



<b>TOTAL MARKET</b>	<b>31.418.063</b>
<b>LORMETAZEPAM</b>	<b>2.163.459</b>
<b>LORAZEPAM</b>	<b>1.778.723</b>
<b>OMEPRAZOLE</b>	<b>1.745.204</b>
<b>AMOXICILLIN</b>	<b>1.271.351</b>
<b>ZOLPIDEM</b>	<b>1.251.310</b>

Source : IMS Selling out Year 2006



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# Belgian Market



## Main current drivers:

- Reference Reimbursement System
- Prescription targets “cheap medicines”
- Information campaign by authorities
- Margins for pharmacists identical

INFORMATION DU GOUVERNEMENT FEDERAL

Les médicaments génériques:  
100% aussi efficaces,  
généralement moins chers.  
Ça fait du bien!



Les médicaments peuvent coûter cher. Heureusement, il existe souvent une alternative. Les médicaments génériques. Ils sont aussi efficaces et généralement moins chers. Leur qualité, leur efficacité et leur sécurité sont soigneusement contrôlés réglementairement et ils sont aussi sûrs que les autres médicaments. Conclusions: Prescriptions de médicaments génériques vous fait faire des économies. Elle permet aussi à l'Assurance maladie de disposer de plus d'argent pour rembourser des médicaments innovants.

Service public fédéral  
Santé publique  
Service public fédéral  
Sécurité Sociale

LES MÉDICAMENTS GÉNÉRIQUES.  
PARLEZ-EN À VOTRE MÉDECIN.

Ministère du  
gouvernement fédéral  
www.fgov.be |  

Source: FeBelGen 05/2007

# Belgian Market



## Main current hurdles:

- Prescription targets for “cheap medicines”
  - Generic medicines
  - Cheap originator medicines (reference price – 30 %)
  - INN Prescription
    - » Prices generics in reality lower than “cheap” originator medicines, but not rewarded in terms of volume!!
- Market is not price-sensitive due to lack of transparency and marketing power of Big Pharma
- Negative campaigns by doctors/pharma.be





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# Belgian Market



## Key New Developments:

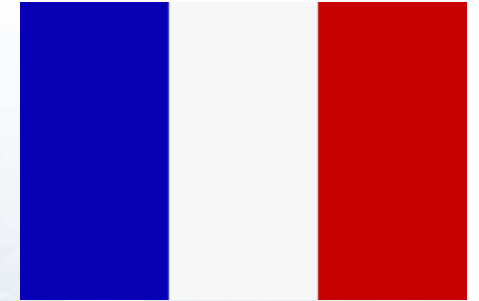
- “KIWI” Tendering system
  - Foreseen in Health law
  - Started for amlodipin/simvastatin
  - No clear implementation date and measurements
  
- Perception that generic medicines in Belgium are too expensive => -30% of reference product
  - » PLANS TO CHANGE IT TO -50% (cfr. FRANCE)
  
- New distribution margins foreseen for 2008

**NEW MINISTRY FROM SEPTEMBER 2007**

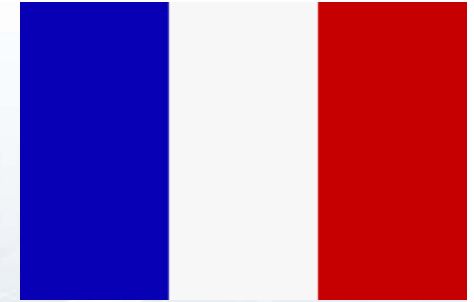
Source: FeBelGen 05/2007



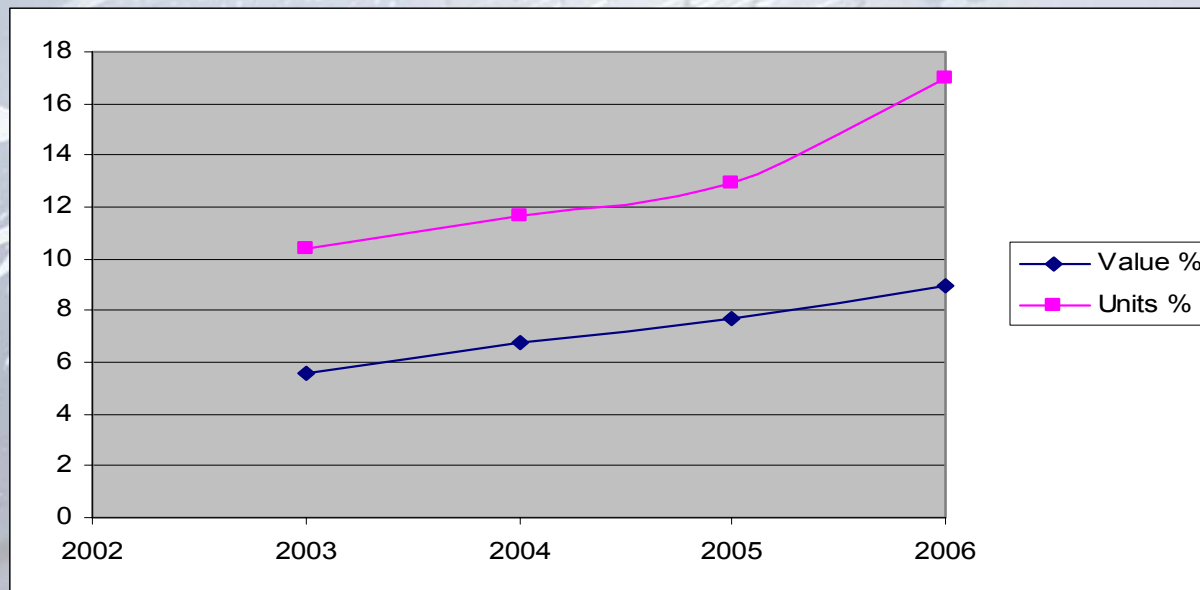
# France



# France – current Market share

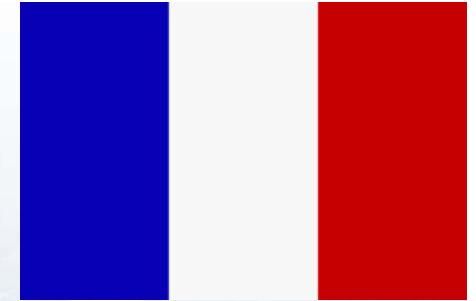


	2003	2004	2005	2006
Value %	5,6	6,8	7,7	9
Units %	10,4	11,7	12,9	17



Source: EGA Market review  
2006 + Gemme 2007

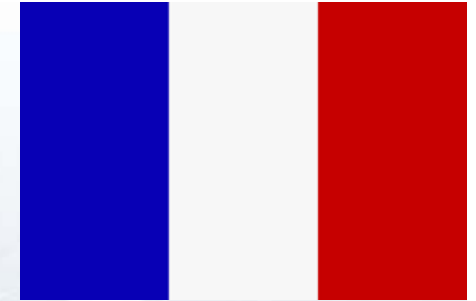
# France – Generic market in value by molecule/TOP 5



<b>TOP GENERIC MOLECULES</b>	<b>VALUE 2005 X 1000 euro</b>
<b>FRANCE RETAIL</b>	<b>15.571.885</b>
<b>FRANCE RETAIL GX</b>	<b>1.203.526</b>
<b>OMEPRAZOLE</b>	<b>131.598</b>
<b>AMOXICILLIN</b>	<b>83.278</b>
<b>PARACETAMOL</b>	<b>78.632</b>
<b>SIMVASTATIN</b>	<b>62.739</b>
<b>CLAVULANIC ACID</b>	<b>54.158</b>

Source : EGA Market Review 2006

# France – Generic market in units by molecule/TOP 5



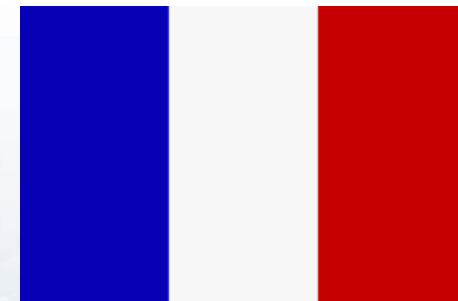
<b>TOP GENERIC MOLECULES</b>	<b>UNITS 2005 standard U</b>
<b>FRANCE RETAIL</b>	<b>69.183.710</b>
<b>FRANCE RETAIL GX</b>	<b>8.926.177</b>
<b>PARACETAMOL</b>	<b>1.258.827</b>
<b>DEXTROPROPOXYPHENE</b>	<b>777.796</b>
<b>METFORMIN</b>	<b>446.084</b>
<b>AMOXICILLIN</b>	<b>353.439</b>
<b>OMEPRAZOLE</b>	<b>213.852</b>

Source : EGA Market Review 2006



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# French Market



## Main current drivers:

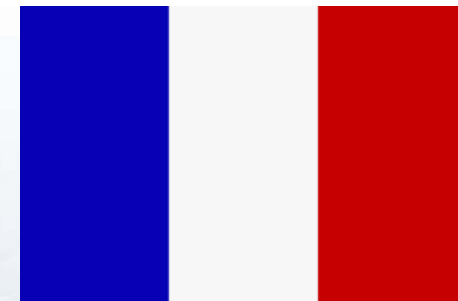
- **Substitution by pharmacists: positive list**
  - Market share 70% in 2006
  - Rebates by Gx companies to max 15% in 2007
- **Patients have no co-payment for generic medicines at pharmacie**

Source: Gemme 05/2007



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# French Market



## Main current hurdles:

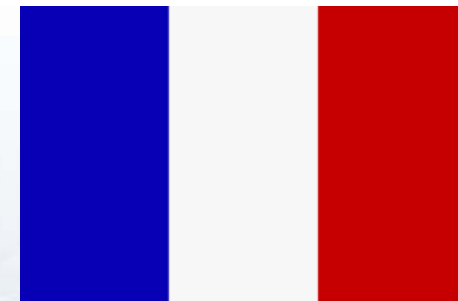
- since 2006: generic medicine has to be at least 50 % cheaper than reference product
  - » PRICE-LINKAGE !!!
  
- Substitution list only for oral forms
  - » NO PATCHES, SPRAYS
  - » NO BIOSIMILARS
  
- Only 5 – 10% generic prescription
  
- No real incentives for patients
  - » Co-payment of originator's products is reimbursed by insurance companies

Source: Gemme 05/2007



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# French Market



## Key New Developments:

- **Big impact in near future of -50% rule !**
- **end 2007 – 2008: high number of patent expiries**
- **2008: implementation of**
  - **INN prescription**
  - **Generic prescription**
    - » **BUT no measurements if doctors do not follow**

Source: Gemme 05/2007





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# EGA Analysis

EGA - European Generic Medicines Association - Home - Microsoft Internet Explorer provided by Novartis

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Address <http://www.egagenerics.com/index.htm> Go Links

**EGA** Making Medicines Affordable  
EUROPEAN GENERIC MEDICINES ASSOCIATION

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**About Generic Medicines**

Quality, safe, effective and affordable. [Click here to see why you should ask for generic medicines.](#)

**About Generics**  
Overview  
Basic Notions  
FAQ on Generics  
Glossary  
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**Biosimilar Medicines**  
Presentation

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Introduction

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**"Making Medicines Affordable"**

**What's New?**

**Forthcoming EGA Events:**

**13th EGA Annual Meeting**

Istanbul: 14-16 June 2007  
"Challenges in the European and Global Environment for the Generic Medicines Industry"

PRESS RELEASE: 24 May 2007  
**3rd EGA SOUTH EAST EUROPE SYMPOSIUM: "Meeting the European Challenge for the National Drug Regulatory Agencies and the Generic Medicines Industry"**

Greg Perry praised representatives from thirteen regional medicines agencies for their commitment to understanding EU legislation, and cautioned against adopting provisions which could negatively impact the availability of affordable generic medicines in the region.  
[More...](#)

PRESS RELEASE: 14 May 2007  
**KEEPING COUNTERFEIT MEDICINES OUT OF THE EU: A PROPORTIONAL AND TARGETED APPROACH REQUIRED**

Greg Perry, EGA Director General, presents the generic medicines industry's position on anti-counterfeiting policy at the European Parliament, expressing strong support for Europe's record of protecting pharmaceutical supplies from counterfeiters.  
[More...](#)

PRESS RELEASE: 3 May 2007  
**BUILDING A "MARKET PATHWAY" FOR BIOSIMILARS**

Now that the science and the regulatory pathway have been established in the EU, industry and regulators must focus on building a "market pathway" for biosimilar medicines.  
[More...](#)

PRESS RELEASE: 13 February 2007  
**LACK OF AGENCY RESOURCES DELAYING GENERIC MEDICINES APPLICATIONS**

While praising EU regulators for the smooth implementation and running of the new Decentralised Procedure (DCP), the EGA is concerned about the serious lack of resources available to Member State agencies to deal with the regulatory workload.

**JOURNAL OF GENERIC MEDICINES**  
**The European Generic Pharmaceutical Market in Review: 2006 and Beyond**

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# Current Situation

## Value vs Volume



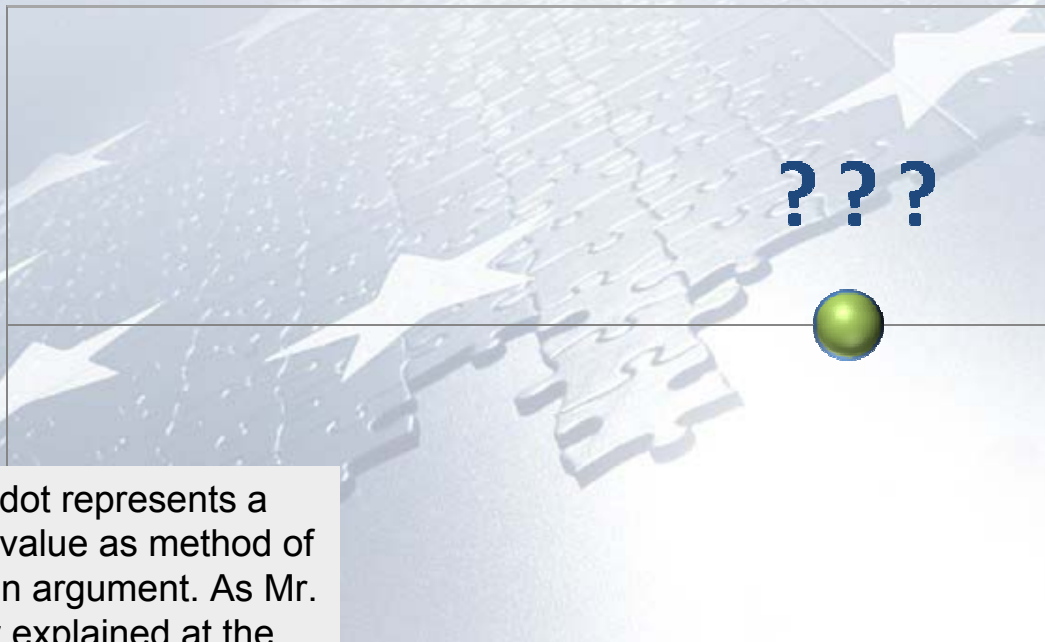
Source: EGA Internal Survey  
2006



# Countries Optimal Solution?



VALUE



The green dot represents a hypothetical value as method of modeling an argument. As Mr. Greg Perry explained at the beginning of the session does not express either an official figure or position from EGA.

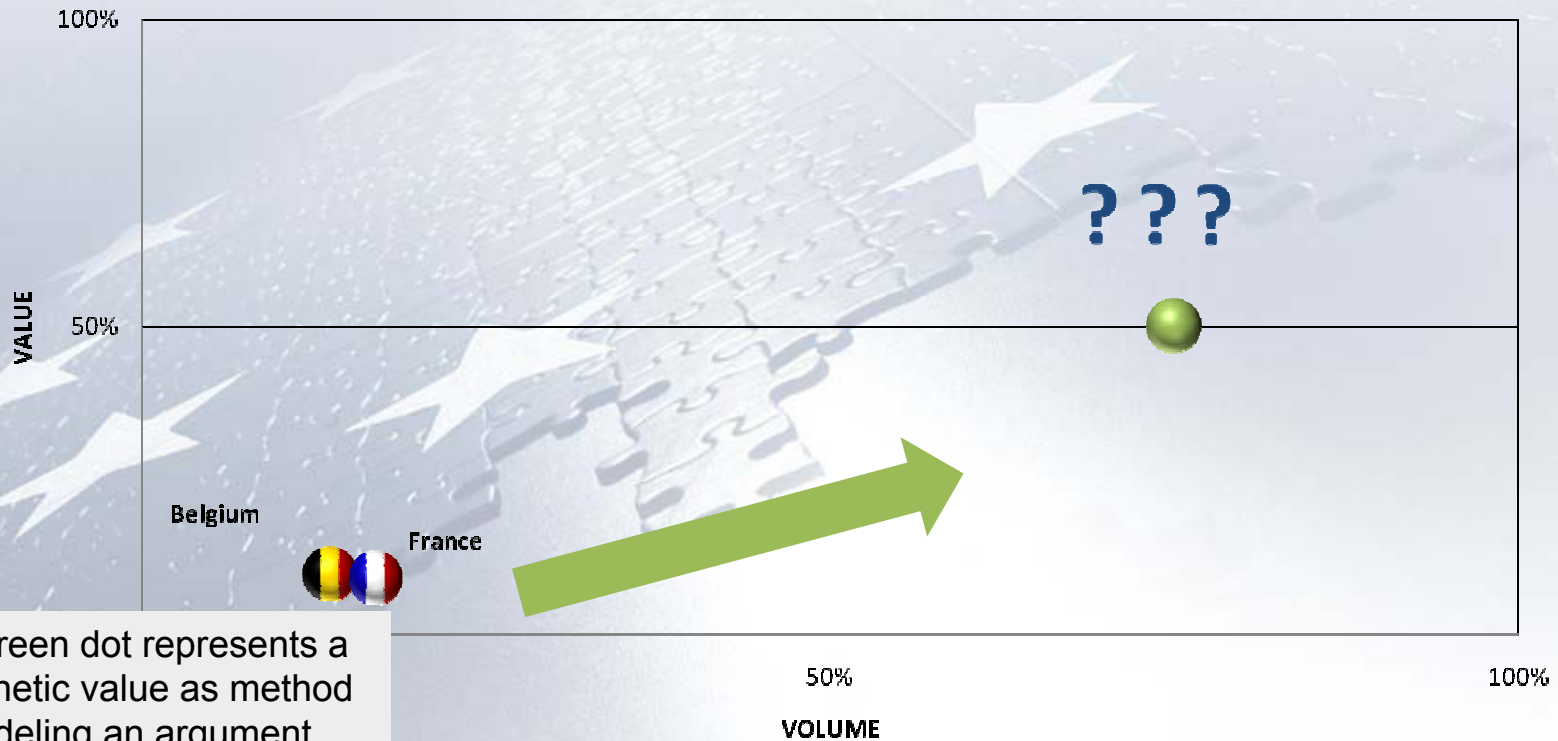
VOLUME

Justifiable savings brought by generic medicines through price differentiation

Room for Innovation and Competition on the Market

# What direction should countries take?

## Value Vs Volume



The green dot represents a hypothetical value as method of modeling an argument. As Mr. Greg Perry explained at the beginning of the session does not express either an official figure or position from EGA.

Source: EGA Internal Survey  
2006



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# The 7 Recommendations of the Simoens Report and how the countries are implementing

Source: National Associations

Simoens Report Recommendation	Belgium	France
1 - Introduce a coherent generic medicines policy	X	X
2 - Encourage price differentiation/ Competition within existing regulatory frameworks	X	X
3 - Disseminate pricing information to actors	✓ (not enough)	✓
4 - Increase confidence of actors in generic medicines	X	✓
5 - Provide incentives for physicians to prescribe generic medicines	X	X
6 - Remove financial disincentives for pharmacists to dispense generic medicines	✓ (will change in 2008)	✓
7 - Provide incentives for patients to demand generic medicines	✓ (not enough)	X



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**Thank you very much  
for your attention**

