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# How did the new generic provisions influence generic substitution in Europe?

**Elke Grooten**

EGA Director Pharmaceutical  
Policy



# Definition of Generic Substitution

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- PPRI Definition of Substitution

Practice of substituting a prescribed pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s).

=> also same administration route, dosage etc.

=> proven bioequivalence/therapeutic equivalence

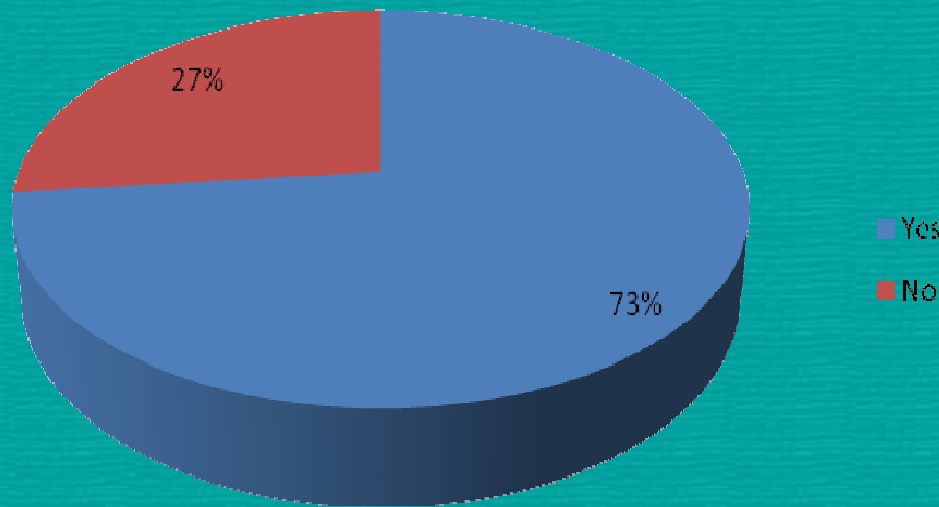
NOT EQUAL TO INN PRESCRIPTION !!



# Legal basis for Generic substitution

6.1. - Is generic substitution legally allowed?

Source: EGA Market Review 2007



Generic substitution is allowed in 19 of the 27 Member States.



# Modalities of Generic Substitution

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## 1. Mandatory or voluntary for pharmacist

- Mandatory only in 5 Member States (DK, DE, NO, SK, SE)

## 2. Substitution can be blocked by physician or patient

- Only in Spain, physicians cannot block substitution
- Prevention of generic substitution is generally indicated on the prescription by:
  - » Ticking a box
  - » Writing
  - » stamp



# Modalities of Generic Substitution

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## 3. Substitution must be supported by financial incentives for dispenser

- More than half of the Member States do not implement a coherent generic policy removing disincentives to pharmacists for dispensing generic medicines.
- Only in 6 Member States, pharmacists are guaranteed absolute margins as for originator products, so that margins are not lowered due to less expensive products.



# Modalities of Generic Substitution

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## 3. Substitution must be supported by financial incentives for dispenser

- Different types of pharmacist remuneration:

- Fixed percentage remuneration
- Sliding scale percentage remuneration
- Same margin in absolute terms on originator and generic medicines
- Percentage of difference between medicine price and reference price
- Higher discounts on generic medicines than on originator medicines



# Modalities of Generic Substitution

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## 4. Dispense practices by pharmacists

- According to the legislation, when a physician prescribes a branded medicine, being an off-patent originator or generic product, the pharmacist will dispense:
  - In 40% of Member States: a generic medicine
  - In 30% of Member States: the least expensive generic medicine
  - In 12% of Member States: a less expensive medicine (generic or originator)



# Benefits from Generic Substitution

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*“Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines.”*

*“Promoting generic medicines requires a good combination of demand-side as well as supply-side mechanisms.”*

Pharma Forum  
Progress Report June 2007



# Benefits from Generic Substitution

- Generic medicines account for nearly half of sold packs in EU and 18 % of Pharmaceutical Sales.
- Generic medicines bring savings of €18-20 Billion pa in EU 27.



# Benefits from Generic Substitution

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Generic medicines play a key role in ensuring the affordability and sustainability of healthcare systems throughout Europe. Encouraging competition in the pharmaceutical market through increasing the use of generic medicines both promotes cost containment and stimulates the innovation needed to provide added value products

EGA Contribution to Public Consultation “Future of Pharmaceuticals in Europe”  
October 2007



# Benefits from Generic Substitution

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## SAVINGS FROM GENERIC SUBSTITUTION IN DIFFERENT MEMBER STATES:

- Denmark: Public Pharmaceutical Expenditure lowered with 15 million euro a year since Generic Substitution was implemented.
  - Finland: in 2005, the total savings generated by generic substitution were 25.7 million euro.
  - Portugal: annual saving of 31 million euro for healthcare system and 14 million euro for patients
  - Sweden: annual saving of approx. 130 million euro
- Source: Andalusian School Report June 2007



# The Generic Reality

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The rate of volume Market Share varies considerable throughout Europe due to different Generic Medicines Policy between European countries

- 60-80% CEE
- 40-65% UK/D/DK/NL
- 10-15% and expanding rapidly in PT/F.....but
- 10% stagnant (Spain and Italy)



# Importance of Generic Medicines in EU

*Common Chronic Conditions treated with affordable generic medicines*

- Cancer
- Viral Infections
- Diabetes
- Bacterial Infections
- Depression
- Osteoporosis
- High Cholesterol
- Epilepsy
- High blood pressure
- Rheumatism
- Asthma
- Pain Relief
- Gastro-intestinal disorders (i.e., heartburn, ulcers)
- Inflammation



# Member State systems: FR

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- Which Products on substitution List:  
medicines registered as generic medicine.
- Pharmaceutical Forms:  
restricted to direct release oral forms
- Therapeutic classes excluded:  
narrow therapeutic margin drugs



# Member State systems: ES

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- Which Products on substitution List:  
decision by Spanish Minister of Health (SCO72874/2007).
- Pharmaceutical Forms excluded:  
inhalers
- Therapeutic classes excluded:  
narrow therapeutic margin drugs (ATC : A10AB, B02BC , B02BD, J07).



# Member State systems: IT

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- Which Products on substitution List:  
based on their generic status and upon the Italian Medicines Agency (AIFA) approval.
- Pharmaceutical Forms excluded: none
- Therapeutic classes excluded:  
all ATC are included



# Member State systems: SE

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- Normally all generics should be substitutable but there are some exceptions:
  - If the warning text differ to much (but indications does not have to be the same)
  - If the drug has too small therapeutic window
  - Medical devices
  - Difference in taste if prescribed for children
  - Slow release sometimes substitutable and sometimes not.



# Country systems: Switzerland

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- SWITZERLAND - Generic substitution:  
Every off patent reference product can be substituted by the pharmacist's choice.  
There are no restrictions and limitation for generic substitution.



# Key success factors for generic substitution

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- Ideally an overall strategy is designed to promote generic use that addresses all potential barriers
- Authorities should educate and inform patients, prescribers and pharmacists on the safety, efficacy and economic advantages of generics.



# Key success factors for generic substitution

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- A successful policy also requires free competition on the supply side.
- The demand side should have no reason to object against generics and should drive the use of generic medicines through some specific incentive:
  - Patients' financial incentives for using generics
  - Pharmacists' financial incentives for generic substitution
  - Physicians' financial incentives for generic prescription linked to target budgets, generic prescription targets, etc.



# References

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- EGA Internal Market Review 2007
- National Associations EGA
- Progress Report 2007 of High Level Pharma Forum
- Country Profiles PPRI
- “Analysis of differences and commonalities in pricing and reimbursement systems in Europe” June 2007, Jaime Espín – Joan Rovira



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Thank you for your attention!

Elke Grooten  
EGA Director Pharmaceutical Policy  
[egrooten@egagenerics.com](mailto:egrooten@egagenerics.com)

