

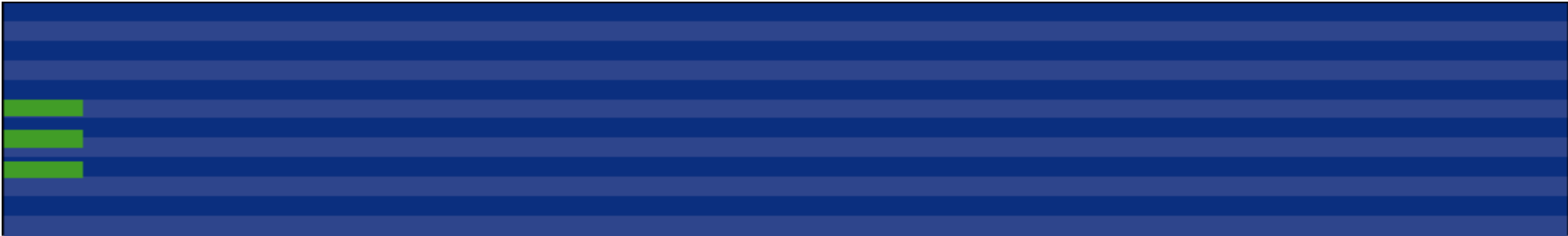


European Commission

Creating a sustainable environment for pharmaceutical competitiveness in the EU – The role of the generic industry. Viewpoint of the European Commission

11th EGA Annual Conference
Berlin, 21 November 2005

Dr. Nils Behrndt
Deputy Head of Unit
Pharmaceuticals
DG Enterprise and Industry



- Competitiveness of European pharmaceutical industry *in general*

- Competitiveness of *generic* industry



Pharmaceutical industry is a core sector for Europe!

- 600.000 employees, often highly skilled
- Limited number of big multinationals and ~ 2.000 biotech companies
- ~160 Billion Euro annual turnover
- ~25 Billion Euro invested in R&D each year

But our competitiveness is declining

Ranking by sales 1992

-  1. Zantac
-  2. Renitec
-  3. Voltaren
-  4. Lopirin
-  5. Mevacor
-  6. Adalat
-  7. Tagamet
-  8. Zovirax
-  9. Ciproxin
-  10. Cardizem

Ranking by Sales 2002

-  1. Lipitor
-  2. Zocor
-  3. Losec
-  4. Zyprexa
-  5. Norvasc
-  6. Erypo
-  7. Ogastro
-  8. Seroxat
-  9. Celebrex
-  10. Zoloft



Key EU actions to strengthen pharmaceutical industry

- | | |
|--------------------------|-----------|
| 1. G-10 High-Level Group | 2001-2004 |
| 2. Pharmaceutical Review | 2004-2005 |
| 3. Pharmaceutical Forum | 2005-2008 |

G-10 High Level Group

Initiative

- Round-table with 10 key stakeholders from industry, Member States and Commission
- « How pharmaceutical, health and enterprise policies can
 - Encourage **innovation and competitiveness**
 - Ensure **public health** and social imperatives ?»



Set of Recommendations

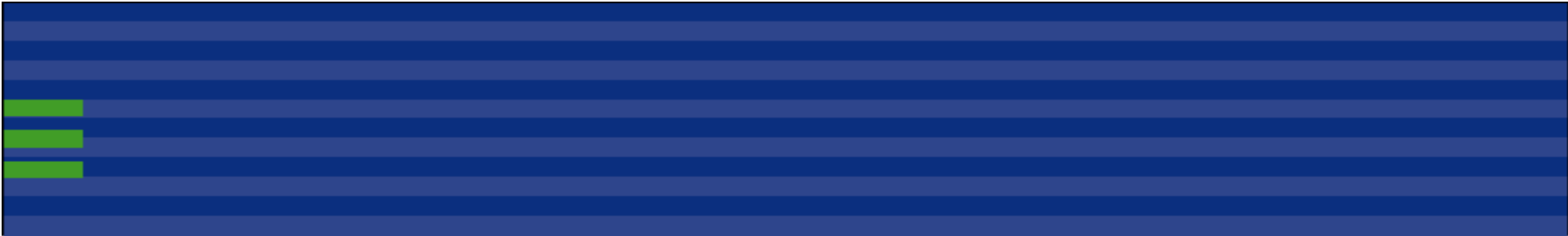
- Benchmark Competitiveness and Performance Indicators
- Regulation and access to markets
 - Timing of pricing and reimbursement
 - Role of Generics, OTC, ...
 - Relative effectiveness
 - ...
- Improving the EU science base
- Patients
 - Information
 - Safety
- Enlargement

Pharmaceutical Review

- Major scrutiny of the Community's modern pharmaceutical legislation of the 90s
- Key objectives
 - To further improve public health
 - To deepen the Internal Market in pharmaceuticals
 - To support the EU's competitiveness, inter alia to “translate” G10 recommendations into law
 - To prepare for enlargement
- Full application as of 20 November 2005

The Pharmaceutical Forum

- Objective: take forward the G10 dialogue
- Topics:
 - « open » G10-recommendations
 - Information to Patients
 - Health Technology Assessments
 - Pricing and Reimbursement mechanisms
 - New topics could be added, such as safety
- Membership
 - European Commission (Directorates General Enterprise and Industry as well as Health and Consumer Protection)
 - All Member States
 - Other stakeholders like patients, health funds, healthcare professionals and industry
- Timing
 - 3 year programme up to 2008
 - First Forum in 2006

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- Competitiveness of European pharmaceutical industry *in general*

- Competitiveness of *generic* industry

The Role of Generics

Need to keep
healthcare
affordable



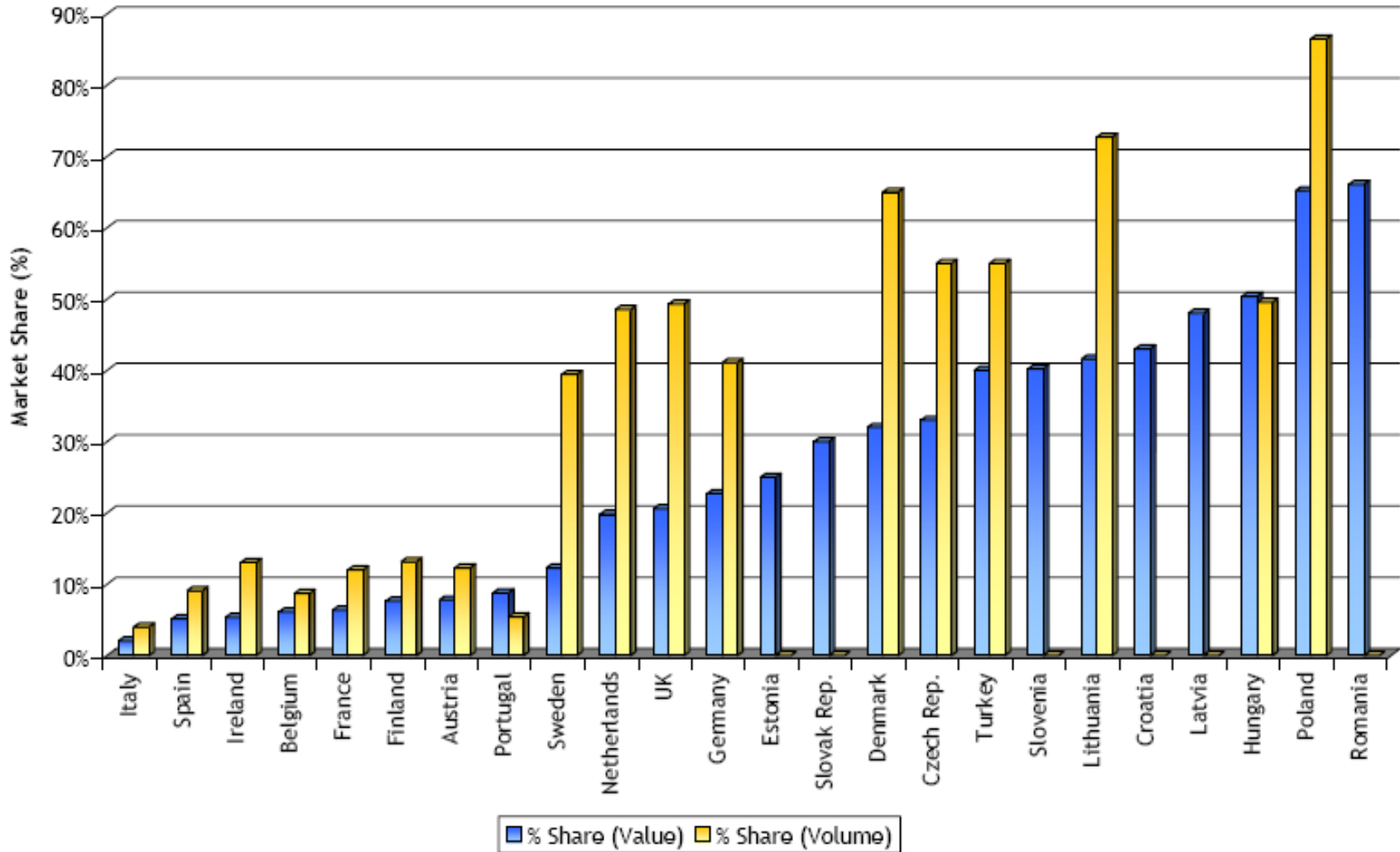
Need to have faire return
on investment in
R&D/innovation



Generics

- Reduce costs
- Improve access
- Lead to growth and jobs

There is still much potential for generics' share in Member State



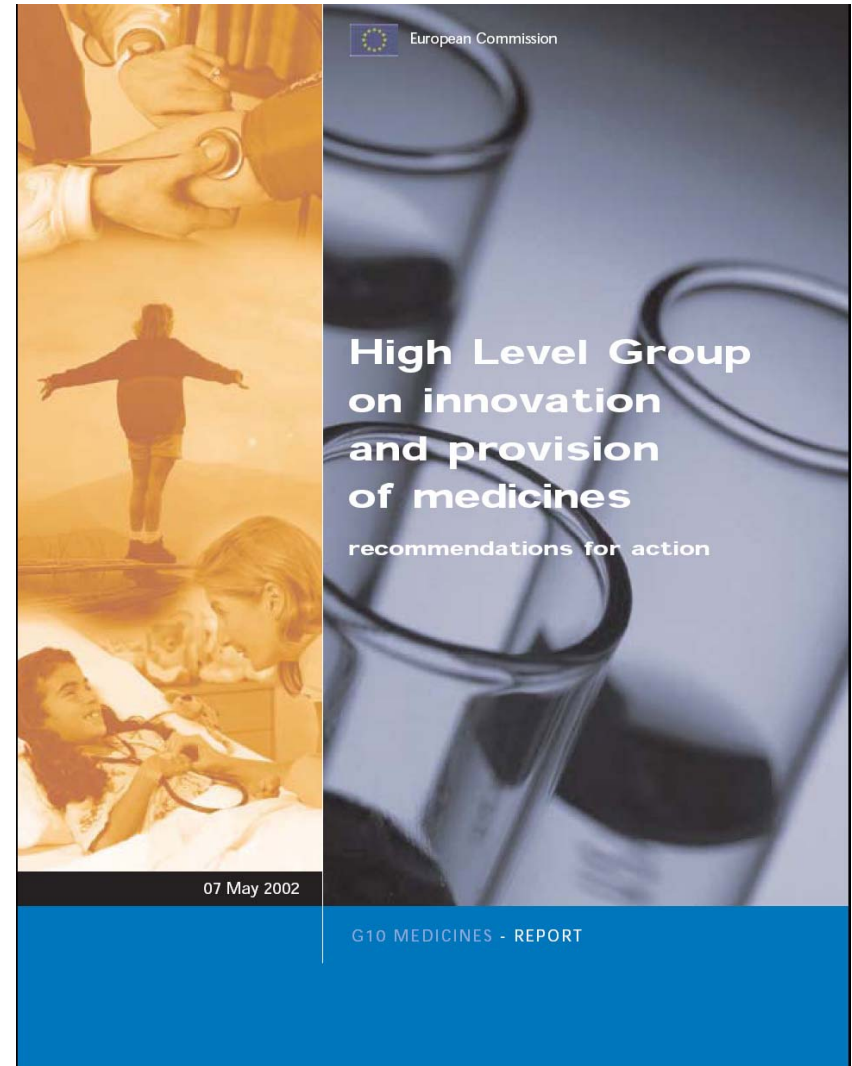


Generics in the three key EU actions

1. G-10 High-Level Group
2. Pharmaceutical Review
3. Pharmaceutical Forum

1. Generics in the G10 - Recommendations

“To secure the development of a competitive generic market, Member States, ..., should explore ways of increasing generics penetration in individual markets (including generic prescribing and dispensing). Particular attention should be given to improved market mechanisms in full respect of public health considerations.”



2. Generics in the Pharma Review

Review contains important steps forward:

a) General provisions

- Improved procedures (MRP, deadlines)
- Support for SMEs

b) Specific provisions on generics

- Clear **definition** of generics
- **Data protection** and generic applications
- Flexibility in the authorisation status of the **reference product**
- **Choice of procedure**

2. Generics in the Pharma Review

- a) Clear definition of generics
- **Generic medicinal product:** product with same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence has been demonstrated
 - Even if **certain changes in the active substance:** different salts etc. of an active substance do not prevent generic status, unless they differ significantly with regard to safety and/or efficacy
 - Various immediate-release **oral pharmaceutical forms** shall be considered to be the same

2. Generics in the Pharma Review

b) Data protection and generic applications

- Protection for innovative products: now at 10 (+1) years
- But important aspects for generic products
 - Immediate market access after year 10 possible
 - Bolar clause: patent rights cannot prevent necessary studies and trials for generic application
 - 1 year for new indication of a well established substance (significant pre-clinical or clinical studies)

2. Generics in the Pharma Review

- c) Flexibility in the status of the reference product
- Reference product does not need to be authorised at *moment* of application
 - Reference product does not need to be authorised in the Member State of application (“*Euro reference product*”)

2. Generics in the Pharma Review

d) Choice of procedure

- Generics of *centrally* authorised products: choice between centralised and national procedures
- Generics of *nationally* authorised products: access to the centralised procedure if “interest of patients at Community level”

2. Generics in the Pharma Review

Challenge now: translating new rules into practice

- Key implementing texts and guidelines adopted or soon to be adopted
- Discussion with Member States on rapid and correct implementation
- Transitional issues, e.g. functioning of new procedures until complete transposition

3. Generics in the Pharmaceutical Forum

Working Group

- Information to Patients
- Health Technology Assessments
- Pricing and Reimbursement

Potential topics related to generics

- Information on medical and economic value of generics
- Benchmark for added value of generic vs innovative products
- Different practices of generic substitution



Conclusion

- Generics and EU generic industry are important for our social and economic well-being
- European Commission is committed to contribute, with others, to creating a stimulating environment for thriving generics/generic industry
- G10 and Pharma Review are important steps, which need to be translated into reality now